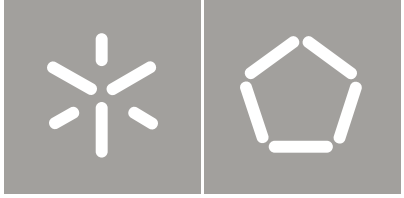
Universidade do Minho
Escola de Engenharia

Shantesh Digambar Hede

An Approach to Develop Sustainable Medical Devices

Junho de 2013

An Approach to Develop Sustainable Medical Devices
Shantesh Digambar Hede
UMinho | 2013



Universidade do Minho
Escola de Engenharia

Shantesh Digambar Hede

An Approach to Develop Sustainable Medical Devices

Tese de Doutoramento
Bioengenharia

Trabalho efectuado sob a orientação de
Doutor Luís Alexandre Rocha
Doutor Manuel José Lopes Nunes
Doutora Paula Varandas Ferreira

Junho de 2013

Acknowledgements

The contribution of MIT Portugal Program, University of Minho and Fundação para a Ciência e Tecnologia (FCT), Portugal (Foundation Of Science and Technology, Portugal) for the scholarship grant SFRH / BD / 33794 / 2009.

Throughout the doctoral research, the feedback from the following experts has been included within the thesis: Dr. Koti Sreekrishna, Senior Scientist at P&G; Narayan Srinivasan, Director of Business Intelligence at Academic Partnerships Inc.; Jaineel Aga and Deepak Bawari, Duke Universiy Alumni; Prof. David Primo, University of Rochester and Prof. Robert Clemen, Duke University; Dd. Dipl.-Vw. Malte Kaufmann, The Bucharest Academy of Economic Studies and Prof. Marieta Olaru, Ph. D., The Bucharest Academy of Economic Studies; Richard D. Wolff is Professor of Economics Emeritus, University of Massachusetts, Amherst and Jen Hill, Co-founder and Communications Strategist of Democracy at Work; Dr. Simona Alba Grano, University of Zürich; Prof. Axel Michaelowa, Institute of Political Science, University of Zürich; Bethel U. Ihugba, University of Wales Cardiff, Greenwich School of Management London; Brian Hasbrouk, iPolitical Risk; Dr. Nagraj Huilgol, Dr. Mekala Chandrasekaran and Mr. Naresh Trivedi (from Balabhai Nanavati Hospital); Manit Patel, Strategy Architect-Sterkem Pharma; P. Sainath, a renowned Indian Journalist; Michael Gillenwater co-founder of the Greenhouse Gas Management Institute.

It is essential to acknowledge the sources of inspiration and insight from the intellectuals from the public sphere whose articles; discussions and interviews have espoused thoughts that have directly and indirectly contributed to certain novel ideas in this paper. However, this does not imply that there was complete agreement with the thoughts disseminated by each intellectual while building a perspective for the thesis. They are namely, Dr. Ian Bremmer, Eurasia Group; Rajiv Malhotra, Infinity Foundation; Dr. Subramanium Swamy, President, Janata Party in India; Prof. Noam Chomsky, Professor Emeritus from MIT; Dr. Christian Parenti and Mr. Michael Parenti, renowned award winning authors; Clive Hamilton; Chris Hedges, an Pulitzer prize winning journalist; Prof. Anil Gupta

Professor at Indian Institute of Management, Ahmedabad; Alex Lightman; James Clark of the World Technology Network (The WTN); Mr. John Hagel III, Co-chairman, Deloitte LLP Center for the Edge; Emanuel Pastreich; Chip Pitts, a Lecturer in Law at Stanford Law School; Gordon Sumner (popularly known as Sting) Musician and Activist; Pierce Brosnan, a renowned Hollywood actor and environmental activist; Def Leppard, a legendary music group.

It is also crucial to acknowledge the role of social media on Linkedin, Facebook and Twitter to provide connections between likeminded people as well people with conflicting viewpoints which eventually brought about shaping certain perspectives that were reflected within the Thesis.

Likewise, the role of my supervisors Prof. Luís Rocha, Prof. Paula Varandas Ferreira and Prof. Manuel Lopes Nunes and specifically the moral support of Profa. Madalena Araújo, Head of Centro de Gestão Industrial e da Tecnologia (CGIT).

Ultimately, the role of Family, Friends and Critics has been crucial for the 'successful journey' of the doctoral research as the doctorate degree is a career milestone and not a destination.

The author gratefully acknowledges the support of the people and institutions previously mentioned. However, the sole responsibility for the content of this thesis lies with the author

AN APPROACH TO DEVELOP SUSTAINABLE MEDICAL DEVICES

Abstract

The development and commercialization of contemporary Medical Devices is inherently of a multidisciplinary nature. Consequently, they have to undergo a stringent regulatory compliance procedure in conformity with an ever increasingly fierce and competitive business environment. Throughout the product life cycle, medical devices would significantly consume renewable as well as non-renewable resources and as a result exert a substantial social, economic and environmental impact(s).

Accordingly, it is imperative to consider the criteria of the aforementioned domains of sustainability in the initial phases of product development. The proposed conceptual multifaceted framework comprehensively explores a broader scope of sustainable product development, mainly from the pragmatic standpoint of systems engineering in comparison to the contemporary evaluation and development approaches. The underpinnings of the proposed framework encompasses the critical role of a decision model titled 'Multi Criteria Hierarchical Model (MCHM)' which is in fact an extensive revision of the Analytical Hierarchy Process decision modelling approach. The MCHM contains three tiers of pertinent criteria to attain overall sustainability. The structure of MCHM illustrates the tolerable level of sustainability in Tier 1, which is non-negotiable and compulsory, and the additional degrees of sustainability that increases from Tier 2 to Tier 3. Furthermore, the proposed framework elucidates the active participation of the MCHM in product design and development by conjoining with a wide spectrum of technical and conceptual tools.

The research methodologies in the thesis are comprised of interviews, questionnaires and case studies that mainly involved active participatory observation. The objective of incorporating case studies in the thesis is to evaluate the effectiveness of the MCHM in an Industrial environment. In this doctoral research the contemporary medical devices explored during the case studies included a wide spectrum of materials and technologies that range from metal and

non-metal prosthesis (external and sometimes internal), instruments, advanced implantable devices and biodegradable scaffolds used in regenerative medicine.

The research activities commenced with a thorough literature review that directed the researcher to the need for an exploratory study, accomplished by interviews with experts from academia and industry. These experts provided their feedback on the Sustainability related criteria outlined in the MCHM based on their expertise and knowledge of product development in diverse economic circumstances. The feedback was obtained in the form of assigning numerical scores during pair-wise comparison between two criteria at a time. The scores and recommendations were documented for being incorporated within the case studies.

In the case studies, the MCHM was incorporated in the early stage of product development to prioritize bare minimum environmental sustainability and profitability in accordance with regulatory compliance. During the decision making process, the product design was investigated in order to simultaneously accomplish the aforementioned facets by way of incorporating the expert recommendations. Furthermore, these expert recommendations obtained in conjunction with business strategies and technical problem solving techniques, such as Case based Reasoning (CBR), Design by Analogy (DA) and Theory of Inventive Problem Solving (TRIZ) were considered for resolving conflicts between the criteria of Tier 1 and other Tiers.

The thesis provides decision makers and the product development teams with a framework to gain a more holistic perspective on sustainable product development with respect to policies, technical/non-technical tools and business strategies. The goal is to enable these product development teams to implement pragmatic solutions for ensuring long-term competitiveness and the welfare of the Stakeholders.

Keywords: Sustainability; Multicriteria Hierarchical Model; Medical Devices; New Product Development.

UMA ABORDAGEM AO DESENVOLVIMENTO DE DISPOSITIVOS MÉDICOS SUSTENTÁVEIS

Resumo

O desenvolvimento e comercialização de dispositivos médicos contemporâneos é por inerência de natureza multidisciplinar. Consequentemente, estes dispositivos têm que passar por um procedimento de regulamentação rigoroso, num ambiente de negócios cada vez cada vez mais acirrado e competitivo. Durante o ciclo de vida do produto, os dispositivos médicos consomem recursos renováveis, bem como recursos não-renováveis, o que origina impactos sociais, económicos e ambientais significativos.

Assim, é imperativo considerar as diferentes dimensões da sustentabilidade nas fases iniciais de desenvolvimento do produto. O modelo conceptual proposto explora exaustivamente um propósito mais amplo de desenvolvimento de produtos sustentáveis, principalmente do ponto de vista pragmático da engenharia de sistemas, em comparação com a avaliação e abordagem contemporânea de desenvolvimento de novos produtos. A abordagem proposta suporta-se no modelo de apoio à decisão intitulado *Multi Criteria Hierarchy Model* (MCHM), que é uma extensão do modelo *Analytical Hierarchy Process* (AHP). O MCHM contém três níveis de critérios relevantes para alcançar a sustentabilidade global. A estrutura do MCHM reflete o que é obrigatório e não negociável no nível 1, e ainda a importância crescente dos critérios de sustentabilidade do nível 2 para o nível 3. Além disso, o modelo proposto demonstra a relevância da inclusão do MCHM no design e desenvolvimento do produto em conjunção com um amplo espectro de ferramentas técnicas e conceptuais.

As metodologias de investigação incluem entrevistas, questionários e estudo de casos que envolveram, principalmente, a observação ativa. A realização de estudos de caso teve como objetivo avaliar a adequação do MCHM em ambiente industrial. Os dispositivos médicos considerados durante o estudo de casos incluíram uma diversidade de materiais e tecnologias que vão desde próteses metálicas e não-metálicas (externas e internas), instrumentos, implantes e suportes poliméricos biodegradáveis usados em medicina regenerativa.

A revisão bibliográfica identificou a necessidade de desenvolver um estudo exploratório, suportado em entrevistas a peritos académicos e industriais. Estes peritos apresentaram a sua opinião relativa aos critérios considerados no MCHM, de acordo com a sua experiência e conhecimento sobre o desenvolvimento de produtos em circunstâncias económicas diversas. A comparação par a par dos critérios permitiu avaliar a sua importância relativa. Os resultados das entrevistas foram documentados para serem incorporados nos estudos de caso.

Nos estudos de caso, o MCHM foi incorporado na fase inicial do desenvolvimento de novos produtos para garantir sustentabilidade ambiental e rentabilidade, em concordância com da regulamentação em vigor. Durante o processo de tomada de decisão, o design do produto foi analisado de modo a cumprir simultaneamente os aspetos acima mencionados e incorporar as recomendações dos peritos. Além disso, estas recomendações foram consideradas em conjunto com as estratégias de negócio e técnicas de resolução de problemas técnicos, tais como o *Case Based Reasoning* (CBR), *Design by Analogy* (DA) e *Theory of Inventive Problem Solving* (TRIZ) para a resolução de conflitos entre os critérios do nível 1 e dos outros níveis.

A tese proporciona aos decisores e às equipas de desenvolvimento de novos produtos um modelo para obter uma perspectiva mais holística sobre o desenvolvimento de produtos sustentáveis, relativamente às políticas, ferramentas técnicas/não-técnicas e estratégias de negócio. O objetivo é capacitar essas equipas de desenvolvimento de novos produtos para implementar soluções pragmáticas que assegurem a competitividade a longo prazo e o bem-estar dos *stakeholders*.

Palavras-chave: Sustentabilidade; *Multicriteria Hierarchical Model*; Dispositivos Médicos; Desenvolvimento de Novos Produtos.

Table of Contents

List of Figures

List of Tables

Abbreviations

AHP – Analytical Hierarchical Process

CAD – Computational Aided Design

CAM – Computational Aided Manufacturing

MPM – Manufacturing Process Management

TPLCM – Total Product Life Cycle Management

CBR – Case based reasoning

CSR – Corporate Social Responsibility

EPA – Environmental Protection Agency

EOL – End-of-life

EuP – Energy using Products

EN – European Standards

FDA – Food and Drug Administration

FMEA – Failure Mode Effects Analysis

IEC – International Electrotechnical Commission

IEEE – International Electrotechnical Commission

ISO – International Organization for Standardization

KM – Knowledge Management

KBE – Knowledge Based Engineering

LCA – Life Cycle Analysis

MCA – Multicriteria Analysis

MCHM – Multicriteria Hierarchical Model

OECD – Organization for Economic Co-operation and Development

OEM – Original Equipment Manufacturers.

PSS – Product Service System

QFD – Quality Functional Deployment

REACH – Registration, Evaluation, Authorization and restriction of Chemicals

RoHS – Restriction of Hazardous Substances Directive

SETAC – Society of Environmental Toxicology and Chemistry

SWOT – Strength Weakness Opportunities Threats

TBL – Triple Bottom Line

TRIZ – Theory of Inventive Problem Solving

UNEP – United Nations Environment Program

UNO – United Nations Organization

UNESCO – United Nations Educational, Social and Cultural Organization

WEEE – Waste Electrical and Electronic Equipment Directiv

Chapter 1

Introduction

Chapter 1 is the primary chapter that outlines the whole structure of the thesis in terms of the motivation and scope followed by methodologies considered to evaluate the proposed approaches and followed by the layout of the chapters.

1.1. Motivation and Scope

Medical Devices are a culmination of various scientific and engineering disciplines. Moreover, Medical Devices have although contributed to society in terms of development, based on the industrial revolution and quantum leaps in technological advancements. Nevertheless, in an economy in which whether the State plays either a dominant role (e.g.: Sweden/Denmark) or minimal role (e.g.: United States), they would still consume substantial magnitude of renewable and non-renewable resources.

Furthermore, from a standpoint of complex theory, in which entities are strongly interconnected and intertwined between each other, the human civilization and its societies (especially their economies) are strongly inter-related with the environment. This implies that the consumption of resources and the undesirable generation of waste/emissions pose an imminent threat to the continuation of the biosphere and our human civilization (or stakeholders) (Hauschild et al, 2005; Parenti, 2011; Sutcliffe et al., 2009). In fact, the paradigm of Globalization, which transcends national and international borders via treaties, is quite contrary to the diffusion of socio-economic and environmental externalities as a result of unfettered economic growth (Parenti, 2011). These considerations have been clearly outlined and addressed by virtue of various initiatives and policy related mechanisms by countries across the globe under the aegis of the United Nations and other institutions of global reputation. For example, the United Nations report

titled “Our Common Future”, published in 1987, by the World Commission on Environment and Development (WCED).

It is important to address the product development activities of medical devices within the aforementioned perspective of social, economic and environmental sustainability (or overall sustainability), especially in terms of a fiercely competitive business environment coupled with stringent regulatory compliance (Sobelman, 2008).

Many research investigations in the past have illustrated that the commitment towards Sustainability by Enterprises and Institutions, both public and private have resulted in more stable ecosystems and improved income distribution which are necessary conditions for the perpetuation of commerce (D’Alessandro et al., 2009).

As a result, it is crucial to redefine the decision modelling and product development approaches with reference to the aforementioned domains of sustainability and the technical/non-technical tools utilized for commercializing a medical device. The endeavour to propose novel methodologies to incorporate overall Sustainability in this thesis emanates from the acknowledgement of a wide array of conflicts/synergies, which are a result of a multitude of specifications based on the criteria of overall Sustainability. Moreover, a series of conflicts and synergies which are embedded within each other should be resolved by the proposed prioritization based decision modelling approach discussed in this thesis coupled with business strategies and known problem solving techniques (Khomenko & Ashtiany, 2007). The prioritization based decision model titled as the Multicriteria Hierarchical Model (MCHM) is devised to execute trade-offs between certain criteria (and its corresponding specifications) in scenarios where the conflicts between them are irreconcilable. Likewise, the MCHM in this thesis is re-structured to propose a novel product development approach that addresses the diverse facets of the products’ life cycles namely cradle-to-cradle/grave and business life cycle which begins from R&D to decline phase (Hauschild et al., 2005; Wejnert, 2002).

The thesis has committed a substantial number of pages to review existing literature in both decision modelling and product development approaches which either include or disregard overall Sustainability. During the literature review it is revealed that certain decision modelling techniques require exhaustive and cost intensive analyses, while certain product development approaches are profound enough to demand the assessment of the maturity levels of various technologies and sciences that forms the basis of the products' functionality (Alexandre et al., 2003). Therefore, the proposed models and approaches address the pragmatic impediments encountered by the Enterprises at the frontiers of their resources namely (but not limited to) time, managerial capacity, material properties and finance.

In addition, the thesis does discuss the critical role of various technical tools for reducing the project timeline of a medical device under development which are specifically pertaining to life cycle management, knowledge based engineering/knowledge management and design engineering approaches (Patil, 2010). Accordingly, a Multifaceted Framework that is proposed by acknowledging the utilization of these diverse technical and non-technical tools in conjugation with the proposed MCHM.

Furthermore, the evaluation of the effectiveness of these proposed decision modelling and product development approaches was based on a case study approach which encompassed detailed interaction with participants and in some cases active participating to ensure that a certain degree of overall sustainability is attained during the initial phases of the product development (Yin, 2003). The case studies did entail interviews with experts from academia and industry who provided their wisdom and tacit knowledge with reference to the criteria in the MCHM and its corresponding product development models. As a result, the feedback was incorporated during the product development process of the Enterprises that were chosen for case studies. The goal was to ensure that the proposed models and approaches were evaluated in the scenarios for which it has been devised.

Towards the end of the doctoral research, the investigation revolved around comprehending the historical, policy centred and philosophical dimensions of technology development and sustainability. This final phase endeavour enables the product development teams to acknowledge the crucial role of policy and Government sponsored research projects and initiatives to foster mutually beneficial public-private partnerships. For example, the GeSI and StEP initiatives, outlined by the United Nations (2009), to enable public and private institutions with policy makers and other experts for developing as well as exchanging technologies for recycling electronic waste. This implies that private institutions are able to attain overall sustainability only up to a certain degree beyond which State sponsored involvement becomes necessary to actualize a more cost effective approach towards overall Sustainability.

1.2. Objectives of the Thesis

The core objective of the thesis is to deliver a holistic and a pragmatic approach towards decision modelling and product development for Medical Devices with the simultaneous incorporation of the three domains of overall Sustainability namely Social, Environmental and Economical.

Concurrently, the research propositions are centred on the critical role played by the following paradigms in attaining overall Sustainability: product design, accessibility and utilization of Enterprises' resources and the role of regulatory frameworks with socio-economic policies that could either promote or impede an Enterprise to incorporate a higher degree of overall Sustainability.

The core objective is further elaborated as follows:

a) Conduct a thorough literature review of existing product development and decision modelling approaches that include or exclude the considerations for overall Sustainability. The review is intended to unearth various shortcomings of the contemporary approaches followed by incorporating preliminary feedback by experts from academia and Industry to determine opportunities for improvement.

b) Proposing a novel approach towards decision modelling for developing Medical Devices with a substantial degree of overall Sustainability. The proposed decision modelling approach is titled as 'Multicriteria Hierarchical Model' (MCHM). The proposed decision modelling approach contains pertinent criteria encompassing overall Sustainability, which is devised to resolve conflicts that arise as a result of considering multiple criteria and its corresponding product specifications to attain a very high degree of Sustainability. Moreover, the role of contemporary problem solving techniques is to be explored for resolving conflicts during the evaluation of the MCHM within the case study approach.

c) To propose a novel product development process based on the proposed decision modelling approach (MCHM). Furthermore, exploring the role of MCHM in product design optimization and to evaluate the effectiveness in pragmatic terms with respect to its implementation.

d) To conduct interviews and discussions with experts from academia and industry in order to evaluate the co-relations between the criteria outlined in the MCHM. The aim is to accumulate wisdom, insight and tacit knowledge for executing decisions in substantially complicated circumstances that requires product development teams to simultaneously address multiple considerations pertaining to overall Sustainability.

e) To conduct detailed case studies that entails discussions, interviews, questionnaires and in certain cases active participation in the Enterprises chosen for the case studies in order to evaluate the effectiveness of the MCHM and the novel product development process. Moreover, to determine the feasibility of incorporating the expert feedback during the early stages of product development during the case studies approaches.

1.3. Methodology

The aforementioned approaches for decision modelling and product development for the incorporation of overall Sustainability have been were devised for industrial application in the near future. This justifies the adoption of the case study approach that was conducted with 6 entities that comprised of research labs,

small-medium sized companies (SME) and large sized companies that develop and/or manufacture medical devices ranging from Class I to Class III categories. To clarify further, a single case study comprised of evaluating the proposed models and frameworks within a single entity. Therefore, 6 entities imply 6 case studies in this thesis.

The case study approach provides substantial flexibility to consider a wide spectrum of data collection methods ranging from interviews, questionnaires, active participation/observation and reviewing relevant documentation. Although, the case study approach is most appropriate when the user can exert only a limited influence on the outcome of the process under examination (Yin, 1994). However, in a few of the cases, active participation was considered to modify and improvise the existing product development process and product design approaches for the incorporation of overall Sustainability. Meanwhile, specific recommendations were provided for some of the cases after thorough observation of the product development process and reviewing opportunities for either incorporating or enhancing overall Sustainability. In this thesis, due to more than one case is considered in terms of multiple enterprises with multiple units (i.e. decision modelling and product development approaches) under review. Hence, the most appropriate category of case study is this thesis is Type 4 (Yin, 1994). The units of analyses were evaluated by the case study approach with respect to the three research propositions mentioned in Section 1.2.

Moreover, the method of informal conversational interviews was considered for obtaining feedback and insights from the experts from academia and industry during the pair-wise comparison of the criteria outlined in the MCHM. The pair-wise approach is adopted from the Analytical Hierarchical Process of decision modelling which has also been substantially restructured to devise the MCHM (Saaty, 1990). Moreover, the informal conversational interview approach is able to provide the flexibility of capturing the insight and tacit knowledge of the experts by co-relating more than one criterion simultaneously with reference to diverse economic circumstances.

The feedback from these experts was incorporated within those case studies that permitted active participation. Similarly, for the evaluation of the multifaceted framework, the interview approach was coupled with a questionnaire to focus on a few relevant questions without expending too much time while simultaneously gaining an appropriate degree of in-depth knowledge on the multifaceted framework from the Experts.

Even though the case study method has been criticized for not being substantially rigorous in nature compared to other evaluation methods. However, as various medical device companies which develop/manufacture a wide array of medical devices ranging from syringes to neural prosthesis. As a result, it is crucial to consider a suitable evaluation methodology such as the case study approach that is flexible in nature in terms of the context of the medical device and the enterprises developing or manufacturing it.

As the product development process of such diverse medical devices do possess their own idiosyncrasies with reference to opportunities for incorporating overall sustainability. Furthermore, the results of one case study within an Enterprise that develops medical devices cannot be necessarily be 'literally replicated' in other cases in which medical devices are manufactured either in a SME or a large sized company. This opens the case study approach towards the paradigm of theoretical replication in which different results are obtained based on specific circumstances of the medical device and the Enterprise under review (Yin, 1994).

1.4. Organization of the Thesis

The research was conducted according to the outlined objectives.

Chapter 2 discusses the existing gaps and shortcomings of the contemporary medical device development approaches. As these devices consume substantial renewable and non-renewable resources that further instigate a series of interconnected social, economic and environmental impacts. The exhaustive list of criteria ranging from regulatory compliance, market competition and aforementioned domains of sustainability is overwhelming for an organization in terms of their human, financial and non-financial resources.

Moreover, the real-life challenges facing medical device development are rising healthcare costs in terms of allocation of Government funding and inclusion of more stakeholders with ever changing requirements. This justifies proposing new product development and decision modelling approaches to enable product development teams to exploit synergies and select suitable trade-offs in terms of cost effectiveness, quality and speed. In this chapter a contemporary product development approach is compared to a systems engineering based development approach in accordance with the quality systems requirements stated by the regulatory agencies such as the FDA.

Based on the discussed challenges and limitations encountered during the incorporation of overall sustainability considerations within the design phase, the product engineers and managers require a comprehensive and simplified decision-making tool for governing their development process. The desired decision model should utilize prioritization of various sustainability considerations in accordance with the regulatory compliance and the desired degree of economic growth (Ambec & Lanoie, 2008; Vogel, 2005). The prioritization would facilitate the product engineers and designers to exploit the synergies and resolve the necessary trade-offs across products and product portfolios.

In Chapter 3, the approach of delivering the utility (the desired outcome) of a medical device, in contrast of the actual physical good is exemplified. Moreover, the strategy of Product-Service System (PSS) is based on Systems Engineering and envisioned to accommodate a more modular structure for easier assembly, disassembly and even End-of-life options. This implies means that not all types of medical devices, which range from heart valve to wheelchairs, can be considered for the Product Service System (PSS) method. Even though savings in cost and energy/materials could occur by adopting the Product Service System approach and end-of-life options; nevertheless they may also incur their own opportunity costs and may not be always be accepted by the market/stakeholders. Furthermore, the medical device company should bear in mind the basic limitations they would encounter during product development in terms of time,

skills/knowledge of human resources, engineering tools, material properties, finance and regulation. These limitations may also pose an impediment for a medical device company to re-organize its value chain partners (such as suppliers, distributors and manufacturers) to counter uncertainties and mitigate undesired risks.

The three tier multicriteria hierarchical model (MCHM) is introduced in this chapter that is inspired from Analytical Hierarchical Process (AHP) only in terms of its hierarchical nature of a wide spectrum of interconnected criteria. The decision model is called Multicriteria Hierarchical Model (MCHM). The AHP approach that forms the basis of the MCHM is considered to be simple and accounts for a wide spectrum of factors, criteria and indicators for decision making in a consistent manner with a common scale without any units. Furthermore, the MCHM aims to address complex product development and engineering scenarios, while concurrently maintaining the inherent simplicity of the AHP. The first tier is compulsory and non-negotiable with the minimal degree of sustainability, while the other two are additional degrees of overall sustainability that have to compulsorily comply with each criterion of the first tier.

Moreover, each criterion is represented by one or more product specifications whose optimal values would be decided during preliminary engineering analysis in Stage 2-3 of the product development process in accordance with the product specifications of other criteria as well. The three tier approach which contains two main criteria namely, Regulatory Compliance and Economic & Business Performance does not only enable the senior management of a medical device company to select suitable projects for further development during stage gate process, but also assists product development teams to define the degree of effectiveness of the tools they need for their activities. In addition to the consideration of conceptual and technical tools for product development, a robust product life cycle management infrastructure with information technology system is crucial to synchronize a wide spectrum of exhaustive activities.

The chapter also simultaneously discusses the various decision modelling approaches used to addressing overall sustainability and their limitations. Especially for techniques such as Cost Benefit Analysis that considers substitutability between various impacts and denotes every undesired externality in monetary terms. However, assigning financial values has proved to be less effective and reductionist in nature, bearing in mind the closely interconnected relations between social structures, environment and economics. Moreover, in our globalized world almost every geographical region has diverse cultures and their own viewpoints in concurrence with on their livelihood that further complicates the geo-political scenario in which a medical device has to operate. Thus justifying the need of a comprehensive as well as simplified approach towards medical device development.

This thesis explores the opportunity of the decision model MCHM inspired from AHP to be an actively participating entity within the product development process of a medical device as opposed to previous research investigations in which AHP has been mostly considered to select or reject alternatives. Moreover, the criteria of the AHP do not have a strong co-relation or co-dependency between each other, as opposed to circumstances in the real world.

The interconnected nature of the criteria in the MCHM would enable the product development teams to define the sensitivity values of one criterion over the other. Moreover, outlining the sensitivity of one criterion over other criteria would also enable the product development teams to ascertain potential risks and even locate the source of undesired outcomes. Consequently, the elucidation of the interconnectedness between the criteria of the MCHM facilitates risk evaluation as well as planning suitable mitigation strategies throughout the life cycle of the product.

In the subsequent chapters, the role of MCHM in medical device development would be discussed in detail. This would be materialized by incorporating the MCHM within a Multifaceted Framework that comprises of a wide spectrum of technical tools and conceptual approaches for product design and development.

Chapter 4 contains a detailed discussion on a wide spectrum of product development approaches that are utilized by the industry. These product development approaches encompass various forms of life cycles of the product life cycle management in order to attain sustainability. Moreover, these conceptual models are required to be integrated with technical tools for design, engineering and production in a seamless manner for streamlining both product development and commercialization. Therefore, this chapter explores the opportunities for incorporating the Multicriteria Hierarchical Model (MCHM) during the design phase of the product under development so as to enable the decision makers to select/reject suitable product design configurations.

Furthermore, the chapter begins with the discussion of various conceptual product development approaches, which have illustrated an extensive focus on long term planning, product configuration and its underlying technologies and flexibility within the value chain to adjust for uncertainties. In this chapter, the most important facet of non-linearity of product development and design is also illustrated and discussed. In addition, the various technical tools in design, engineering analyses and product development planning are briefly outlined. Moreover, the critical role of identifying, storing and ensuring the accessibility of engineering and non-technical knowledge is ascertained to be crucial for adhering to the project timelines. Similarly, product development teams have to define an engineering analysis (or simulation) strategy to ensure that the evaluation of the virtual product is more comprehensive without expending excess of time and resources.

Notwithstanding, the advantages of customizability of the proposed multifaceted framework for a wide array of medical devices, the product development teams would have to manually assign the values to each specification for every criterion. The arduousness of the customizability is governed by the complexity of the device that may or may not relevant to the pre-defined classes of the medical devices. Nevertheless, Knowledge Based Engineering applications can be incorporated for automating unproductive repetitive tasks to mitigate the aforementioned impediment. The proposed multifaceted framework has been

devised by considering the critical role of the MCHM for product design optimization by conducting an exhaustive literature research and validation by expert opinion. Furthermore, the literature review reveals that the coordination of a multitude of technical tools and computer-based systems could elucidate conflicts in terms of their data formats and programming structures. The objective of this chapter is to demonstrate the active participation of the MCHM Design Optimization Procedure.

Chapter 5 details the research methodologies adopted in this thesis.

Chapter 6 is divided into three exhaustive sections to provide in-depth discussions of the results pertaining to the methodologies adopted in Chapter 5 for evaluating the decision modelling and product development approaches in Chapter 2, 3 and 4. The first section that discusses the one by one pair-wise comparison of the criteria outlined in the MCHM by the experts reveals that in pragmatic circumstances each criterion should be co-related with multiple criteria, simultaneously. Furthermore, the experts also pointed out that an Enterprise, which intends to incorporate overall Sustainability, should adopt novel strategies for product design, business operations and even interaction with relevant policy makers. As the AHP approach requires pair-wise comparison on a one to one basis, while reality as stated by the experts is far more complicated to co-relate multiple criteria simultaneously and also consider the flexibility of disregarding a few irrelevant criteria (except Tier 1) to adhere to the project timelines. The second section discusses the feasibility of the multifaceted framework by using informal conversational interviews, questionnaires and literature review in accordance with experts from both Academia and Industry.

The justification for considering expert opinion is because most of the conceptual frameworks, technical tools and optimization approaches have been comprehensively studied by both Industry and Academia for almost more than a decade.

As per the experience of the experts, the multifaceted framework is suited for large sized companies with enormous research and development infrastructure.

Moreover, incorporating non-technical knowledge within design optimization, which is pertaining to socio-economics and business strategy, would reduce the effectiveness of the optimization activity, as it would require continuous human intervention. Concurrently, as concluded from the expert opinion, the effectiveness of the multifaceted framework in design optimization is determined to be entirely dependent on the complexity of the product configuration and the magnitude of design optimization required. In addition, the experts emphasized on the ability of the product engineering teams to address incompatibilities originating from the data formats and programming structures of the technical tools pertaining to computer design and engineering, ecological impact evaluation and regulatory compliance systems.

The goal of the multifaceted framework is to evaluate the effectiveness of the MCHM and its ability to go beyond conventional decision modelling into design optimization at a comprehensive scale. Ultimately, it was concluded that the MCHM is most effective as a conventional decision-modelling tool for selecting suitable projects and even solving conflicts within product design as opposed to playing a critical role in design optimization.

The third section discusses each entity (Research Lab, Small-Medium Enterprise and Large sized Enterprise) for which the case study approach was adopted to evaluate the effectiveness of the decision modelling and product development processes with reference to the previously mentioned research propositions in Section 1.2. This section provides the basic description of the Entity with the justification for its selection followed by relevant information on the data collection methods considered for the case study and the categories of case study approach which were applicable such as Explanatory, Exploratory and Descriptive.

The final chapter of Conclusions and Future Research not only summarizes the preceding chapters but also co-relates it with certain pertinent concepts in Economics, especially the economic circumstances considered in the first section of Chapter 6 during pair-wise comparisons interviews of the MCHM criteria. The

conclusions from the case studies revealed that entities by themselves can incorporate overall sustainability only to a limited degree beyond which the role of State or State based Institutions play a more dominant role in defining policies, fostering partnerships and even providing subsidies or grants for developing robust technologies.

To conclude, this thesis on decision modelling and product development of medical devices is unique owing to its strong co-relation with economic and social paradigms which not only leads to a successful medical device but even provides a justification in terms of need and market demand for a medical device to be commercialized.

Chapter 2

Fundamentals of Sustainability with respect to the Development of Medical Devices

2.1. Introduction

Recent published work in academic journals has pointed out the need for more research on the identified gaps and shortcomings of the current strategies employed in the development of sustainable medical devices. The facet of sustainability comprises of social, environmental and economic considerations.

This chapter discusses the existing gaps and shortcoming of contemporary medical device development. As these devices consume substantial renewable and non-renewable resources that further instigate a series of interconnected social, economic and environmental impacts. Consequently, these aforementioned categories of interconnected impacts would pose an impending threat to the continuation of an Enterprise that develops and/or manufactures Medical Devices across Class I to Class III. Likewise, the chapter entails a detailed review of the contemporary product development processes from a business perspective as well as a systems engineering standpoint.

The objective of this chapter is to illustrate the shortcomings in the existing product development processes of medical devices and in addition highlight their incapability to accommodate for the three domains of Sustainability.

2.2. Basic introduction to Medical Devices and Sustainability

The sector of medical devices comprises of products as simple as a tongue depressor (Class I) to complex and interdisciplinary devices as an implanted pacemaker (Class III) <http://www.fda.gov/MedicalDevices/default.htm>. Moreover, the development of medical devices is an extremely resource intensive

endeavour throughout its development and production life cycle, namely, at the frontiers of energy, materials, human (man hours) and knowledge (skills and expertise).

The onset of globalization has placed immense pressure on both stringent regulatory compliance and business performance (Sobelman, 2008). Moreover, the medical devices sector similar to every other industrialized sector consumes non-renewable energy and resources on a massive scale, especially single-use devices (Hanson & Hitchcock, 2009). Consequently, both regulatory agencies and governments across the globe have raised their concern for the continuation of the global scale Industrialization with reference to the current global socio-economic and environmental circumstances (World Commission on Environment and Development 1987) **<**http://www.un-documents.net/ocf-03.htm**>**.

Meanwhile, the availability and accessibility of non-renewable energy and resources are gradually diminishing for every other business sector including the medical device industry, which intends to capture a larger global market share (Hanson & Hitchcock, 2009).

These three facets of sustainability are social, economic and environmental sustainability, which are strongly interlinked and interdependent upon each other. Consequently, the environmental impacts initiate significant pressure onto the business performance and the dimensions of socio-economic welfare (Hauschild et al, 2005; Parenti, 2011; Sutcliffe et al., 2009). Thus making it imperative for the medical device industry to consider overall Sustainability (i.e. social, economic and environmental sustainability) within the initial phases of its development and throughout its life-cycle phases, namely, extraction, production, distribution, utilization, disposal and end-of-life (Hauschild et al., 2005).

This thesis intends to simultaneously address the social, environmental and economic dimensions, following the Triple Bottom Line Approach (Sutcliffe et al., 2009). The Triple Bottom Line Approach enables the product developers to develop tools and techniques (both conceptual and technical in nature) to identify and address various synergies/trade-offs during the early stages of the product

development cycle (Sutcliffe et al., 2009). For example, a new material for the external casing of a pacemaker is both environmentally friendly and compliant with FDA regulatory standards. On the other hand, surgical tools that require certain alloys owing to their strength and surgical performance could consume significant non-renewable resources for its production that results in large quantity of emissions. In such cases the medical device company can optimize the consumption of resources in order to minimize the release of the corresponding emissions. Furthermore, the company should consider replacing the alloy by a more sustainable material, provided it complies with the FDA regulatory standards <http://www.fda.gov/MedicalDevices/default.htm>.

The exhaustive list of criteria for both regulatory compliance and sustainability are determined to be overwhelming, especially in terms of a fiercely competitive market, managerial capacity (e.g.: availability of time and human resources) and technological limitations (e.g.: limitations of modelling software and material properties) (Project Management Book of Knowledge, Project Management Institute, 2010).

This scenario necessitates the need for establishing a priority based decision-making and product development approach, to address various synergies and trade-offs. Therefore, the essential criteria would be prioritized in order to deliver a significant magnitude of sustainability without compromising the regulatory compliance and basic economic growth objectives that would result in a more profitable product.

The core focus of this chapter is to discuss the importance of a priority based decision-modelling approach for governing the product development of a sustainable medical device. The subsequent chapters would outline and discuss in detail the structure of the priority based decision modelling approach and a novel product development approach for sustainable medical devices. Likewise, the thesis briefly discusses the other critical success drivers for developing sustainable medical devices, including the role of knowledge management and a robust Information Technology Communication infrastructure. The motivation to do so is

based on the significant presence of interdisciplinary research in medical devices that originates from diverse scientific and engineering disciplines.

The priority based decision model is envisaged to enable product engineers and managers so as to implement sound decisions at the upper management level (e.g.: project selection of the most sustainable and economically viable project, out of a list of alternatives) as well as the level of critical engineering details in a product development endeavour. For example, the product engineers and managers can finalize the level of customization needed for a computational modelling tool to be considered for product design and simulation.

The priority based decision modelling would be primarily based on the weights assigned to the pertinent criteria of the decision model. The assigned weights would be based on the degree of importance with reference to the regulatory compliance criteria, business growth criteria and relevant criteria pertaining to overall Sustainability. Moreover, in certain circumstances medical devices are exempted from adhering to RoHS compliance (Restriction of Hazardous Substances Directive).

2.3. Challenges faced by medical devices companies

The dynamics of the business, economic, political and regulatory scenarios exert a substantial influence on the innovation and product development strategy of a medical device company. The resultant impact would be the inability of a medical device company's product development strategy to simultaneously address multiple and diversified challenges. Therefore, leading to the failure of the company or transformation of the company into a competitive market player.

In this respect, Faniel (2011) has identified two challenges that medical device companies and other healthcare organizations would have to surmount in order to stay competitive: rising healthcare costs and its impacts on users, device developers and regulatory bodies and inclusion of multiple stakeholders and their ever-changing requirements. In the same document of Faniel (2011) mentioned that the recently published report by OECD (Organization for Economic Co-

operation and Development) stated that nations invest around 10% of GDP on healthcare, which is expected to rise up to 16% at the same rate of growth by 2020.

This has also resulted in the current inability of governments, citizens and institutions, such as insurance companies to afford rising healthcare costs. Furthermore, limited funds for a large number of patients subjects the medical devices to a much more rigorous evaluation procedure; thus leading to delays in time to market, delayed profits and eventually revenue losses. Meanwhile, the end-user and clients of the device desire a significant improvement in the medical device in order to justify their purchase. This is also applicable to medical device organizations that need to justify the expenditure of resources for the development, regulatory approval and marketing of a new medical device (Miller, 2007).

Accordingly with reference to the economic challenges, the medical device companies are required to consider various stakeholder requirements, which further leads to a higher degree of uncertainty in the product development process. For example, changing knowledge about various diseases, modifications in the regulations for insurance and reimbursement, competitive negotiation concerning the cost management objectives between the device developers and hospital purchasing departments. Additionally, identifying, developing and implementing of methodologies to maintain the equilibrium between the consumption of renewable and non-renewable resources versus its rate of replenishment (Cohen & Howard, 2006; Fiksel, 2006).

As mentioned in the introduction that the above mentioned challenges encountered at the frontiers of environmental and socio-economic dimensions coupled with the demand for higher patient satisfaction, subjects the medical device companies to substantial pressure in their product development approaches and innovation strategies. However, these pressures both compel the medical device companies to identify pre-existing gaps and the newly created gaps in their existing methodologies.

The medical device companies are therefore required to implement methodologies and devise pertinent business processes for the identifying the relevant gaps and shortcomings in order to resolve conflicts and synergies between their business objectives and the various cross organizational boundaries pertaining in to their stakeholders (including end-users, regulatory bodies and insurance companies). These cross organizational boundaries pertaining to their stakeholders include but are not limited to environment, socio-economic domains, human resources, end-users, patients, regulatory bodies, suppliers, distributors, manufacturers, development collaborators, shareholders, remote/distant communities, government(s), healthcare institutions and insurance companies (Charter, 1998). The inclusion of stakeholders within the business growth objectives results in a more holistic and sustainable approach towards product development.

2.4. An insight into the best practices of the Medical Device Industry's Product Development Process

The utilization of certain business processes and best practices in collaboration with disciplined engineering efforts could enable medical device companies to identify the various gaps and shortcomings in their development methodologies for addressing the social, economical and environmental dimensions of sustainability.

Accordingly, Vogel (2005) has enumerated a list of numerous facets in the product development process of medical devices that indicate the various gaps/shortcomings and the demarcation between successful market leaders in contrast to their contemporaries.

Bearing in mind the previously stated challenges by Faniel (2011), medical device companies are working towards a shorter development cycle for enhancing their cash flow of revenues. Moreover, for a shorter product development cycle, a well-defined engineering process embedded with regulatory controls serves the market needs with higher reliability and quality of performance towards the stakeholders. These are mainly, but not limited to Food and Drug Administration (FDA) for Device Regulation, International Organization for Standardization (ISO),

International Electro-technical Commission (IEC), European Standards (EN) and Directive on Waste of Electrical and Electronic Equipment (WEEE).

In addition, Vogel (2006) stated that the "Design Control" and "Validation" within the Quality System Regulations prepared by the FDA are nothing more than a collection of good engineering practices that a medical device company should consider in its product development programs (Vogel, 2001).

The most crucial regulatory compliance procedure in itself provides the bare minimum social and environmental sustainability, in terms of safety standards for the end-users and minimization of environmental hazards, respectively <http://www.iso.org/iso/home/store/catalogue_ics/catalogue_ics_browse.htm?ICS1=13>. Meanwhile, the profitability (also a part of economic sustainability) entirely depends on the medical device company and the external drivers to its business such as volatility in the price of raw materials.

The objective to achieve a shorter product development cycle with the highest product quality and regulatory compliance, a medical device company would always encounter a complex relationship between the parameters of quality, speed and cost effectiveness. As a result, the medical device company would need to resort to exploiting the synergies and executing suitable trade-off between these aforementioned parameters (Almonor, 1998). The source for the trade-off usually is a result of the Pareto optimal frontier wherein one parameter cannot be improved without worsening the other (Zhao et al., 2010). Moreover, it is the role of the project manager to determine the appropriate balance between the 3 facets of sustainability based on the fulcrum of regulatory compliance (specifically FDA and ISO) so as to exploit the synergies and/or make the desired trade-offs. It is advisable for medical device companies to implement a disciplined mode of engineering and project management practices in order to actualize a continuous improvement of the business processes with minimal degree of any undesired inconsistencies.

Following are the facets of product development process and business practices that would enable medical device companies to determine the gaps and shortcomings in their product development methodologies:

i. Defining the quintessential of Quality

It is essential for the medical device company to primarily identify its criteria of quality, as various stakeholders of a medical device company perceive quality related criteria in their own perspective such as:

•Regulatory agencies desire demonstrable evidence of performance, sustainability and safety.

•Users perceive quality in terms of meeting the needs of cost, quality, performance and ease of use.

•Sales department defines quality in terms of the device attributes that can be sold at competitive prices.

•Service departments define quality in terms of devices that are low maintenance.

•Engineers sometimes perceive quality in terms of the implementation of the latest technology with superior reliability.

The project manager must establish the most appropriate degree of trade-offs so as to address the above needs with the highest priority assigned to the regulatory compliance requirements and bare minimum economic growth without which no medical device would be approved for commercialization.

ii. The Speed of Development with respect to Allocation of Resources

The pressures of a fiercely competitive market and the sustainability commitment to consume lesser quantity of renewable/non-renewable resources, drives the medical device company to compress the development schedules and squeeze the resource consumptions in order to deliver a profitable product. Enhancing communication between the project participants/stakeholders and streamlining the utilization of resources in a non-linear fashion can improve the development speed. Meanwhile, inconsiderate compression of the schedule without due diligence and paying less attention to the validation and verification steps such as

the General Principles of Software Validation, FDA (2002) <http://www.fda.gov/downloads/MedicalDevices/.../ucm085371.pdf> could result in a series of maintenance releases towards the end of the project. This would result in the service department being overwhelmed with multiple end-of-the moment tasks to be completed. Therefore, the objectives have to be realistic in order to motivate the engineers, managers, and financers of the project to channelize their efforts, accordingly. Likewise, in terms of allocation of resources, sometimes multiple projects are squeezed into a limited set of resources, which results in the aforementioned detrimental effects. Both these facets if improperly addresses could negatively affect project schedules, product performance, reputation and safety related hazards

iii. Regulatory Compliance: The Final Decision for the approval of a Medical Device

The medical device company, as stated by the FDA should implement the business processes and design controls throughout the product development cycle in order to lower costs and improve product quality with a shorter development cycle.

Regulatory compliance acts as the fulcrum of the interdependency between the factors of cost effectiveness, quality and speed. It is imperative that throughout the product development endeavour, the regulatory compliance is to be maintained and the documentation should be regularly updated with the least possible time delay. Accordingly, Patil (2010) recommends the utilization of a robust information technology communication infrastructure as a key important driver for the comprehensive product life cycle management of medical devices. The advantages stated by Patil (2010) are the continuous iterative design and development of the medical device. Meanwhile, the IT communication infrastructure also permits the traceability and auditability of the tasks/activities involved. The IT Communication infrastructure also assists in automated updating of the regulatory documentation in order to prevent any project schedule overruns and errors that stem from manually handling the

documentation procedure. The end result is enhanced accuracy in the overall development process and significant savings in time/resources that can be focused on other essential parts of the project.

A delayed regulatory approval, due to poor regulatory compliance during the initial phases of development, can result hamper the creditability and continuity of the medical device company. From a market share standpoint, the medical device company must bear in mind that each medical device product has a finite saleable time and consequently, each day in the Research and Development shortens the window of the sales period by one day. Furthermore, the shortening of the sales window implies that the company has much lesser time to sell its medical devices in order to gain a desired level of Return on Investment and unfortunately this could also increase the uncertainty concerning stakeholders' requirements. Furthermore, delayed product launches leads to the competitors gaining advantage and also increases the probability of becoming out dated as practices and standards change at a rapid pace. The costs related to human resources, administrative and overheads can eradicate any profits expected from the market due to the additional costs of unused resources of sales, marketing, distribution, manufacturing and engineering. Therefore, finalizing the most suitable trade-offs for identified conflicts and exploitation of synergies is critical for the success of medical devices under development. Similarly, the application of comprehensive and simplified decision making tools and techniques are of the utmost importance.

iv. Verification and Validation: According to the FDA regulations, verification and validation is of the utmost importance for developing a robust and reliable medical device. Verification comprises of evaluating the technical requirements that are translated from the user requirements. Validation is to assess the product based on its ability to address the overall user/stakeholder needs. The verification/validation activities should be conducted for both the software, hardware and all other associated systems/sub-systems of a medical device throughout the development cycle. The early identification of product deficiencies enables to improve quality, cost and decreased time to market.

Sobelman (2008) recommends the verification and validation activities to be incorporated upstream into the design cycle, through virtual and rapid prototyping coupled with testing and user-environment evaluation. The early incorporation of validation/verification would enable the shortening of the development cycle without compromising any of its advantages.

v. Traceability: The need to include numerous and diverse requirements of all the concerned stakeholders is overwhelming for any medical device development endeavour. Therefore the validation/verification stages require the inclusion of a strongly connected traceability network in order to enable the "tracking" and "linking" of the various higher level requirements (such as lower emissions of CO_2) to the numerous lower level requirements (user safety such as visual indictors to inform elderly patients about the correct mode of use) and finally up to the exhaustive design related elements. The traceability assists the product development teams to determine the relevant the metrics for monitoring the project.

Traceability has further roles and advantages enumerated as follows:

•To identify the high-level requirements that have not been defined and implemented for designing.

•To identify the design elements that do not trace back to lower-level or higher-level requirements.

•To enable the ease in maintenance of the overwhelming documentation pertaining to regulatory compliance, business processes and product development.

vi. Risk Management: The ISO 14971 standard is applicable to systems, subsystems, hardware and software of medical devices <http://www.iso.org/iso/catalogue_detail?csnumber=38193>. The risks can range from schedule overruns caused by ineffective design simulation [to] erroneous use of a device by the user due to poor user safety design [to] health hazards caused by toxic waste disposal and emissions during the production of the medical device.

Risk Management is not the same as conducting a Failure Modes Effects Analysis and Fault Tree Analysis since it comprises of identification and analysis of various risks and designing of risk control measures. It is essential to devise and implement a Risk Management Plan throughout the Development Cycle since most of the failures that appear during the initial phase of development can be included within the "iterative" proactive risk management programme of the company and its collaborators.

The project engineers and managers should encompass a systems level approach for their Risk Management Plan, as every medical device consists of independent and dependant systems and sub-systems that have to function in synchronicity with each other. For example, the assessment of the device software cannot be completed without the evaluation of the complete device performance in coordination with the functioning of the software.

Therefore, a Systems Approach for Risk Management assists the managers and engineers to focus on engineering design approaches and the device validation activities in the higher risk as well as lower risks functional areas. Once the risk areas are identified, the development activities can be optimized and the validation procedures can be completed within a shorter time span which would further result in improving the development cycle time.

The aforementioned facets and their associated business processes, demonstrates the role of effective and timely decision making for addressing the stakeholders' needs and ensuring commercial success. Therefore, the cost of the indecision of the manager should be considered as an additional cost, because it can result in schedule overruns. This includes extended time to make a decision or bad decisions that are made quickly without due diligence. However these costs are difficult to calculate as they express their negative impacts towards the later stages of the product development.

This section concludes that a systems based approach utilized during medical device development would assist in early identification and management of risks/hazards relevant to the stakeholder's requirements. Meanwhile, a

comprehensive and simplified decision making approach would be most suitable for such intensive product development endeavours so as to prioritize various criteria for addressing synergies, conflicts and trade-offs pertaining to the diverse set of stakeholders' requirements.

2.5. Product Development Process for New Medical Devices

This section intends to explain the various activities and stages of the product development of a new medical device.

Yang et al. (2006) discussed the various methods, tools and processes for the stages of product development, especially idea generation, concept definition, proof-of-principle, and conceptual design. The commercialization of a medical device requires systematic and disciplined investment of substantial resources (as stated in section 2.2). The endeavour requires in-depth expertise in the innovation process (including competition and marketing strategies), quality assurance, safety management and regulatory compliance in order to address the fierce competition brought about by large and small-medium medical device companies (Garnsworthy & Bell, 2004; Rainey, 2005).

2.5.1. Introduction to the Medical Device Development Process

Yang et al. (2006) proposes an iterative and integrated product development approach that incorporates strongly interconnected structures, activities, information flows and resources (see Figure 2.1). The aforementioned interconnected facets permit changes in the engineering design after inconsistencies are identified during the stages of prototyping, clinical testing and validation/verification stages. Moreover, the concept definition together with the engineering activities plays a key role in planning the manufacturing process.

The mentioned approach as shown in Figure 2.1 systematically transforms stakeholders' requirements as inputs into well-defined deliverables; thus, resulting into a product ready for commercialization. The product development process activities are outlined into various stages with in-between decision-making gates, namely innovation (idea generation, concept definition, proof of

principle), creation (engineering design, prototype, testing), realization (manufacturing, clinical trial, validation) and launch.

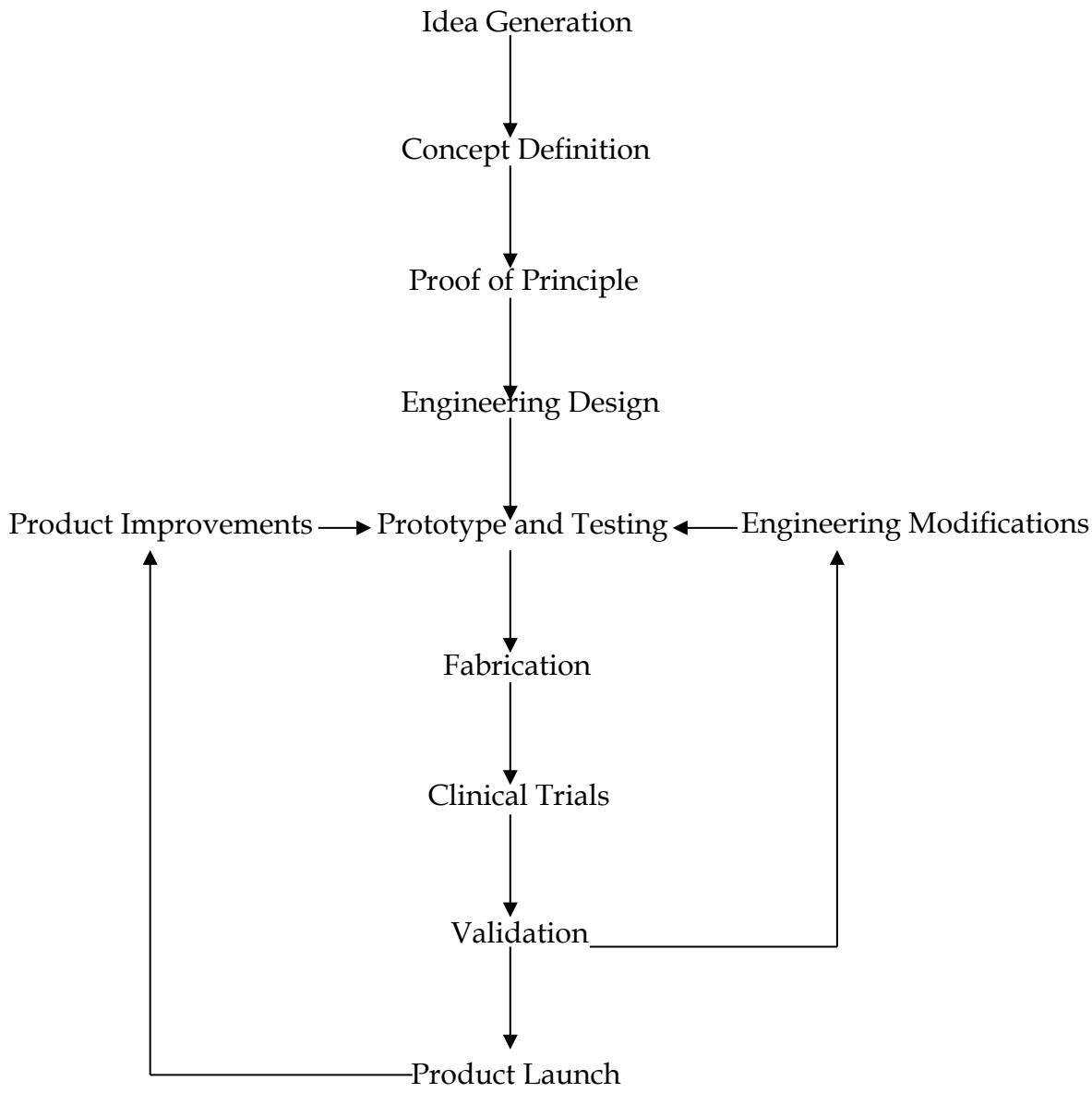


Figure 2.1. – Schematic representation of a widely used product development methodology for medical devices (Adapted from Yang et al., 2006; Borja et al., 2000).

2.5.2. Critical Segments of the Medical Device Development Process

Following are the stages that are carried out concurrently and in an integrated manner for shortening the development cycle:

a) Assessing Market Opportunities

It is essential for the medical device company to identify suitable market opportunities with respect to the corresponding stakeholders' requirements. The medical device company should be capable of addressing the market opportunities through comprehensive investment analysis techniques (e.g.: cost-benefit analysis) for determining the benefits and pitfalls. In relation to the device under consideration for development, the medical device company should be able to align its technological and human resources infrastructure with its business objective (Andrews, Foster Miller Inc. <http://thekenshogroup.com/docs/StrategiesforDevelopingandCommercializing.pdf>

b) Idea Generation

The identification of a lucrative market opportunity is followed by the idea generation phase that comprehensively attempts to address the desired market. However, ideas need to be filtered in terms of its feasibility and potential for success.

Yang et al. (2006) have listed six techniques to obtain innovative ideas for medical devices, namely: interviews (with internal and external parties), brainstorming, literal benchmarking; theory of inventive problem solving (TRIZ), axiomatic design, clustering and ranking (Suh, 2001; Zlotin et al., 2000). The stakeholder needs should be categorized into essential needs and nice-to-have needs (using the Kano diagram preferably), which are required to be prioritized based on the technical and market feasibility, regulatory compliance and sustainability (Project Management Book of Knowledge, Project Management Institute, 2010).

c) Concept Definition

The ideas generated must be defined for the creation of a tangible product that can be validated and transferred for production. Once the final set of ideas are obtained from idea generation phase, they are subjected to the evaluation criteria namely product attractiveness, fitness, cost, safety, overall sustainability, market potential, patent analysis and intellectual asset strategy. This phase usually experiences the utilization of the Quality Function Deployment (QFD) tool (Akao, 1990). The QFD tool translates the user requirements into technical characteristics, which can be utilized to obtain the desired product features and its corresponding production controls/processes (also known as Concept Definition).

d) Proof of Principle

The product concepts need to be verified and validated as per their technical requirements and the ability to satisfy concerned stakeholders, respectively. The finalized product concepts are verified for their functionality, characteristics, features and limitations, using software or hardware based testing or both. For example, Yang et al. (2006) proposed a development approach of a blade type lancet. The product concept for the lancet had to incorporate a safety feature that is the automatic retraction of the lancet's sharp blade after use without the use of any springs. The material properties and geometries of the lancet's plastic frame were calculated to demonstrate the ability of the frame deformation to deliver sufficient restoring forces so as to actualize automatic retraction of the blade after removal.

To add further, the device operability by the user is essential for minimization of user related hazards, which could originate from the erroneous use of the medical device. Edwards (2008) stated that the resources invested in medical device design and manufacturing must address the users' operational convenience within their working environment. The Human Factors Engineering (HFE) features ensure product functionality coupled with minimal probability of hazards as a result of erroneous use. For instance, engineers need to design medical devices that address the needs of the various disabilities of the home-health care device users without consciously reminding them of their disabilities since that could result in

abandonment of the medical device (Gitlin, 1995). The approach is titled as Universal Design or Inclusive Design. The users include but are not limited to medical and nursing staff, medical doctors and engineers, clinicians. For example, Micromedics Inc. had developed a range of single use sterile surgical instruments for surgical incorporation of biomaterials that was accepted by surgeons and clinicians. However, only after consultation with the operating room nurses did the company include a kit of ancillary materials for delivering the surgical instruments into the hands of the surgeons in sterile condition (Miller, 2007).

e) Patent Search, Analysis and Risk Management

After the proof of principle stage it is imperative for the medical device company to conduct systematic intellectual property analysis for evaluating any possibilities of infringement on the previously filed inventions and other forms of intellectual properties rights (such as patents, copyrights, trademarks and trade secrets). Furthermore, the patent citations are assessed for the evolutionary path of the technology in order to identify prior/subsequent art. This enables the medical device company to design around the previously filed intellectual property in order to avoid any infringement lawsuits. It is also advisable to have access to intellectual property legal advice to address any potential or on-going infringement and conflict litigations (Andrews, Foster Miller Inc.)

g) Competitive Assessment

Similar to the patent search and analysis, the medical device company needs to conduct a business competitive assessment of its competitors and other market players. In the IV Catheter case discussed by Yang et al. (2006) in which the competition assessment was conducted primarily by identifying the companies (existing and new entrants) in the market followed by evaluation of their business performance, including Strengths-Weaknesses-Opportunities Analysis. Meanwhile, the pertinent end-users and stakeholders were identified for steering the product development process.

h) Safety and Quality Compliance

Usually pertinent regulatory agencies require medical device companies to submit relevant design and compliance related documents. For instance, the Food and Drug Administration (FDA), USA demands a Design History File (DHF) that contains safety considerations for each individual device to be marketed in the USA. Similarly, the FDA also recommends the use of Quality System Regulations (QSR) frameworks (ISO 9001 or ISO 13485) for the Medical Device Development Organization to follow as good engineering and project management practices (Reliance Medical Consortium, Successful Medical Device Development: Critical Factors, <http://www.clinquest.com/Collateral/Documents/English-US/med_device_critical_success_factors.pdf>; Vogel, 2001).

i) Reimbursement and Payment

The medical device company should be proactive in ascertaining potential impediments on the frontiers of insurance payments and reimbursement. The companies that fail to do so would result in a significant waste of resources and delayed product launch; thus, resulting in loss of market share. In countries with privatized medical healthcare such as the United States in which the use of a 3rd party payment system can pose paradoxical dilemma for the medical device company. In terms of the reimbursement and payment of medical devices in the United States; wherein the Centre for Medicare and Medicaid Services (CMS) cannot reimburse the medical device development company unless it obtains a request from the Insurance Company. However the Insurance Company would not put forward request unless it is confirmed that the CMS can reimburse the device. Furthermore, Miller (2007) recommends medical device companies hire competent consulting services to improve the odds in their favour.

j) Animal Testing

In some cases, medical devices under development have to undergo animal trials in order to confirm the performance and effectiveness, prior to human clinical trials. Under FDA regulations, animal testing should be carried out under Good Laboratory Practices and in accordance with Quality Management Systems to obtain evidence of safety and performance within a living system (Reliance

Medical Consortium, Successful Medical Device Development: Critical Factors). Any inconsistencies in performance would result in additional iterations of design changes and prototyping activities (including verification/validation) until the desired clinical effect is attained.

k) Clinical Testing

Once animal trials are satisfactory (if required), the medical device with additional evaluation can be considered for human clinical trials under strict medical supervision of the Institutional Review Board (IRB), especially for medical devices being developed for markets in the United States. The IRB is an independent committee made up of doctors, analysts, community advocates and others in order to ensure that the clinical trial protocol is ethical and the rights of clinical trial participants are protected. The IRB is empowered by the FDA and Department of Human Health and Services to monitor and approve the clinical trials (Spine-Health, <http://www.spine-health.com/glossary/institutional-review-board>).

The 510(k) and other recommendations devised by the FDA state that Medical Device companies should demonstrate efficacy and safety in both animal and human clinical trials and accordingly, submit the relevant scientific information to the regulatory authorities in order to obtain FDA approval (Food and Drug Administration; Reliance Medical Consortium, Successful Medical Device Development: Critical Factors).

To elaborate further, the 510 (k) of the Federal Food, Drug and Cosmetic Act requires that the medical device company register in order to notify the FDA of their intentions to market a medical device that is equivalent to a pre-existing regulatory approved device, categorized in one of the 3 classes. Moreover, if the device is "substantially equivalent" to a pre-existing marketed and regulatory approved product before May 28th 1976, a pre-market notification is required. However, if the medical device is significantly different from a pre-existing marketed and regulatory approved product before May 28th 1976 in terms of design, material, chemical composition, energy source, manufacturing process, or

intended use, then a pre-market approval is required (Food and Drug Administration).

l) Regulatory Filings

All new medical devices are classified by the FDA as Class I e.g.: examination gloves (General Controls), Class II e.g.: infusion pumps (Special Controls), or Class III e.g.: cardiac pacemaker (Premarket Approval), according to the perceived risk they pose to patients and users (Food and Drug Administration; Miller, 2007).

The product development teams must obtain access to expertise with in-depth knowledge of regulatory filings and interactions with the FDA, especially in challenging circumstances of Pre-Investigational Device Exemption. An investigational device exemption (IDE) allows the investigational device to be used in a clinical study in order to collect safety and effectiveness that is required to support a "Premarket Approval (PMA) application" or a "Premarket Notification (510(k)) submission" to the FDA. The IDE is quite a different scenario, wherein the IDE requires "clinical trials for supporting the PMA/PMN application", as opposed to a regular scenario where "clinical trials are conducted to obtain PMN/PMA approval". Therefore, the submission guidelines are far more stringent than non-IDE cases. Moreover, the medical device company's development teams require thorough preparation for the pre-Investigational Device Exemption meetings in coordination with its collaborators (Reliance Medical Consortium, Successful Medical Device Development: Critical Factors).

m) Supply Chain Structure

A smooth flow of materials/resources for the development and production of a medical device into its commercialization phase requires an efficient and optimized supply chain structure. The supply chain structure can be devised during the iterative design phase based on the inputs received from the clinical trials, validation/verification and performance tests. Moreover, Krishnan and Ulrich (2001) state that the supply chain comprises both incoming and outgoing flow of materials, intellectual property and services. Hence, the supply chain decisions need to address the selection of the suppliers as well as the parties

associated with the product design, process development for production and configuring the distribution system. The overall sustainability can be significantly achieved if the suppliers and other associated parties are included based on their commitment to overall sustainability (Charter, 1998).

n) Product Launch and Production Ramp-Up

Post finalization phase and production eventually leads to the launch of the product for commercialization in order to be used by patients [or] end-users. Moreover, Krishnan and Ulrich (2001) state that post-finalization phase of the design with prototype testing and validation. The company needs to select the products poised for continuing the test marketing phase and/or commercial launch into the desired markets. The launch dates in accordance with the competition analysis and the product design would govern the production ramp-up specifications and eventually the success of the product in the desired market space.

The integrated and iterative correlation between the design phase and other subsequent phases is essential for the optimization and shortening of the product development life cycle without compromising regulatory compliance and safety. The next section would briefly discuss the phases of the product development cycle in the form of a project management process based on a systems engineering approach.

The next section would discuss the systems engineering approach to the development of medical devices

2.6. A Formal Systems Engineering Approach towards the Development of Medical Devices

This section gives a brief description of the formalized product development process based on Systems Engineering Approach for medical devices which involves various phases of the product development life cycle and its decision making stages/gates. Jones and Masters (2008) devised the process for medical device development at Battelle MDS involving the utilization of Systems

Engineering (Systems Engineering Handbook version 3.2.2 2011, International Council on Systems Engineering).

i. Definition and Introduction to Systems Engineering: A contemporary functional device is composed of multiple independent and dependent systems, sub-systems and assemblies. These entities are required to function with a high degree of synchronicity. Accordingly, the systems engineering approach is an interdisciplinary approach that enables the realization of successful systems. It focuses on defining customer and stakeholder needs with the required functionality early in the development cycle. Further, it proceeds with the design synthesis and system validation without ever loosing focus on the objective. Systems Engineering is also responsible for the integration of the pertinent disciplines and specialty groups into a coherent team effort; thus forming a structured development process that proceeds from concept to production and finally to utilization (Systems Engineering Handbook, International Council on Systems Engineering).

The Jones and Masters Systems Engineering approach based product development is in compliance with international regulations and includes a Safety Risk Management process (as defined in ISO 14971:2007 and ISO 13485:2003) for Quality Management Systems. The aforementioned combination promotes scalability and customization with iterative design and development.

ii. A Systems Engineering based Product Development Approach for Medical Devices

The product development processes for the development life cycle of a medical device should be repeatable so that it can be applied consistently across varying scopes of development projects. The product development process should also be inclusive of the entire life cycle of a medical device. Therefore, the milestones and its corresponding validation processes need to be well defined and addressed accordingly (Robertson & Robertson, 2006).

2.6.1. Life Cycle Phases of the Medical Device Development Process

The development process is composed of various stages with in-between gates for evaluation of the output from the preceding stage. Both the end-user/stakeholder and the medical device development teams need to acknowledge the ascertained risks and implement the mitigation strategies in order to align with the business objective (Hwang & Park, 2006).

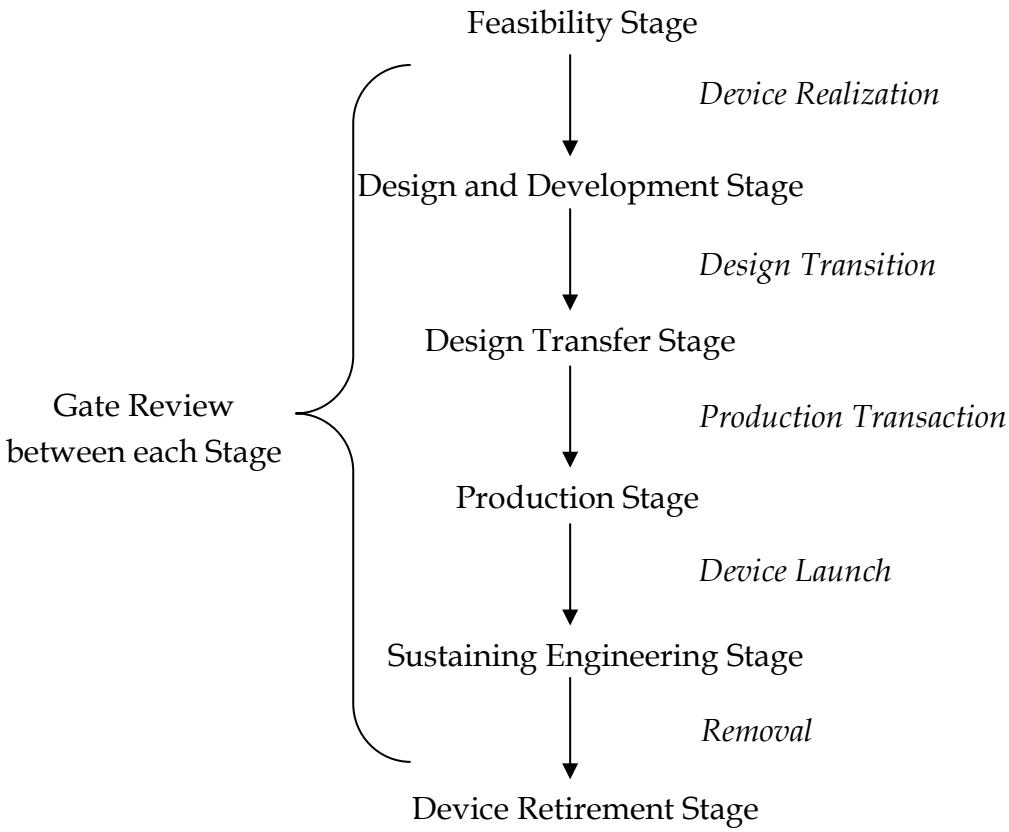


Figure 2.2. – Schematic representation of a Stage-Gate Process (Adapted from Jones and Masters, 2008)

Following are the stages of the systems engineering based product development cycle:

a) Feasibility Stage: The feasibility stage is defined as the ability of the medical device to perform its desired clinical action with the appropriate standards for safety, market acceptance and ease of operation. The technical and clinical risks

are evaluated in order to formulate a mitigation plan within the design stage. The outputs are as follows: feasibility concept, market needs assessment, identification of the technical risks with mitigation strategies, management buy-in or approval, return on investment, viability study, project proposal, and selection of a regulatory route to market (e.g. 510k for targeting desired markets in the United States).

b) Design and Development Stage: The feasibility stage provides a list of constraints and opportunities; accordingly the engineering team must proceed with their design and development activities. This stage comprises the diverse set of requirements for the end-user/stakeholders satisfaction and regulatory compliance for translation into a verified/validated design. The output that is the verified/validated design is transferable to manufacturing stage in the form of a Design History File (DHF). The Design History File (DHF) documents all the design inputs and outputs. Moreover, the activities that comply with the required Design Controls are to be in accordance with Quality Systems Regulation, devised by the FDA (Vogel, 2001).

The Design and Development Phase further contains the following sub-sections (Food and Drug Administration; Systems Engineering Handbook, International Council on Systems Engineering):

***i. Design Inputs*:** The Design Inputs comprise of the physical and performance requirements of a device that are used as a basis for device design. This phase of Design Inputs consists of identification of users, stakeholders and business needs followed by translating the needs into quantifiable requirements (the functional, ergonomic and aesthetic attributes). Furthermore, devising the device architecture/specifications leads to concurrently updating the regulatory documentation.

The categories of Design Inputs with suitable examples are as follows:

- User Needs (e.g.: inclusive of usability and human factors)
- Business Needs (e.g. target market implications; business model)

•Regulatory Constraints (e.g.: device safety and effectiveness)

***ii. Design Review*:** This activity is conducted at the end of every stage and is a documented, comprehensive and systematic examination of a medical device design.

The objective of the Design Review Phase is to evaluate the following:

•The adequacy of the design requirements

•The capability of the design to meet stakeholder requirements

•To identify any problems and inconsistencies, pertinent to the design and stakeholders' requirements.

***iii. Design Outputs*:** Post review and acceptance of the Design Inputs (with Design Review) is the Design Process and submission of Design Outputs. Design Outputs are results of a design effort at each design stage and at the end of the total design effort with the Device Master Record (DMR). The DMR is a compilation of records that contain the procedures and specifications for a finished device.

The outputs of this phase are stated as follows: Device Master Records, Prototyping, Prototype Testing and Iterative Design Changes, Labelling Sterilization Protocol, Packaging Design, Transportation Testing, Cost Analysis, Test Development, Material Selection, Biocompatibility Testing, Accelerated Ageing Study, Part Inspection Plan, Design and Commission Inspection Jigs and Fixtures, Commission Production Tooling, Select Route to Market i.e. Clinical Trial or Evaluation Report Source Suppliers, Instruction for use and Design/ Process Failure Mode Analysis.

***iv. Design Verification and Design Validation*:** Starts at the end of Design Outputs, as discussed previously.

c) Design Transfer Stage: The design from the research and development phase needs to be translated into a framework suitable for manufacturing. The information pertaining to the manufacturing of the device is appropriately documented and specified in accordance with a validated manufacturing process. The manufacturer is required to establish and maintain procedures to ensure that

the device design is correctly translated into production specifications, in accordance with the pertinent FDA guidelines for medical devices.

d) Production Stage: Following the design transfer stage, the design outputs (a device with its details of manufacturability) have to be appropriately translated into production specifications and accordingly, the corresponding production process controls have to be defined. This phase confirms for the commercialization and sale of the device. Moreover, a clearance for 510 (k) pre-market notification or pre-market approval is essential before product launch. The details regarding the clinical and pre-clinical trials have already been previously addressed.

e) Sustaining Engineering Stage: Following the production phase is the device launch phase, where the field results of sales and performance are thoroughly assessed. The provision of technical support, corrective and preventive actions, resolving regulatory compliance issues, production process optimization, addition or removal of certain features are conducted to achieve higher market acceptance.

f) Device Retirement Stage: This is the stage when the sale of the device moves towards the end and is not supported by the medical device company, customers and regulatory authorities anymore (or even other pertinent stakeholders). The device can be subjected to a suitable end-of-life option, namely, removal, dismantling [or] recycling/reusing/remanufacturing (Nasr & Thurston, 2006; Pennsylvania Department of Environmental Protection, 2009).

Moreover, Sobelman (2008) states that for any of the end-of-life options, the Design-reuse approach provides savings in time and monetary resources through reduction in testing time if only a few sub-systems are modified/changed. As described by one executives of a medical device company who was interviewed by Noel Sobelman (2008) "if the design is 20%new and 80% design re-use, we now test only 20% not 100%". The company interviewed by Noel Sobelman (2008) utilized modular platform architecture with software automation tools to improvise archival access and retrieval of previous test/ design reports.

Nasr and Thurston (2006) stress on the importance of product end-of-life such as re-manufacturing to ensure a closed loop of the material flows of every phase of

product life-cycle, to be considered as an integral part of the product design. This approach can lead to societal advantages of reduced energy with reduced material consumption and waste generation. Similarly, Pujari (2006) and Charter (1998) recommend the need of a strong alignment between new product development professionals, environmental specialists, suppliers, marketing expertise and product life cycle evaluation to be key factors for ensuring the success of sustainable products.

Therefore, companies committed to sustainability require a comprehensive tool to implement informed decisions about the social impacts throughout the product life cycle in order to prevent their reputation from being tarnished.

The relevancy of considering design reuse for a suitable end-of-life option such as reuse, recycling and remanufacturing is because it results in reduced waste disposal/resources consumption and thus contributes to sustainability. It is therefore concluded that a medical device can gain a significant magnitude of sustainability throughout its life cycle, especially when the sustainability considerations are included within the design and development phases (Hanson & Hitchcock, 2009).

The inclusion of sustainability in the medical device development process would be discussed in detail, in the subsequent sections.

2.7. Landscape of Sustainability Measures and Regulations

Regulations and Legislations are essential for governing the sustainability related activities in the product development endeavours of every industrial sector. Both United States of America and the European Union have established legislations for promoting sustainability such as WEEE (Directive on Waste Electrical and Electronic Equipment), RoHS (Restriction of Hazardous Substances in Electrical and Electronic Equipment), REACH (Registration, Evaluation and Authorization of Chemicals), and the EuP regulations (Energy Using Products) (Kadamus, 2008).

Trotta (2010) identified some of the measures for promoting sustainability at a global scale, which has been initiated by some of the globally renowned and influential institutions:

•The World Business Council for Sustainable Development (WBCSD) is to provide a platform for companies to explore sustainable development possibilities. The organization enables sharing of knowledge, technologies and best practices.

•The United Nations Environmental Program (UNEP) has called for a "Global Green New Deal" in response to the financial and economic crisis for reviving the global economy, boosting employment and simultaneously counter climate change related crises, environmental degradation and poverty.

•The European Union has developed the International Life Cycle Data System (ILCD) to encourage qualitative applications (in accordance with the international standards on Life Cycle Analysis ISO 14040/44) in business and the public sector.

•Solving the E-waste Problem (StEP) is an initiative of United Nations with Industry partners, Governments, International Organizations, Non-Governmental Organizations and the Scientific Community. The objective is to address the electronic waste (e-waste) problem and facilitate approaches towards the sustainable handling and disposal of electrical and electronic equipment.

As stated by Kadamus(2008), innovative medical device companies who believe in both complying with the newly established regulations and staying competitive would be able to accomplish lower long-term costs and defend their market leadership. Medical device companies can incorporate the contemporary product development tools such as Lean Manufacturing, Design for Six Sigma, Good Manufacturing Practices and Process Flexibility to incorporate sustainability within early phases of product development. Moreover, while adopting these tools, the definition of 'value' can include not only economic growth criteria such as profit/cash flows but stakeholder considerations and even environmental safety. Furthermore, the tools when combined with an exhaustive Life Cycle Management and Engineering framework would be in a position to synchronize a

wide spectrum of multiple activities to optimize the time to market (Patil, 2010). Organizations, implementing novel product development approaches are guaranteed to be in a position to address multiple trade-offs/synergies more effectively in terms of sustainability, device performance and economic growth. Moreover, the establishment of a continuously evolving and robust knowledge curve would ensure a stronger competitive advantage in comparison to their competitors (Kadamus, 2008).

The interdisciplinary nature of medical devices requires materials, tools/machinery and expertise from diverse engineering and scientific fields, which by itself are always continuously co-evolving. As a result, the role of a knowledge management infrastructure for building and utilizing a knowledge curve is a critical driver for success in medical device development. For example, a pacemaker is composed of various engineered polymers, electronics coupled with mechanical parts and radio-frequency communication to communicate the patient data to the hospital server. This is viewed as a quantum leap advancement compared to its predecessors wherein the doctor/nurse would have to spend more time monitoring the patients' heart rate with not as much accuracy as offered by the advanced version (Arntzen-Bechina & Leguy, 2007).

Moreover, the utilization of sustainable business/product development practices to promote a win-win situation can be promoted through strong stakeholder interconnectivity by formation of conglomerates between medical device companies, government bodies, insurance agencies, public welfare institutions and hospitals (Kadamus, 2008).

2.8. Role of Product Life Cycle Management for attaining Sustainability

Product life cycle management for attaining sustainability employs systemic thinking and hence is capable of addressing the sustainability requirements throughout the life cycle of the product. For addressing sustainability, the product engineers and managers are required to utilize life cycle management coupled with systemic thinking tools and criteria for sustainability within the design stage

(Fiksel, 2006; Sutcliffe et al., 2009; Trotta, 2010). Accordingly, with the culture and capabilities of the participating organizations for both products and services, the sustainable design should address every stage of the production, the project management, the market and the usage life cycles (Trotta, 2010). The justification of incorporating life cycle related parameters and considerations for sustainability within the product design stage as opposed to the later stages of the life cycle are discussed in detail in the subsequent sections.

Following are the facets of Product Life Cycle that are utilized for the systemic assessment and management of Product Life Cycle Management in order to achieve overall Sustainability throughout the life cycle of a product (Trotta, 2010).

2.8.1. Life Cycle Systemic Thinking

Sustainability assessment and implementation primarily begins with identification, followed by interlinking, tracing and articulation of the pertinent considerations with their corresponding indicators. These indicators are essential for evaluation throughout the life cycle (Dobbs & Cormican, 2007).

2.8.2. Life Cycle Assessment (LCA)

In combination with Life Cycle Systemic Thinking, the medical device company is required to conduct a comprehensive life cycle assessment. This tool is a recognized scientific methodology in accordance with Environmental Protection Agency (EPA) from USA. The life cycle assessment methodology is derived from Tool for the Reduction and Assessment of Chemical and Other Environmental Impacts (TRACI) (methodology studied by EPA, USA). LCA is also an objective and internationally recognized (ISO 14000). The tool assists engineers and managers to systematically identify and quantify the energy/materials consumed and the waste/emissions that are released in the environment.

Some of the widely used proprietary LCA softwares are Gabi, SimaPro, Eco-it and Bounsted. These softwares consider the effects of material choices and manufacturing processes. Moreover, the tools perform graphical and numeric representations to assist the product development teams with their decisions during the design phase (Kadamus, 2008).

The life cycle assessment is carried out iteratively in the following sequence:

•"Goal and scope definition" (ISO 14041): Planning of the analysis (identifying pertinent considerations of the product life cycle which are to be considered, data requirements, the geographical area, methodology to assign potential impacts).

•"Inventory analysis" (ISO 14041): Data collection and calculation of inputs and outputs for each process involved in the life cycle (For example: the raw materials and their quantities).

•"Impact Assessment" (ISO 14042): Evaluation of each inventory element with respect to environmental impacts (e.g.: the potential contribution to global warming and acidification by choosing Poly vinyl chloride plastic as opposed to Polyurethane plastic).

•"Interpretation" (ISO 14043) combines the results and conclusions from the previous phases and devises recommendations to address the goal and scope definition. Furthermore, decision to modify the goal and scope definition and re-initiation of another iteration can be pursued <http://www.basf.com/group/corporate/en/sustainability/eco-efficiency-analysis/index>.

The other tool that is less comprehensive as compared to exhaustive LCA for evaluating the ecological sustainability is the Eco-Indicator 99 by Pre Consultants BV. This tool addresses the environmental impact of products by breaking them down to elemental components, materials and processes. The Eco-Indicator 99 can be combined with the Eco-efficiency ratio that is the ratio of service provided by the activities with respect to its environmental impacts (Kadamus, 2008; Trotta, 2010).

2.8.3. Life Cycle Management (LCM)

Life cycle management involves the utilization of engineering efforts and sound management decision making for ensuring long term overall sustainability through the utilization of Life Cycle Assessment and Systemic Thinking approaches (Fiksel, 2006; Hauschild et al., 2005). This also includes the

incorporation of a Total Product Life Cycle Management Infrastructure with information technology systems (Patil, 2010).

The LCA tool can be utilized for taking decisions and implementing measures pertaining to overall sustainability. The LCA tool enables the product development teams to ascertain the critical processes in order to evaluate opportunities for optimizing the consumption of resources (e.g.: materials and machinery), waste disposal (e.g.: CO2 emissions). In addition, it can be used to evaluate suitable metrics for analysing the process performance and establishing a firm control to maintain the Organization's position on its sustainability objectives (Almeida et al., 2005; Gonçalves et al., 2009). Once the product life cycle is well understood, the product design can be regularly updated (Annes, 2005). Thus resulting in product improvements and successful implementation of an appropriate end-of-life option.

2.8.4. Life Cycle Engineering (LCE)

Life Cycle Engineering is composed of engineering activities that are considered within the Life Cycle Management in coordination with Life Cycle Assessment and Systemic Thinking. It entails the application of technological and scientific principles to the design, manufacturing, and maintenance and end-of-life of products that promotes environmental welfare and conservation of resources, without compromising economic progress and simultaneously optimizes the product life cycle (Hauschild et al., 2005; Jeswiet, 2003; Wenzel and Alting, 2004).

In order to initiate Life Cycle Engineering activities for incorporating sustainability, it is essential to develop a methodology that combines Life Cycle Assessment Tools with Computational Modelling Tools (such as 3-Dimensional Computer Aided Design/Engineering) in accordance with Sustainability guidelines (e.g.: EcoDesign guidelines) (Cappelli et al., 2006; Gaha et al., 2011). This would result in the interconnection of the environmental compliance parameters with the computational design approach. The sustainability of the environment is well known to promote the sustainability of the other 2 domains,

namely social and economical sustainability (Hauschild et al., 2005; Linnér & Selin, 2003).

Chang and Chen (2004) have identified the need of an articulate strategic approach towards sustainability-oriented engineering. These authors have devised the CAD Eco Design tool (a combination of CAD and Eco-Design guidelines). Their objective was to deliver technical support to the design engineers for developing products that address environmental sustainability through evaluation of components, materials and processes. Similarly, Capelli et al. (2006) also have proposed a novel approach to integrate EcoDesign and Life Cycle Assessment into a Virtual CAD Framework.

Chang and Chen (2004) and Capelli et al. (2006) illustrate some reasons for considering CAD/3D design tools and Eco-Design Guidelines for building an integrated framework with Life Cycle Assessment. Firstly, modern CAD/3D tools are in a position to incorporate a higher number of parameters and provide significant savings in time for realizing a virtual prototype (Magne, 2010). Accordingly, Choi and Cheung (2008) had stated that a sophisticated virtual prototyping system could assist engineers and product managers to rapidly and iteratively optimize the product to obtain a desired trade-off between costs, product shape, manufacturability, profitability and reliability. The utilization of virtual prototyping minimizes dependency on multiple and expensive prototype development techniques so as to reduce the cost of failure and any potential user-related hazards. Moreover, the virtual prototype designs can be sent via Internet to obtain feedback, especially concerning user-friendliness, production feasibility, supply chain and other essential facets of product commercialization and stakeholder requirements. The production feasibility assessment using virtual prototyping can even be extended to the cost effective design and modelling in terms of the shop floor controls, production process simulation, manufacturing planning, training, testing and verification/validation.

Secondly, in order to conduct an environmental impact analysis via the Life Cycle Assessment technique, a designer must know the volume geometries, types of

materials used and their corresponding manufacturing processes. CAD/3D tools easily deliver this type of information. By using a Life Cycle Assessment, the environmental impact data for each part, sub-assembly and its corresponding process can be obtained to calculate an impact score (Goedkoop & Spriensma, 2000). The integrated framework can also assist the designers to make the appropriate trade-offs and exploit synergies between efforts invested and time duration required for the entire development cycle (Bovea & Gallardo, 2006).

Thirdly, EcoDesign guidelines are a set of best design practices, represented by a database of ecological challenges and questions with their most suited solutions. The authors of the database have categorized these solutions and questions through a collection of well-known standard design parameters. After a thorough survey of the occurrences of these parameters it is possible to determine the most suitable solution for improving the environmental impact (Capelli et al., 2006).

On similar lines, Hanson and Hitchcock (2009) have utilized life cycle assessment and engineering for addressing the sustainability of a single use medical device namely a dialyzer. These authors improvised the sustainability of the dialyzer by optimizing the material (expensive and polluting petrochemicals) and energy utilization, within the design phase. In order to achieve their objectives, they obtained the statistics on the number of patients who undergo dialysis on a worldwide scale followed by determining the opportunity to significantly reduce carbon emissions through the reduction of the material quantity without compromising any aspect of functionality. Therefore, less material incorporated in the product resulted in significant decline in carbon emissions caused by incineration of used dialyzers.

Hanson and Hitchcock (2009) carried out the LCA, through the using of software known as yED from yWorks Inc. The Life Cycle Evaluation provided the environmental impacts of the various parts and components of the dialyzer. Meanwhile, the functional assessments provided significant inputs for conducting geometric and stress analysis to identify suitable design structures in order to reduce the material required without compromising functionality, respectively.

For example, the LCA illustrated a substantial negative environmental impact due to polycarbonate, while functional analysis recommended the replacement of polycarbonate by another material with lower ecological impact in order to maintain the desired level of functionality.

Furthermore, Hanson and Hitchcock (2009) studied the design of the dialyzer to determine the parts that do not come in direct contact with body fluids. The objective was to select the components which could be re-used and which survives the sterilization protocols.

The need to shorten product development cycle time and address pertinent synergies/trade offs across a diverse spectrum of criteria for incorporating sustainability is discussed in the subsequent section.

2.9. Balancing the Sustainability Objectives

Addressing the various consequences of potential impacts on overall sustainability within the design phase of a product does have its own downside. Especially, negatively influencing the sustainability of one product by improving the sustainability of another product in a portfolio or across portfolios (Sutcliffe et al., 2009). As mentioned previously in Section 2.2 the crucial role of the Pareto optimal frontier comes into picture (Zhao et al., 2010). Therefore, it is critical to balance the product portfolio, through optimization of the resources consumed/ waste disposed in accordance with the regulatory compliance and the desired economic growth (Ambec & Lanoie, 2008; Vogel, 2005). Moreover, any number of decision models and product development frameworks devised to address sustainability has to maintain their focus as they offer insight to the product designers and engineers. It is important to note that these frameworks and decision models do not substitute for the critical and sound judgment of the product engineers and designers. The others constraints in addition to conflicting sustainability demands could be legal requirements, limited time for obtaining data or market dynamics pertaining to the product under development. The role of the designer and product engineer is to include as much sustainability as possible without compromising the essential aforementioned criteria.

The subsequent chapters would explore in detail the paradigm of prioritizing the pertinent criteria of overall sustainability with respect to the trade-offs to be executed and synergies to be exploited.

2.10. Concluding Points

This chapter discusses the existing gaps and shortcoming of contemporary medical device development. As these devices consume substantial renewable and non-renewable resources, which further instigate a series of interconnected social, economic and environmental impacts.

As a result, the exhaustive list of criteria ranging from regulatory compliance, market competition and aforementioned domains of sustainability is overwhelming for an organization in terms of their human, financial and non-financial resources.

Moreover, the real-life challenges facing medical device development are rising healthcare costs in terms of allotment of Government funding and inclusion of more stakeholders with ever changing requirements.

This justifies proposing new product development and decision modelling approaches to enable product development teams to exploit synergies and select suitable trade-offs in terms of cost effectiveness, quality and speed.

In this chapter, a previously conducted case study by Yang et al. (2006) has been discussed to illustrate the contemporary product development approach of medical devices from a management. The development process entails idea generation and selection based on the company's capabilities followed by assessing market opportunities wherein these capabilities and resources are evaluated with scrutiny to transfer the creation into a tangible product with compelling clinical performance. This would involve conducting proof of principle as well coupled with intellectual property evaluation and SWOT analysis towards the competitive forces. Moreover, the critical role of documenting and preparing the Design files in accordance with Quality System Regulations for regulatory approval should be conducted simultaneously (Vogel, 2001). The

marketing and regulatory compliance teams need to resolve the impediments concerning payment options in terms of Insurance and Government reimbursement. The company when considers the stakeholders early in the design phase is able to ensure its success in the post development phase. Hence, initial phases of test marketing and end-user trials are recommended.

From a systems engineering standpoint, a medical device is perceived, as a system comprised of multitude of synchronized sub-systems, components, assemblies that are independent and dependent in nature. Systems Engineering, is also responsible for integration of the pertinent disciplines and specialty groups into a team effort, forming a structured development process that proceeds from concept, feasibility analysis, transfers phase to production and finally to operation. This approach reduces development cycle time and ensures reliability in terms of reusing the design in the future for innovations that are incremental.

In this chapter, a contemporary product development approach is compared to an systems engineering based development approach in accordance with the Quality Systems Requirements stated by the FDA (Vogel, 2001). Based on the previously discussed challenges and limitations encountered during the incorporation of overall sustainability considerations within the design phase, the product engineers and managers require a comprehensive and simplified decision making tool for governing their designing process This utilizes prioritization of various sustainability considerations in accord with the regulatory compliance and the desired economic growth (Ambec & Lanoie, 2008; Vogel, 2005). The prioritization would assist the product engineers and designers to exploit the synergies and resolve the necessary trade-offs across products and product portfolios. In addition to the consideration of conceptual and technical tools for product development, a robust product life cycle management infrastructure with information technology system is crucial to synchronize a wide spectrum of exhaustive activities.

Chapter 3

Decision Modelling and Sustainability in Medical Devices

3.1. Introduction

Medical Devices are required to comply with the most stringent regulatory requirements, while simultaneously addressing the economic growth of the Enterprise amidst the on-going volatile economic environment. The inclusion of criteria pertaining to overall sustainability poses not only a series of challenges, but even as a commitment towards stakeholders to ensure an extended continuation of an Enterprise's business goals. As a result, a major focus on decision modelling in conjunction with Business Processes and Design Engineering related activities is envisioned in the form of a coordinated framework to alleviate shortcomings of contemporary approaches in product development and decision modelling. Moreover, the anticipated exhaustive volume of data and information required to be processed and articulated for implementing sound decision demands a more simplicity and improvised accuracy for decision making and hence a simplified multicriteria based decision model is proposed and discussed in this chapter.

Furthermore, Section 3.2 discusses the underpinnings of Sustainability and notwithstanding the advantages the section would illustrate the major impediments that are encountered while incorporating the considerations for overall Sustainability. As a result, not each and every criterion can be accounted for during the development of medical devices. Thus, justifying the need for a prioritization based decision-modelling approach in the form of a simplified multicriteria model.

3.2. The Underpinnings and Advantages of Sustainability

The acclaimed United Nations report titled "Our Common Future" in 1987 published by the World Commission on Environment and Development (WCED) had practically spearheaded the objective of overall Sustainability. Moreover, the renowned International Conferences including the Earth Summit of 1992 in Rio de Janeiro and of 2002 in Johannesburg have clearly postulated the emphasis on the commitment required by the Business, Regulatory and Political Institutions towards a worldwide approach for sustainable development (Vidal, 2012). Thus resulting in a "market" and "policy" oriented pressure on various institutions, which can bring about tangible transformation in the arena of Sustainability (Xu & Morrison, 2005).

Ever since a few decades, businesses have demonstrated their commitment towards sustainability by implementing various measures such as carbon offsets projects (i.e. Clean Development Mechanism) for attaining sustainability (Buen, 2013). Moreover, such measures are on the path for continuous improvements to resolve the criticisms that emanate from ineffectiveness and negative impacts onto stakeholders (Sutcliffe et al., 2009; Ambec & Lanoie, 2008). Nevertheless, as proposed by Xu & Morrison (2005), the consideration of Sustainability related criteria in the product development process and the corporate governance structure of the Organization, would ultimately result in the smooth transition between each of its product development phases and the extended continuity of the enterprise by virtue of active stakeholder participation. These authors have enumerated the advantages with which the companies could attain provided their business goals are effectively and efficiently aligned with the Sustainability objectives. The benefits are namely higher employee and stakeholder satisfaction; further strengthening loyalty; long term improvised financial performance and access to capital; reduction in cycle time for product development due to proactive risk management for addressing stakeholder requirements.

As stated previously, the acute interdependency between the social, economic and environmental facets of sustainability determines welfare of the society as a whole

(Sutcliffe et al., 2009; Hauschild et al., 2005). For Example: The direct impact of health hazards caused by toxic emissions, leads to poor productivity of the population and ultimately affecting their purchasing power (Ding & Strong, 2010; Bhargava et al., 2001; Wilkie & Young. 2009; Linnér & Selin, 2003). This implies that an Organization should extend its Sustainability commitment beyond environmental compliance and accommodate other crucial social responsibilities pertaining to labour practices; transparency; human rights and fair business practices. These paradigms in our globalized world are increasingly becoming more obligatory in nature. The subsequent section would discuss a few real life cases of medical devices, which have attempted to incorporate overall sustainability (more environmental than social).

The pre-existing stringent regulatory compliance and business performance requirements do pose a major impediment for companies to adopt sustainability (Faniel, 2011), notwithstanding the presence of critical market drivers including environmental sensitive consumers and cost savings brought about by environmental friendly materials. For example: Rollprint Packaging Products Inc. is a slow adopter for sustainability (Dodrill, 2010). On the other hand, companies can explore the opportunity to deliver the utility dimension of the medical devices to their customers by providing a portfolio of products; services; network of actors based on a supportive infrastructure, in contrast to the sale of physical goods similar to the Xerox Model (2003). This restructuring of the product value chain titled as "Product-Service-System" is an encouraging scenario for incorporating the underpinnings of Modularity and Platform/Derivative approaches in Product Design. This further facilitates the End-Of-Life Options for recovering the product value towards the end of its use phase (Filho et al., 2009; Goedkoop et al., 1999; Mont, 2000). End-Of-Life Options namely, reuse; remanufacture and recycle, nevertheless it should be noted that these options could consume significant resources during transportation and the limitations posed by product design for regulatory compliance and limitations of materials (Long, 2008) may hinder the possibility for utilizing the parts for multiple life cycles. This includes but not

limited to the hazards posed by contamination and limited opportunities for sterilization/reprocessing for the stated reasons (Kadamus, 2008).

Following are two remarkable examples of incorporating Sustainability with Medical Device Design:

a) 'Syreen', a revolutionary "green" pre-filled syringe developed by Cambridge Consultants Inc. 'Syreen' is a highly effective, safe, and easy-to-use drug delivery device for self administration. The device is designed to reduce the intensity of resource consumption and material wastage associated with traditional syringes. The 'Syreen' syringes are made with COP (cyclic olefin polymer) plastic, in contrast to glass and it does not require secondary packaging. The product design permits multiple syringes to be packed together conveniently without the use of any conventional wasteful fillers. These innovations reduced the packaging weight by 30 percent and volume by 50 percent in comparison to contemporary standard packaging. As a result, the fuel costs attributed to transportation are reduced (Cambridge Consultants, 2010)< http://www.cambridgeconsultants.com/news/pr/release/49/en>.

b) Abbott targeted a 5% reduction in packaging for one of its products, through re-design. The engineers at Abbott Labs redesigned one of its re-closable 0.24 litter plastic bottles in order to reduce the plastic used by 8.3% that resulted in savings of 1.65 million litters of annual fuel cost (Dodrill, 2010).

These examples implies that although initially since the past two decades, the demand for sustainable medical devices has slowly gained momentum and accordingly, a few companies have resorted to design and materials engineering related innovation to accomplish at least environmental sustainability and their desired degree of profitability.

3.3. Prioritized Decision Modelling: Function and Scope

As identified previously, that one cannot attain an infinitely high level of overall sustainability with a desired degree of patient and user satisfaction, as it requires the inclusion of an exhaustive list of criteria and its corresponding parameters and

specifications (Zhao et al., 2010). Moreover, such an endeavour is identified to be overwhelming for a product development team of an Organization, which has to address a fiercely competitive market. The key sources of limitations are observed from the standpoint of managerial capacity (e.g.: availability of time and human resources) and technological limitations (e.g.: limitations of modelling software and material properties) (Wyatt et al., 2009; Tikare et al. 2005; Long, 2008).

Following are the known sources of limitations that can presumably pose as an impenetrable impediment for satisfying every sustainability related criterion:

a) Managerial capacity (e.g.: availability of time and human resources) (Project Management Book of Knowledge, Project Management Institute, 2010)

b) Innovativeness and Intellectual acumen, Cognitive abilities, and Collaborative Strength (e.g.: skills, know-how and expertise) (Akgün et al., 2003a; 2006b).

c) Properties and Accessibility of Materials & Energy Sources (Long, 2008).

d) Organizational Infrastructure, Financial Capital and Value Chain Partners.

e) Regulatory Frameworks, Socio-Economic Policies (e.g. Subsidies, Controls and Taxes).

f) Technological feasibility of Engineering Tools

i. Software:

-Interoperability (Hu et al., 2006) between software and hardware platforms.

-Limitations of modelling software to accommodate a majority of the life cycle parameters (Wyatt et al., 2009).

-Need for customization and manual intervention for geometric processing and automation of meshing during CAD/CAE simulation (Shimada, 2011).

ii. Hardware: Instruments/Machinery (e.g.: tolerances, accuracy, precision, flexibility of scope and capacity) (Kumar & Suresh, 2007).

These sources of limitations are also in co-relation with the resources of the medical device company.

Therefore, it is imperative to establish a comprehensive 'priority based decision making and product development approach', to address the various key essential synergies and trade-offs while shortening the development cycle to attain higher economic growth.

In this prioritization based decision modelling, the essential criteria would be prioritized in order to deliver a significant magnitude of overall sustainability without compromising any of the regulatory compliance and critical economic growth objectives. The advantages of a 'prioritization based decision making approach' is the attempt to be holistic in nature; wherein it would not only accompany the product development teams to implement sound decisions at the upper management level (e.g.: project selection) but even at the most vital engineering paradigms (e.g.: the level of customization of an existing design and simulation tool). This clearly points out that the aforementioned decision making approach does actively participate in the product development process.

Meanwhile, during the incorporation of Sustainability criteria and executing the 'prioritization'; the product development teams need to undertake design engineering, project management and operations management endeavours for optimizing the consumption of resources and reducing the waste generation (Sutcliffe et al., 2009; Vogel, 2005; Ambec & Lanoie, 2008). In the attempt to conduct optimization, which is to address the underlying synergies/trade-offs, the product development teams would come across a scenario; wherein reducing the emissions pertaining to one facet of product design would result in producing higher emissions at another end (Hermann et al., 2007; Rebelo de Mira & Kroeze, 2006; Brink et al., 2005). For example: While switching the materials from toxic to non-toxic would result in higher emissions and waste that is attributed to the procurement or production of the non-toxic material (Esposito, 2011). This scenario would remind the product development teams of the Pareto Optimal Frontier as mentioned in Chapter 2 (Zhao et al., 2010).

In order to exemplify the relation between Medical Devices and Sustainability, Bill Evans, the founder and principal of Bridge Design Inc., USA stated that not a

single medical device could ever achieve a zero negative impact, despite employing any number of measures to minimize it. To explain further in the most humorous manner, during the Conference on Plastics in Medical Devices 2011, held on April 11-13 in Huron, Ohio, USA, he said "It shouldn't be about emotions as You're not going to start making bamboo surgical tools" (Esposito, 2011).

The subsequent section will discuss the basis for a more comprehensive and simplified decision modelling approach based on the on-going interconnected facet of our human civilization, ecosystem and economics. Furthermore, the comparison of the contemporary decision models to the chosen technique of using a multicriteria approach is also discussed in detail.

3.4. Decision Modelling for Sustainability

3.4.1. Synopsis

Today's interconnected globalized world that involves diverse cultures and value systems results in a complicated political decision making scenario. This renders the 'sole use of intuitive reasoning' obsolete and demands a more comprehensive as well as a simplistic approach. Moreover, the sources for overall satisfaction and dissatisfaction in life do differ from region to region with respect to their cultures. This complexity is not free from a wide variety of disparities in terms of access towards resources and welfare related opportunities, in addition to the multiple layers of interdependencies between far and diverse geographical regions on the face of this planet. Therefore, it is imperative to account for the most essential criteria for attaining overall sustainability in order for a company whose obvious goal is to ensure its longevity (Ramjerdi, 2008).

Decisions are made at Planning, Strategic, Tactical and Operational Levels. The differences in the levels are based on complexity, magnitude of uncertainty, nature of stakeholder involvement and the ability to make decisions transparent and equitable. Decision-making should be done in consistency with the Organization's values and objectives (Petrie et al., 2006). The approaches towards decision modelling are enumerated in the following steps from 1 to 9, which are cyclic in nature:

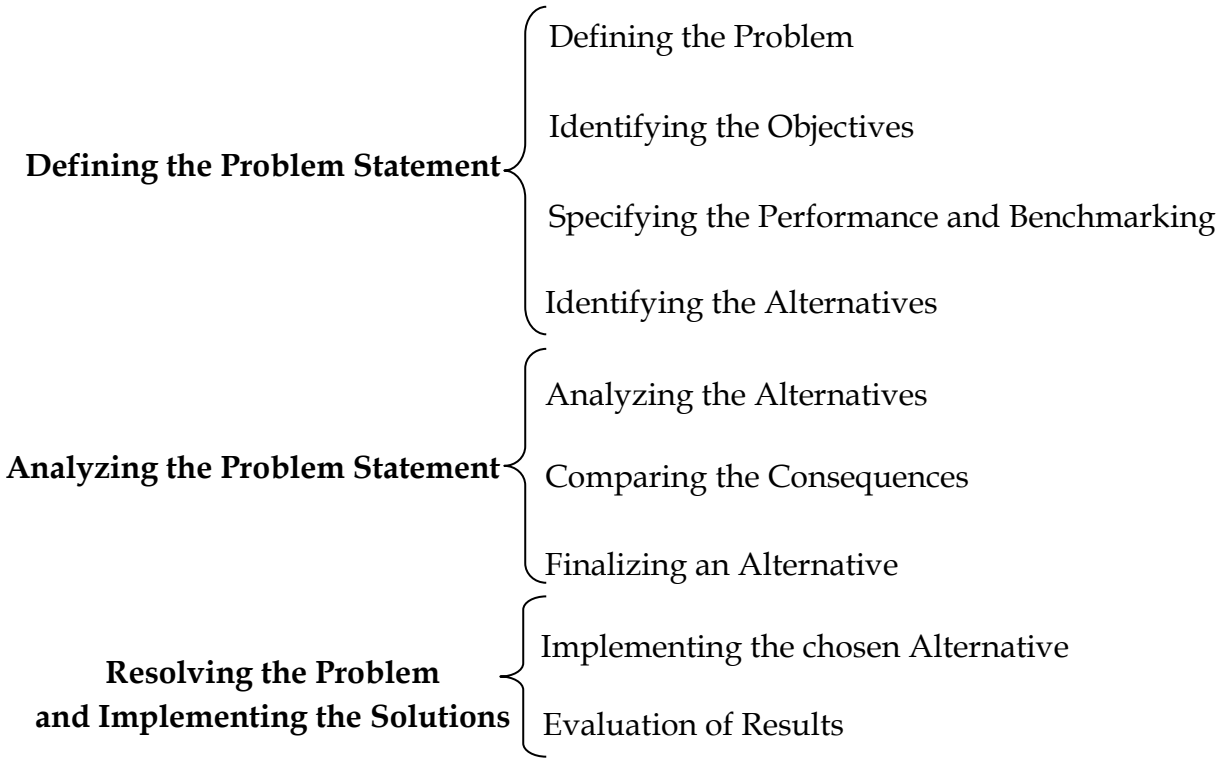


Figure 3.1. – Decision Modelling Approach

The subsequent sections will discuss an overview of various decision modelling techniques used regularly in evaluating overall Sustainability followed by the explanation of the proposed multicriteria based decision model.

3.4.2. The Fundamental Basis of Decision Modelling and its Implementation

Decision making process for addressing overall Sustainability would entail the incorporation of various indicators and criteria that measure environmental sustainability in accordance with other social and economic impacts of outlined projects, plans and policies. The criteria, indicators and parameters deliver their own characteristic balance of constraints and opportunities throughout the product development process.

There exists a multitude of decision making techniques to evaluate various alternatives pertaining to Projects; Products; Policies and Services and hence to name a few others in addition to the regularly used Cost Benefit Analysis or Cost Efficiency Analysis are namely Life Cycle Assessment, Ecological Risk Analysis,

Eigen Vector Method, Compromise Programming, Sustainable Process Index and Best Practicable Environmental Option Index (The Royal Commission on Environmental Pollution, 1988). These evaluation techniques aid the decision maker and product development teams to estimate as well as monitor the consumption of natural resources with the corresponding generation of waste/emissions for the proposed alternatives. Acknowledging the complex interconnected relations between the social; economic and environmental domains of our eco-system poses an enormous impediment for decision makers (or decision model users) to clearly outline the social sustainability criteria. Previous attempts to assign financial economic values have been carried out (Van Erck, 2003), notwithstanding the identified intrinsic challenges of improving the accuracy of the process (Jansen, 1992).

Therefore, in this thesis, the utilization of a more qualitative approach towards decision modelling is discussed that simultaneously considers diverse set of criteria ranging from social; emotional; environmental; technical; rational; intuitive; economical and others with a substantial degree of consistency and simplicity, known as the Multi-criteria method. Furthermore, both qualitative and quantitative evaluation methods have been considered in the past in combination with subjective scale and guidelines for implementing informed decisions (Winpenny, 1991). For example, Labuschagne and Brent (2005) proposed the Sustainability Cost Accounting procedure. This technique accounts for various externalities (benefits and detrimental impacts), additional uncertainties and inventory of the resources consumed with their resultant environmental impacts. The results of the analysis are translated into financial terms for appraising the overall sustainability of an engineering project.

To address the exhaustive complexities and gaps in Sustainability evaluation requires the utilization of sophisticated and interconnected computational systems that employ advanced modelling techniques. For example, the utilization of system dynamics and thermodynamic analysis in order to study the dynamics between various segments of eco-systems and institutions (public; profit; non-profit; private). A few examples include but not limited to climate change and

extinction of flora-fauna of a certain region by virtue of in discriminate Industrial activity. The aforementioned approach towards the evaluation of complex systems and their interdependencies is titled as Systems Thinking (Fiksel, 2006).

Notwithstanding the inundating nature of this approach, a partial insight is delivered that is considered sufficient by decision makers of large influential institutions, including Global Corporate Institutions (E.g.: Microsoft) or International Organizations (E.g.: UNO) and policy makers to invest in the most ecologically effective projects and account for possibly every long term impact on every stakeholder (near and far).

During the execution of a comprehensive and a substantially complex evaluation procedure, it is imperative to map the decision making process which is further represented by the data and information flows emanating from various parameters; factors; drivers; criteria illustrated in the decision model. The goal is to determine the pertinent decision making nodes that adjoin the various impacts on the diverse set of stakeholders. This approach enables the decision maker for devising sound risk management plans and decision implementation strategies.

The decision process mapping is conducted by installing robust computational systems. A known example would be the Structured Systems Analysis and Design Method (SSADM) that is capable of structuring, mapping and tracing the flow of data and information in conjugation with a reliable Information Technology System to promote interconnectivity between the systems under investigation (Ashworth and Goodland 1990; De Marco 1979). Ironically, the life cycle of the computational and IT systems generate an enormous environmental impact of up to 2% global CO2 emissions (Parliamentary Office of Science and Technology, 2008). This factor is poised to stimulate innovation for devising improvised analysis models and techniques to optimize the computation with reference to the energy consumption.

3.4.3. Multi-Criteria as a Prioritization based Decision Model

As stated previously, the prioritization of the sustainability related criteria is crucial for acknowledging synergies and trade-offs encountered during the

Product Development process that intends to accommodate diverse and conflicting requirements, which are irreconcilable by any amount of feasible engineering design solutions.

For instance: A medical device with multiple features that further corresponds to a multitude of sub-systems and components to satisfy a broad range of end-user requirements. The physical weights and the material properties would exert its ecological impacts. Moreover, in the case that overall ecological impact cannot be substantially reduced by feasible engineering solutions. Then it is advisable for the medical device company to mainly account for the Regulatory Compliance (e.g.: FDA, ISO, IEC) coupled with minimal environmental compliance (e.g.: RoHS) and the most essential end-user customer needs have to be prioritized.

Also, care has to be taken to identify the Pareto Optimal Frontier for overall Sustainability in order to satisfy every involved stakeholder up to a tolerable level (Zhao et al., 2010). Therefore, in this thesis the prioritization of the sustainability related criteria are in accordance with two braid categories namely Regulatory Compliance and Economic and Business Performance. The Regulatory Compliance mainly encompasses Production; Performance; Safety and Ecological Considerations and the Economic and Business Performance include both socio-economic axioms of Sustainability.

The Multi-criteria Analysis (MCA) is both qualitative and quantitative; wherein the weights are assigned by participatory methods involving expert opinion in order to highlight their level of importance (or ranking) between the criteria. The unique feature of MCA is the possibility to address the aforementioned domains of Sustainability on a common scale of measurement without any standard units (Hermann et al., 2007; Ramjerdi, 2008; Zopounidis & Doumpos, 2002).

Above all, the ability of the MCA to unearth the explicit or hidden conflicts could eventually channelize the innovation efforts of the medical device company in the appropriate direction for its own longevity. The comparison of the regularly used Cost-Benefit Analysis technique to the Multi-criteria Decision modelling reveals that the only similarity between these 2 techniques lies in the prioritization of their

pertinent criteria. Meanwhile, unlike the multi-criteria method the Cost benefit Analysis method does consider the substitution between various impacts.

The core reason for multi-criteria to not consider the substitution between various impacts is due to the pragmatic nature of inability to substitute monetary compensation for any remotely or even irreversible environmental or social damage. For example: The Gulf of Mexico oil spill in 2010 destroyed vast amounts of aquatic flora and fauna which eventually lead to the end of small business associated with local fishing activities. Although financial compensation could be provided to the victims but the irreversible damage done to the aquatic ecosystem is remotely or in fact irreparable. Unless, engineering processes are employed for cleaning the aquatic ecosystem under consideration, the probability of natural recovery is almost negligible. Nevertheless, the activity would again consume significant non-renewable resources, further contributing to environmental degradation either in the same vicinity or elsewhere (McConnaughey, 2013).

One of the most remarkable advantages of the MCA is its ability to conjugate with various other evaluation methods; namely financial and/or environmental such as life cycle assessment and environmental performance index. The life cycle assessment technique in combination with an environmental management system conducts a comprehensive "cradle to grave" environmental evaluation throughout the product life cycle (Zobel et al., 2002). The evaluation encompasses the classification, characterization and normalization of the output data in the form of impact categories. For instance, global warming, acidification potential, eutrophication potential, ozone layer depletion and human health. Meanwhile, the multi-criteria decision making tool when applied to the exhaustive life cycle evaluation provides a singular overall index for illustrating the sustainability (Benoit & Rousseaux, 2003; Zobel et al., 2002; Pineda-Henson and Culaba, 2002a; 2004b), despite the loss of certain information during the aggregation of data. The method of data/information aggregation; accuracy of data and decision makers' perspective are the decisive drivers for the effectiveness of the decision model. The advantages of multi-criteria decision making is mainly due to the fact that the fundamentals of the technique has its foundations rooted in economics, including

welfare economics; utility theory; voting oriented social choice theory (Stadler, 1979; Bouyssou, et al, 2000).

Moreover, from the plethora of MCA tools available this research report utilizes the Analytical Hierarchy Process (AHP) as the foundational scaffold to devise the proposed multicriteria decision making model. The AHP technique possesses both the simplicity and the stated benefits of the multi-criteria method. In addition, the criteria (with their sub-criteria) of AHP are closely pertinent to the quintessential axioms of medical device development, which is further based on a systems engineering approach (Jones and Masters, 2008; Saaty, 1990a; 2006b; 2008c).

Notwithstanding, the advantages of the Analytical Hierarchy Process, the methodology continues to be dependent to a certain degree on expert opinion for scoring in some way or the other, especially in a development environment affected by inadequate information on technology complexity and project uncertainty. To minimize or even to eliminate this dependency, Halog (2002) devised a novel approach to include Quality, Environment and Cost Requirements of various stakeholders using a multi-attribute decision-oriented life cycle approach. Accordingly, the framework utilizes the concept of Fuzzy linguistic approach to translate linguistic terms (in terms of natural language) of the requirements put forward by the stakeholders and product development teams into numerical codes for evaluation.

The proposed MCA decision-making method in this thesis acts as a critical segment of a board multifaceted product development framework, which is also discussed in subsequent chapters. In contrast to the contemporary multi-criteria approach that does not explicitly permit optimization of the included criteria; the proposed multicriteria decision model in conjunction with the proposed multifaceted framework enables optimization of the criteria with reference to their corresponding product parameters/specifications. The optimization is conducted by virtue of continuous and comprehensive interaction between product development teams and their pertinent stakeholders in accordance with engineering based design optimization tools (Tzeng et al., 2002).

3.4.4. Versatility and Shortcomings of Analytical Hierarchy Process

The conventional forms of AHP and MCA Methods have been in use for selecting the most suitable alternative out a given list of opportunities. The application case studies have spanned across a variety of sectors ranging from selecting suitable Information Technology Software to opting for an appropriate product development strategy suited for the Taiwan Semiconductor Industry (Tzeng et al., 2006; Wu et al., 2009). Similarly, collecting customer preferences for pursuing a lean product design and evaluating the automobile competitiveness in the South East Asian region (Putri & Yusof, 2009; Venkatamuni & Ramakrishna Rao, 2010).

The other innovative approaches for utilizing multi-criteria methods are in which fuzzy logic has been combined with AHP and the Delphi Participatory Process. One of the motivating factors for the researchers to choose a fuzzy approach is to identify the suitability of each available alternative with higher accuracy and less dependency on the weights assigned by expert opinion. To explain further, the comparison matrix proposed in Saaty's AHP ranges from values of 1 (equally important) to 9 (extremely important) and other intermediate values (Saaty 1990a; 2006b; 2008c). As exhaustive evaluation requires more criteria and sub-criteria, which could further add to confusion while conducting pair wise comparison and even result in inconsistency. For instance, a project that is expected to increase the employment of members from the local community and simultaneously should also incur higher profits, although are considered critical for the sustainability of the enterprise; nevertheless these two criteria could be contradictory towards each other. Therefore, in place of scores ranging from 1 to 9, the research reports that discuss AHP with fuzzy logic have considered the membership equations to accurately address the weighting between the criteria. Nevertheless, Buyukozkan and Feyzioglu (2004) ventured a step ahead to ascertain and characterize the uncertainty factors in the new product development process for risk minimization.

The concept of incorporating decision making should not be limited only to be application of decision models but also include other evaluation methods as well for overcoming its own limitations and aiding the user in the implementation of

an informed decision. For instance, Javadi and Dambatta (2008) devised an Analytical Hierarchy Process decision-making model to identify the most sustainable (social, environmental and economical) remediation strategy to counter the contamination caused by Petroleum processing. From their research they identified that the Monitored Natural Attenuation is the most sustainable option as compared to Enhanced Natural Attenuation and Soil Vapor Extraction. Nevertheless, the AHP Model without the inclusion of a comprehensive life cycle evaluation is handicapped to outline the potential drawbacks and environmental impacts caused by the remediation strategy itself, as the fundamental laws of thermodynamics execute no process without consumption of materials and energy.

Similarly, the multi-criteria method has also been combined with other evaluation and application tools for user specific applications. Eshlaghy et al. (2011) utilized a multi-criteria method in conjunction with discriminate regression method for evaluating the most effective engineering process in order to maintain the desired level of adherence with the specified standards.

In certain scenarios, the multi-criteria methods to which the AHP is a category, notwithstanding the effectiveness, could still possibly suffer from poor accuracy due to inadequate understanding. This would further demand additional modelling only possible by virtue of an exhaustive computational technique. Therefore, the computational modelling for both Systems and Processes is carried out to assign the weights to the Multi-criteria method and calculate the consistencies amongst the diverse range of criteria (Bouchard et al., 2010).

In comparison to the conventional AHP proposed by Saaty (1990a, 2006,b 2008c) proposed in the early 1990s, significant modifications in the Analytical Hierarchy Process have been justified in order to address Comprehensive Product Development Requirements that further demand a more effective decision modelling approach. Accordingly, Yang et al. (2009) instead of considering AHP as a decision making model for evaluating various technologies for coating car wheels, have used a multi-criteria hierarchical matrix method. Their conclusion

purports that the hierarchical multi-criteria matrix model provides a flexible and practical approach to define overall sustainability of manufacturing processes. Furthermore, they have also used a comparative evaluation of various criteria and the alternatives by engaging the domain participants and potential users quite closely in the evaluation phases. Their studies further reveal that in comparison to powder coating, the sol-gel coating delivers better technical, economical and environmental sustainability.

At the moment, pertaining to the interdisciplinary nature of medical devices and other dimensions of developing and delivering healthcare, the authors have identified a limited number of studies on the application of Multi-criteria decision methods. One of them was a review report published by Liberatore and Nydick (2008) discussed the suitability of AHP decision-making process in the field of medical and healthcare. The duo reviewed around 50 research articles from 1980s onwards and identified a surge in AHP utilization for decision-making since 1997, particularly in the areas of joint decision-making between patient and doctor, evaluation and/or selection of therapies/treatments and the evaluation of health care technologies & policies.

The authors of this research have not come across significant research articles related to the application of Analytical Hierarchy Process actively participating in the Medical Device Development. Although such attempts have been made in other engineering industries namely aerospace, automobile and defence, which involve interdisciplinary product design, that is largely prevalent even in the Medical Device sector.

Cho &Kim (2003) have utilized only the Analytical Hierarchical Process (AHP) for assessing and ranking a list of selected medical devices, to receive funding from Korean Ministry of Health and Welfare. In their research investigation, due to budget restrictions on healthcare expenditure by the Korean government, Cho &Kim (2003) established priorities to select the most relevant medical devices for receiving funding. The goal was to satisfy the needs of the stakeholders that are include people, medical institutions, government and patients. Moreover, the

authors implemented the basic principles of 'exclusiveness,' 'marketability', 'technology applicability', 'public benefits', 'completeness' and 'optimum size', while identifying their evaluation criteria and the hierarchical structure on the basis of the presumption that the criteria independent of each other.

Acknowledging the customized modifications of the Analytical Hierarchy Process and conjugating the methodology with a variety of evaluation and product development strategies, a Multi-Faceted Product Development Framework was devised. In this multifaceted framework a novel and modified Analytical Hierarchy Process is proposed whose participation is assured throughout the Product Development Cycle of a Medical Device.

The novel (or modified) AHP approach in this would be hereafter titled as "Multicriteria Hierarchical Model (MCHM)".

3.5. Structuring the Proposed MCHM

The proposed MCHM in this thesis is envisioned to participate actively in the product development endeavour, in addition to the conventional project selection and evaluation role of the contemporary multi-criteria methods such as AHP.

As illustrated in Figure 3.2, the Model comprising of 2 main criteria namely Regulatory Compliance and Economic and Business Performance that are further divided into 3 Tiers. The Tier 1 consists of the most critical sub-criteria without which no medical device can be qualified by the FDA; ISO and other Regulatory Bodies. Satisfying the criteria is Tier 1 results in a attaining a acceptable degree of overall Sustainability from the perspective of regulatory agencies and the senior executives of the medical device company.

As safety considerations of all the involved stakeholders (e.g.: Environmental Protection Agency (EPA); ISO) and the minimal environmental compliance (e.g.: ROHS; REACH; WEEE) in conjunction with reasonable profitability satisfies the bare minimum threshold after which the company can chose to increase its overall Sustainability by satisfying Tier 2 and 3 as per their own preferences. However,

the product development teams should not violate any of the criterions in Tier 1 to satisfy any other criterion or criteria in Tier 2 and Tier 3.

As these criteria in Tier 2 and Tier 3 are negotiable in nature and dependent on the company's profitability, for instance charity and employee housing are addressed mostly by investing financial resources. The Medical Device Regulations, Mutually Beneficial Labour Practices and Safety Norms are assigned the highest priority compared to environmental compliance (ROHS; REACH; WEEE). As in certain cases these ROHS; REACH; WEEE regulations could be irreconcilable with Product Specifications critical for the medical device functionality and regulatory compliance. Therefore, in certain cases medical devices are exempted from these ROHS; REACH; WEEE related regulations and accordingly, the company is responsible to execute the necessary due diligence to obtain the required certifications and exemptions.

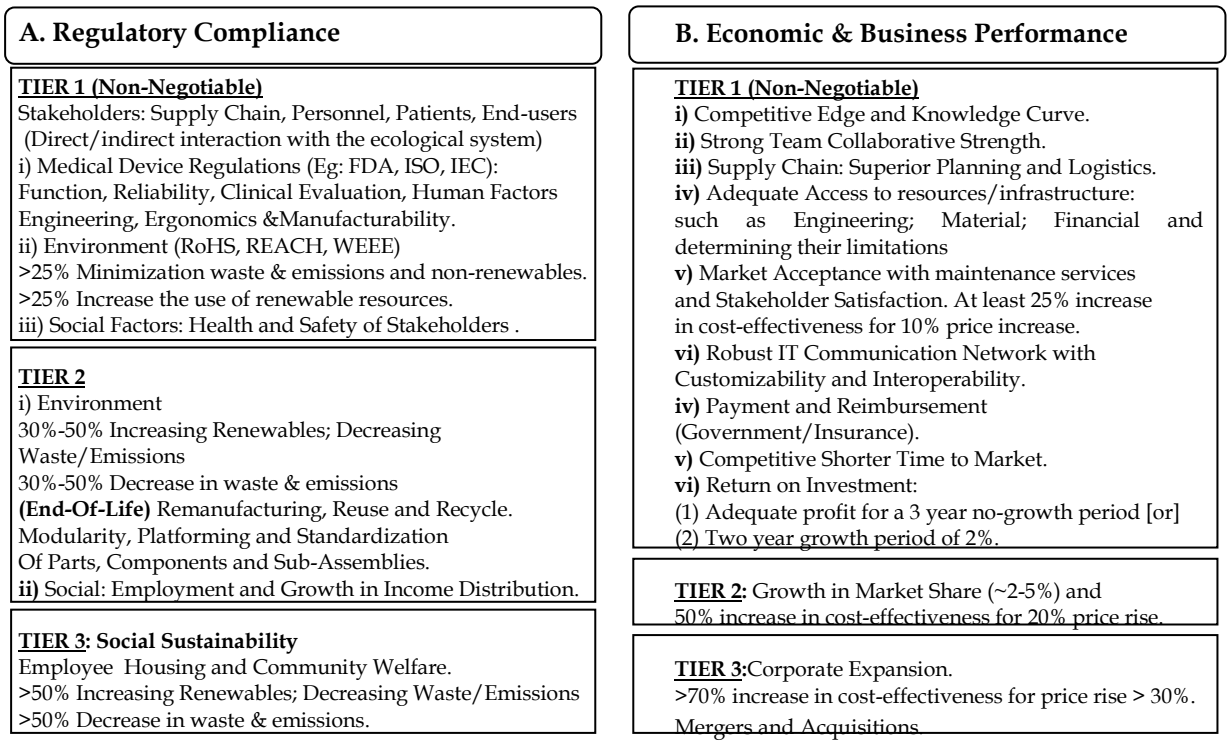


Figure 3.2. – Multicriteria Hierarchical Model

Nevertheless, the company can still improvise its environmental sustainability quotient by adopting lean product development and sourcing practices to minimize wastage and consumption of resources (Kadamus, 2008). Since the last decade, research endeavours to recover precious materials from semiconductors and treatment of industrial emissions/ waste have achieved a quantum leap in their ingenuity (Cui and Zhang, 2008; Pubule, 2011).

The known concept of Value Engineering can also be employed with the MCHM; wherein the focus is on identifying the "Value" of a developmental and/or production process. The "Value" can be elucidated by the attainable magnitude of product functionality; safety; business performance (e.g.: profits and administrative cost effectiveness); regulatory compliance and overall Sustainability. The "Value" of each process is not necessarily additional in nature in combination with other processes as it can be exponential, compounding or even inversely co-related if the Pareto Optimal Frontier is encountered (Zhao et al., 2010; Hede et al., 2011).

Each Criterion of the proposed MCHM is in fact composed of one of more Product Specifications, which embodies the objective of attaining the criterion under consideration. Moreover, the instead of compelling the users of the MCHM to assign scores for any particular criterion in Tier 1 and End-of-Life/ Modularity of Tier 2; the authors suggest the usage of the "maximum achievable and minimum acceptable values" associated with the pertinent specifications.

For example, the Criteria of Functional Performance and Reliability are dependent upon the specifications of 'uninterrupted cycles of operation' and 'mean time between failures (MTBF)' respectively. The "maximum achievable and minimum acceptable" range values for the two specifications are (100-1000 cycles per minute) and the MTBF is 300-1000 hours, respectively. In due course of time during the conceptual design phase and design engineering activities, the product development teams can finalize the most optimal values. Nevertheless, the teams would have to conduct a preliminary investigation to ascertain the range of values, deduce the feasibility to incorporate multiple life cycles/product

modularity and ultimately, unearth any underlying conflicts and synergies. Under no circumstances, the modularity and end-of-life options should be considered if it is identified to be irreconcilable with the Tier 1 criteria. Therefore, these two sub-criteria are placed in Tier 2. The fundamental concept behind the justifying the use of specifications for each criterion is based on Quality Function Deployment. The aim of the stated conceptual tool was to transform user requirements into the quality of product design and recommend approaches for achieving thereof.

For clarification purpose, the stakeholders in the proposed model are the people, societies and ecosystems that are both directly and indirectly affected by the company's business practices. For example: The 2010 Gulf oil spill not only affected the aquatic ecosystem and the livelihood of local industries on the coast, but in fact threatens to pollute other geographical regions in the coming future (McConnaughey, 2013). Also, in today's modern globalized world, the medical device development starting from the design to production and sale is conducted across various continents. Therefore, the stated example is also applicable towards the safety, labour laws, welfare/benefits, sourcing, development, exports and imports of medical devices to countries with regulatory compliance frameworks quite different from the parent country of the medical device manufacturer. In line with this, the organization titled as the "Global Harmonization Task Force" has been conceptualized in 1992 by the regulatory authorities of European Union, United States, Canada, Australia and Japan for establishing a higher degree of uniformity between the various national medical device regulatory systems.

The Tiers of criteria in the MCHM as denoted in Figure 3.2 are also categorized with respect to two more categories in Figure 3.3. The first one is the "Design related criteria" (e.g.: Human Factors; Safety; Functionality; Clinical Evaluation and others), which can be incorporated as a part of the Product Design. The second category is the "Non-design related criteria" that although is closely related to Product Specifications but not necessarily can be modified by the design engineering activities directly, namely Aesthetics in terms of market acceptability; Finalizing the Payment/Reimbursement options; Ability to execute advanced

technology/product development processes and Knowledge Management; Information and Communication Technology Infrastructure and Management.

The aim of Figure 3.3 is to enable the users of MCHM to allocate suitable human resources and the appropriate magnitude of effort in terms of man-hours to monitor those criteria that regularly require human intervention. For instance, the reliability of a component in terms of Mean Time Between Failures can be addressed by using suitable automated design engineering optimization tools with limited human supervision. However, challenges pertaining to payment and reimbursement demands continuous interaction between the pertinent employees of the medical device company and the regulatory agencies, which cannot be substituted by an automated system. This implies that the product development teams have to plan the logistics/operations between designs related engineering activities and business process related activities in order to shorten the product development life cycle.

Design related criteria:

- Performance, Reliability, Clinical Evaluation, Emissions, Human Factors Engineering and End-of-Life.
- Regulatory Compliance
- Minimization of emissions and waste
- Safety, Cost and Time to Market

Non-design related criteria:

- Market Acceptance (such as Aesthetics and Selling Price)
- Policies of Payment and Reimbursement by the Government and Insurance Companies.
- The medical device company's infrastructure to uphold safety standards and execute advanced technology/product development.
- Information & Communication Technology (ICT) Infrastructure.
- Strong Team Collaborative Strength.
- Economic & Business Performance criteria in Tier 2 and Tier 3.
- Employment and Growth in Income Distribution (Tier 2 of Regulatory Compliance)
- Employee Housing and Community Welfare (Tier 3 of Regulatory Compliance)

Figure 3.3 – Categorization of the Criteria in Multicriteria Hierarchical Model

As described previously, the pertinent criteria are structured into three tiers; wherein Tier 1 is compulsory and non-negotiable and Tier 2/Tier 3 are negotiable in nature and hence medical devices companies can chose certain design candidates. In conventional AHP terms the design candidates can be considered as Alternatives, out which the most suitable one has to be selected.

Following is a description of each criterion of Figure 3.2 and the numerical values in terms of emission reductions. The cost effectiveness was provided by the Experts (from Industry and Academia), which were interviewed to conduct the pair-wise comparison of the Tier 2 and Tier 3 (negotiable Tiers). The discussion of the methodology and results of the pair-wise comparison have been outlined in Chapter 5 and Chapter 6, respectively.

TIER 1 (Non-Negotiable) (Left hand side A. Regulatory Compliance)

The crucial regulations pertaining to FDA, ISO, IEC and others are necessary for the product to be qualified to enter the market. There are also additional policies by the government to prevent any safety related hazards and even human rights related issues that a company must comply before commercializing its products/services.

i) Medical Device Regulations (e.g.: FDA, ISO, IEC):

Function, Reliability, Clinical Evaluation, Human Factors Engineering, Ergonomics & Manufacturability.

These facets are to be conducted in a concurrent manner on the basis of the configuration of the medical device and the knowledge curve (in addition to other resources outlined in Section 3.3) of the medical device company.

ii) Environment (RoHS, REACH, WEEE)

>25% Minimization waste & emissions and non-renewables.

>25% Increase the use of renewable resources.

iii) Social Factors: Health and Safety of Stakeholders.

The medical device should not engage in any engineering process as a part of its design, development or production, which could harm local or distant stakeholders. For instance, indiscriminately dumping toxic waste in rivers and not adopting safety standards pertaining to waste disposal.

Once the company is in a position to attain the Tier 1 criteria, they can consider any one or few or all criteria of Tier 2/Tier 3. These criteria are capable of adding a strategic value to the company for its future prospects. As commitment to incorporate criteria such as end-of-life options and increase in employment within the business practices of an Industry have demonstrated long term success via improvement in income distribution (D'Alessandro et al., 2009; Nasr and Thurston, 2006). The facet of cost effectiveness and increase in price gradually increases as we go from Tier 1 onwards to Tier 2 and 3. The objective is to recommend companies for delivering 'better value for their money' in order for them to stay competitive in the long run (Xu and Morisson, 2005).

TIER 1 (Non-Negotiable) (Right hand side B. Economic & Business Performance)

i) Competitive Edge and Knowledge Curve.

A medical device company's products should possess substantial competitiveness compared to its competitors. This is in addition to the company's organization in terms of leveraging its resources (financial/non-financial) to produce new products/services. The knowledge curve which is a key decisive factor for commercializing robust customer centric products at lower costs (Corallo et al., 2009).

ii) Strong Team Collaborative Strength.

A team that is able to collaborate effectively and exchange their knowledge as well as expertise are able to develop superior products with a smoother process of product development (Akgün et al., 2006).

iii) Supply Chain: Superior Planning and Logistics has proven to be a strategic factor in access to raw materials and delivery of finished goods/services to pertinent consumers in the most effective manner. This enables the company to gain better product feedback and provide maintenance services, so as to demonstrate better customer services and maintain customer loyalty (Marra et al., 2011)

iv) Adequate Access to Resources/Infrastructure: such as Engineering; Material; Financial and determining their limitations (refer Section 3.3).

The properties and limitations of materials (e.g.: steel is strong and heavy so higher fuel costs for transportation) are crucial in determining the scope of application of the medical device, which uses a certain combination of materials to lower costs and provide the desired utility to the end-user. For instance, certain polymers cannot be used as implants owing to their eventual fragmentation and disintegration, which can result in allergies; nevertheless metals can be expensive as well as heavy. Thus resulting in higher costs (Nag & Banerjee, 2012).

v) Market Acceptance with maintenance services and Stakeholder Satisfaction: At least 25% increase in cost-effectiveness for 10% price increase.

The Experts (from Academia and Industry) recommended that the medical device company adopting the MCHM should consider at least 25% increase in cost-effectiveness in terms of customer satisfaction for a 10% increase in price, in order to increase profit margins and add more value to their customers who choose to pay more.

Similarly, the same Experts (from Academia and Industry) recommended additional degrees of cost effectiveness for increase in product price in Tier 2 and Tier 3 of the Economic and Business Performance.

These two are the most crucial criteria, which are considered before 'killing a project'. As the market interest in terms of demand (and buying power of the relevant customers) and the support from the stakeholders are critical for the device to be made accessible or even justifiable (including end-users, regulatory bodies and Insurance companies). This includes support of local and distant

communities who are directly and indirectly affected by the company's actions (Pacelli, 2004).

vi) Robust IT Communication Network with Customizability and Interoperability.

IT (Information Technology) communications network enables a more agile continuous iterative design and development of the medical device by virtue of improved traceability of the tasks/ activities involved. This includes the automated updating of the regulatory documentation for minimizing the risk of any project schedule overruns (Patil, 2010).

iv) Payment and Reimbursement (Government/Insurance).

As mentioned in market and stakeholder considerations, this criterion is crucial for the utilization and sale of the medical device, especially in scenarios where Insurance companies and Governments require substantial time for reimbursement (Miller, 2007).

v) Competitive Shorter Time to Market.

The activities of product development of a medical device should never fall behind the time to market plan of the competitors. However, a late entry can be strategically considered to incorporate better features after learning from competitors' failures, which creates a need on the market for a better product. This is the reason the criterion is labelled a 'competitive' shorter time to market.

vi) Return on Investment:

(1) Adequate profit for a 3-year no-growth period or (2) Two year growth period of 2%.

The criterion of minimal profitability is critical to filter out design candidates that although meet certain advantageous aspects such as recycling, nevertheless may not provide the desired rate of profit for the medical device company. Moreover, this criterion should not violate the crucial regulatory compliance requirements.

TIER 2 (Left hand side A. Regulatory Compliance)

i) Environmental Sustainability

30%-50% Increasing Renewables; Decreasing Waste/Emissions

30%-50% Decrease in waste & emissions

End-Of-Life: Remanufacturing, Reuse and Recycle.

Usually the End-Of-Life comprises of a systems based approach of a product configuration namely Modularity, Platforming and Standardization Of Parts, Components and Sub-Assemblies to name a few. In Chapter 5 and Chapter 6, this sub-criterion of End-Of-Life is renamed as End-Of-Life and Modularity as they are closely inter-related (Nasr & Thurston, 2006). As it become easier for pair-wise comparison related interviews with the Experts (from Industry and Academia).

ii) Social Sustainability: Employment and Growth in Income Distribution (in terms of benefits, perks and incentives).

Both these sub-criteria have been considered for pair-wise comparison pair-wise comparison related interviews with the Experts (from Industry and Academia).

TIER 2 (Right hand side B. Economic & Business Performance)

Growth in Market Share (~2-5%)

50% increase in cost-effectiveness for 20% price rise.

TIER 3 (Left hand side A. Regulatory Compliance)

Social and Environmental Sustainability

Employee Housing and Community Welfare.

Activities pertaining to community welfare in terms of Corporate Social Responsibility and providing any suitable form of support for productive as well as deserving employees not only leads to boosting employee morale with commitment for a higher degree of productivity, but also eventually contributes towards income distribution (D'Alessandro et al., 2009). Moreover, both these sub-criteria i.e. Employee Housing and Community Welfare have been considered for

pair-wise comparison pair-wise comparison related interviews with the Experts (from Industry and Academia).

>50% Increasing Renewables; Decreasing Waste/Emissions

>50% Decrease in waste & emissions.

TIER 3(Right hand side B. Economic & Business Performance)

Corporate Expansion.

>70% increase in cost-effectiveness for price rise > 30%.

Mergers and Acquisitions (M&A) of Organizations is one of the approaches towards the economic growth objectives of a company. However, in certain cases when companies face bankruptcy they could opt for an M&A (Denning, 2012).

In Chapter 5 and Chapter 6, the sub-criteria of Business Growth is considered instead of Mergers and Acquisitions, as Business Growth can be attained by increasing sales, M&A, entering new businesses as well as corporate expansion. Hence the sub-criterion of Business Growth is more holistic in nature and ensures that the pair-wise comparison activity with the Experts (from Industry and Academia) becomes less exhaustive without losing the scope of the thesis. Meanwhile, the sub-criterion of Market Share is still considered as a separate sub-criterion as market share growth does not necessarily indicate the other aforementioned business growth related facets.

With respect to the brief description of each pertinent criterion outlined in the three tiers, the product development teams should take note of a few important points that for any development endeavour, the key important resources with their corresponding properties and policies/regulations have to be in place for the company to attain mutually beneficial relationship with its stakeholders. Accordingly, the role of the ICT infrastructure is critical in attaining a synchronicity and assures traceability between project management; knowledge management and interdisciplinary engineering activities (Patil, 2010). The product life cycle management also encompasses 'Digital Manufacturing' to integrate the shop floor activities and equipment so as to actualize product-related information

between design and manufacturing activities in a computerized virtual environment. The virtual environment can model the incorporation of Tooling, Assembly Lines, Work Centers, and Facility Layout, incorporation of Ergonomics and optimal use of resources (SIEMENS<http://www.plm.automation.siemens.com/en_us/>). The advantages of a coordinated networking of activities are including but not limited to cost savings, minimizing expensive downstream modifications and reduce time-to-market.

A robust and interconnected company would always move faster in the learning curve and disseminate knowledge throughout its organizational structure to stay competitive. As the ICT systems efficiently transfer knowledge pertaining to the complex engineering data/information generated during the design phase for product and production processes of components and sub-assemblies. The knowledge transfer processes can be conveniently correlated with the automated updating of regulatory documentation such as FDA or environmental compliance e.g.: WEEE, FDA and ISO. The product development and ICT systems have to coordinate with other information systems by way of interoperability to communicate with activities pertaining to other phases of the product life cycle, namely supply chain; distribution; maintenance and end-of-life. For example: The Enterprise Resource Planning Systems; Quality Management System; Product Data Management; Portfolio Management; Laboratory Information Management (LIMS); Document Management System (DMS); Clinical Data Management System (CDMS); Submission Management and Publishing; Inquiries and Adverse Event Reporting (AERS); Learning Management System (LMS). (Patil, 2010; Parametric Technology Corporation (PTC), 2008).

One such remarkable example of product life cycle management is from SIEMENS, who have developed a software based digital platform to provide its clients with single, easily configurable and open/flexible source of Product, Business and Production Process Information. The Open/Flexible architecture enables introduction of additional business processes while minimizing undesired complexities that arise during integration, implementation and interoperation. The

SIEMENS software based digital platform permits integration of leading engineering systems from other vendors such as SAP, Oracle and Microsoft (SIEMENS <http://www.plm.automation.siemens.com/en_us/>).

The other functional paradigms of ICT systems are enumerated as follows (Filho et al., 2009; Goedkoop et al., 2000; Mont, 2000):

a) The Innovation Management Component embraces Innovation Strategic Planning and with Portfolio Management through a stage-gate process. This business process involves assessment of trends in the market and technology of products and services.

b) The Configuration Management (ECM) is related to engineering oriented modifications across the product life cycle that also assists in maintaining the complete information and knowledge of the involved PSS (Product Service System). The Configuration Item (CI): A collection of all components and sub-systems that form the PSS and the Configuration Document (CD): the complete information that characterizes the CIs (Ekos International <www.ekosi.com/>).

c) Business Process Management (BPM) is sector that builds and evolves knowledge, which is obtained through the intersection between management and information technology. This sector includes various methods, techniques and tools that are crucial to design, control, and analyse operational business processes involving humans, organizations, applications, documents and other sources of information (Van der Alst et al., 2003).

The additional advantages are traceability of work activities to the compliance of each system element with the validation standards for addressing stakeholder considerations. Traceability monitors the progress and actively materializes risk mitigation objectives by enabling the product development teams to identify, trace and rectify the source of failures and accordingly, monitor the resultant consequences to the company (Wysoki et al., 2000; Wilde Analysis <wildeanalysis.co.uk>). Simultaneously, the Product Design and Optimization Phase enables graphical modelling of the requirements, behaviour and functionality of both the systems and software. Graphical representation permits

iterative assessment, testing and validation, throughout the development process. The results can be automatically transferred into a production quality code, which would be evaluated in accordance with Manufacturing Process Management (MPM). The MPM would further enable communication with the value chain partners through the attributes of the Enterprise Resource Planning (ERP) Tools. Moreover the visual models facilitate the teams' understanding of the interdisciplinary project and enables better communication to its engineers and stakeholders.

The Validation of IT Communication Software Systems for Medical Device Industry is stated in the Quality System Requirements (QSR) put forward by the FDA (Vogel, 2001). The QSR demands validation of the software solutions implemented for the new product development in the medical device industry. The QSR states that if "computers or automated data processing systems are used as part of production or the quality system, the [device] manufacturer shall validate computer software for its intended use according to an established protocol" (see 21 CFR §820.70(i) Code of Federal Regulations) (Sobelman, 2008). In addition, Sobelman (2008) has determined that Companies who purchase their enterprise software systems from vendors, who also provide a validation protocol for the base-line implementation state of their software systems, save around 50% of time and cost for the validation procedure. The discussed QSR requirements are: Traceability (820.65), Production and Process controls (820.70), Process Validation (820.75), Device Master Records (820.181), and Device History Records (820.184). These aforementioned Code of Federal Regulations are located in the CFR - Code of Federal Regulations (2012) Title 21, PART 820 of the Food and Drug Administration <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=820>.

Furthermore, notwithstanding the drawback of the proposed decision making approach pertaining to its capital intensive nature and demand for due diligence throughout the development path. The model does deliver the advantage of customization subjective to each medical device, although substantial effort is

needed for preliminary investigation as stated before for ascertaining the optimal values for the product specifications. The proposed MCHM and its criteria can also be considered as a 'Benchmarking Tool' and a 'To-do List' as it elucidates the position of the Organization from a competitive standpoint and encourages the development of a reliable roadmap for the "overall" success of the Organization (Damelio, 1995). The approaches for design optimization and strategies for reconciling conflicts objectives and constraints would be discussed in detail in the subsequent sections of this thesis.

3.5.1. Project Selection

If one observes the list of criteria with close observation, then the proposed MCHM is capable to acting a decision model to choose suitable medical devices for development. The proposed MCHM for Project Selection is demonstrated in an example. In this example the choice to pursue development has to be made between a Pacemaker, a Syringe and an Infusion Pump for injecting fluid intravenously and the decision modelling steps are outlined as follows:

STEP 1: Identify the magnitude of commitment desired for each criterion pertinent to the shortlisted candidates of Medical Devices. For example, A Pacemaker would have more stringent regulations than a Syringe and hence requires more expertise for design and manufacturing.

STEP 2: Identify the magnitude of financial and expertise related commitment that can be invested by the Organization for each criterion in order to achieve the desired results.

STEP 3: If the medical device company determines substantial impediments pertaining to addressing regulatory compliance, knowledge curve and monetary resources then the company is advised to "Reject" the particular Medical Device under evaluation. Nevertheless, if the Organization has access to relevant expertise, resources, partners, and leadership and marketing strategies for leveraging a successful market entry, then the option can be "Selected".

STEP 4: Post selection, the product development teams have to identify the pertinent specifications of the device. For example: For a pacemaker to perform for

4 year life-span, then the mean time between 2 failures should be around 20,000 hours.

STEP 5: Deduce a list of "minimum acceptable and maximum achievable" values for each criterion and especially for the specifications pertaining to of Reliability and Material Properties for ensuring an End-Of-Life Option namely, Remanufacturing, Reuse and Recycling.

For the illustrated example in Figure 3.4, it is to be inferred that the company is sufficiently capable of commercializing a Syringe from an engineering standpoint as compared to Pacemaker. Nonetheless, the market competition for the Syringe is the highest due to a multitude of pre-existing players. Moreover, the company through additional investment of expertise, resources, partners, leadership and marketing strategies, is in a stronger position to launch an Infusion Pump that lies between the extremities of a Syringe and Pacemaker. Meanwhile, for a Pacemaker, the investment and challenges would be much larger, and therefore a thorough internal and external assessment is required before the option is pursued for development.

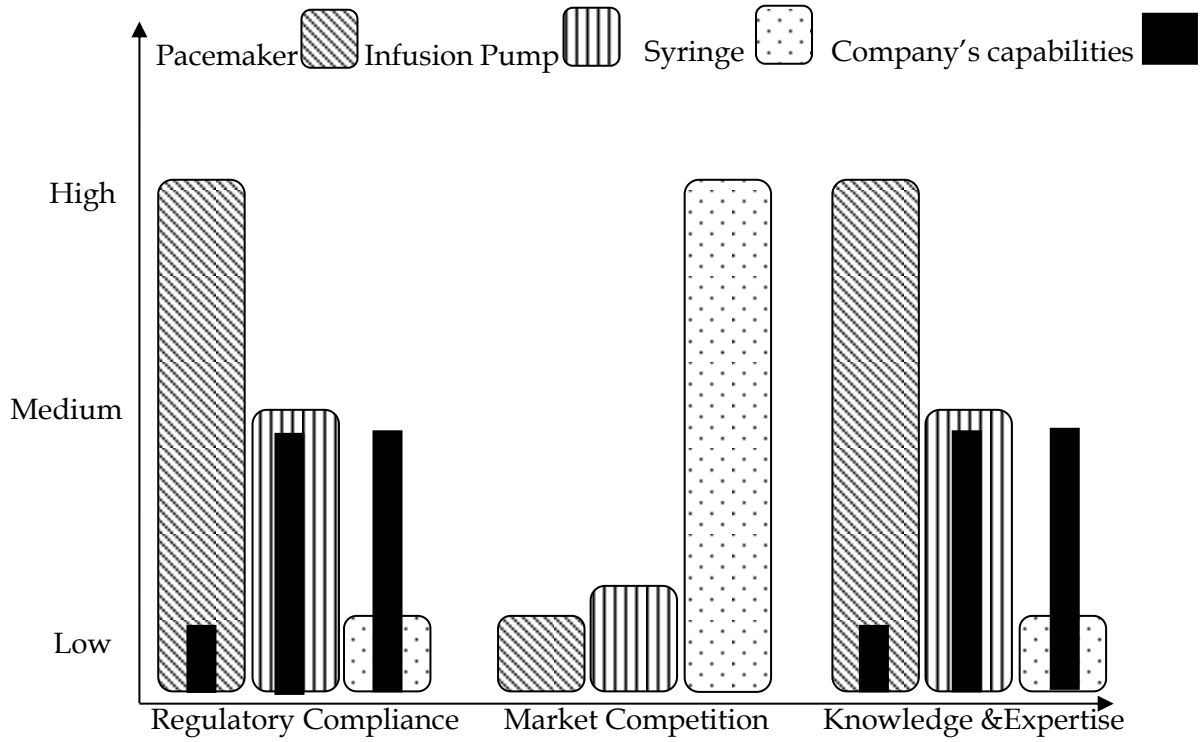


Figure 3.4 – Multicriteria Hierarchical Model in Project selection

Notwithstanding the technical and project related challenges that the development teams would encounter, the Business Management dimension of the medical device company has to face its own share of insurmountable challenges. To begin with, once the patient benefits are accounted for in the medical device design, then it is recommended by Miller (2007) to launch medical devices that offer a higher degree of cost effectiveness (and savings) to the healthcare service provider such as a Hospital.

Moreover, the healthcare service providers sign "group purchasing contracts" with renowned medical device vendors and pharmaceuticals and accordingly, buying a better product that is cost effective with enhanced patient satisfaction but not "under contract" is a major impediment for business (Miller, 2007). The regulatory hurdles and payment/ reimbursement options are the most critical for the success of the product development endeavour as confirming a third party payer (e.g.: Insurance Company) could turn out to be impossible unless there is a decision for reimbursement by the healthcare policy of the nation and vice versa. The involvement of sound expertise for guiding the regulatory and reimbursement procedure is vital throughout the development activity. Similarly, other pragmatic challenges a medical device company would encounter is during identification and collection of ergonomics/human factors engineering requirements from the patients; medical personnel (doctors; nurses; staff) and healthcare providers. Although these pertinent stakeholders are always occupy and not readily available for prolonged interactive discussions. The Medical device companies do not necessarily possess the prerequisite facilities and expertise to scout for all the explicit/latent needs of their stakeholders and accordingly simulate them to be incorporated into their products. However, medical device companies can hire the services of consultants who specialize in the aspect of human factors engineering.

3.5.2. Comparison between contemporary AHP and the proposed MCHM

The three tier multicriteria hierarchical model was introduced in this chapter, which is inspired from Analytical Hierarchical Process (AHP) only in terms of its

hierarchical nature of a wide spectrum of, interconnected criteria. The AHP approach is identified to be simple and accounts for a wide spectrum of factors, criteria and indicators for decision making in a consistent manner with a common scale without any units. It is noted that AHP has undergone substantial modifications to address complex product development and engineering scenarios:

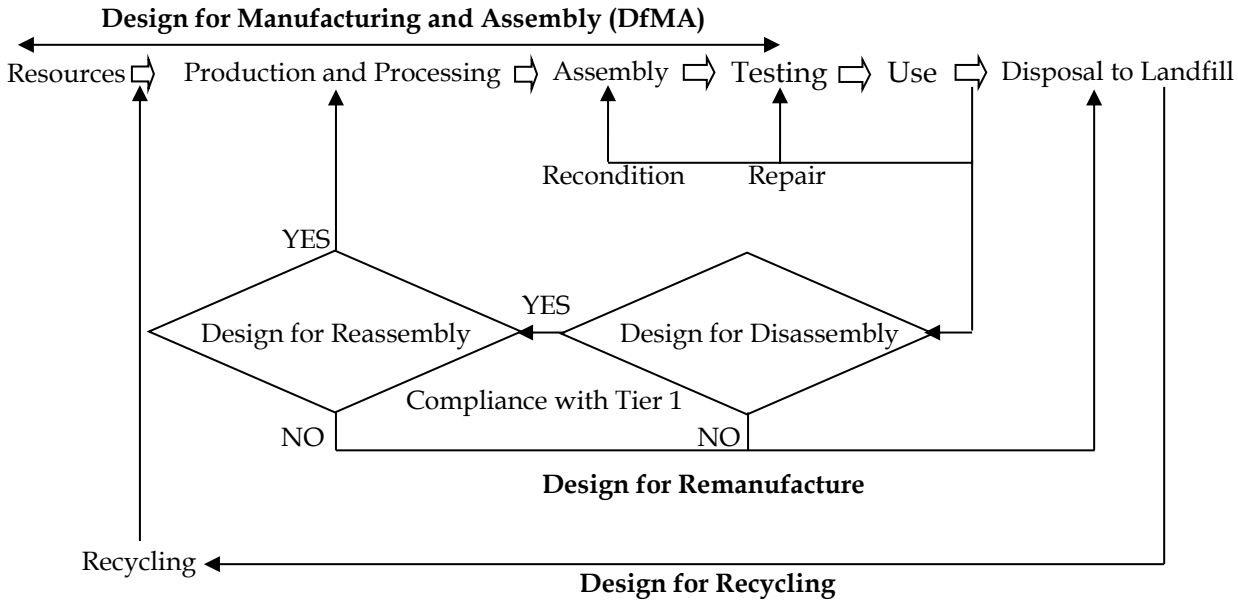
1) The contemporary AHP does not necessarily address the complexity of the inter-relationships between the Criteria of the uppermost hierarchy with the Criteria of the same hierarchy and its sub-criteria levels (Saaty 1990a, 2006b, 2008c). Moreover, in the conventional AHP each criteria needs to be addressed, while the proposed MCHM demands that only the first Tier be satisfied and the other tiers to be optional in nature.

2) The contemporary AHP is more focused on choosing a certain alternative out of a list of other Alternatives. This although is applicable only for the "Idea Screening Phase". Meanwhile, the proposed MCHM participates in addressing conflicts/synergies and highlighting the limitations elicited by the Organizations' and their Value Chain Partners for selecting a Project of interest for stakeholder satisfaction. The proposed MCHM includes by default the holistic assessment of the Balance Score card and Strength; Weaknesses; Opportunities and Threats (Hill & Westbrook, 1997). This is unlike the Analytical Network Process that also elucidates the co-relation between various criteria (Saaty, 2009). For example: 20-30 years ago, when new applications were encountered for the field of Micro-Electro-Mechanical Systems (MEMS). MEMS are systems in which micron sized parts are fabricated using modified semiconductor fabrication processes. The major impediment for innovation in MEMS was that the existing industrial electronics industry was not well equipped to accommodate the new sector in a cost effective manner. Thus, resulting in a time delay of a few decades to launch a simple and robust accelerometer (Baltes et al., 2008).

3.5.3. The Role of Multicriteria Hierarchical Model for Addressing the End-Of-Life Options

Optimizing the consumption of materials and waste/emission generation without compromising the facet of regulatory compliance and bare minimum economic objectives of the company can incorporate the Sustainability quotient in a product design. Alongside, the product development teams should include end-of-life options namely Recycling; Remanufacturing; Reuse; Reconditioning for products, which have longer life spans, coupled with higher reliability and short market life cycles. The "flow of materials" can be transformed into a closed loop. Thus, reducing the dependency on energy and extraction of raw materials (Nasr and Thurston, 2006; Scharnhorst et al., 2006; Stahel, 1982).

Similar to Stahel (1982) the illustration of the length of the loop for each End-Of-Life option in Figure 3.5 proportionally corresponds to the consumption of time; monetary; human expertise/labor and material resources. Moreover, when the company opts for any one or all of the End-Of-Life options it also has to accept the ownership and responsibility of its products and services through the life cycle(s) for satisfying its Sustainability objectives towards its stakeholders.



Criteria for End-If-Life are available at the web resources of Systems Realization Lab of Georgia Institute of Technology.

Figure 3.5 – Multicriteria Hierarchical Model for Addressing End-Of-Life Options

As stakeholders desire a utility delivered by a product and not necessary the possession of a physical product. For example, consumers desire a cell phone for a long distance conversation but not necessarily need to permanently own one owing due to the rapidly evolving cell phone alternatives available (Parlikad et al., 2005). Consequently, the company can provide the consumers with a combination of products and services with warranty and take-back benefits constituting the product-Service-System (PSS) Model. The inclusion of end-of-life requires the products to be Modular in nature; wherein they can be disassembled into distinct elements (such as sub-systems, sub-assemblies, components and parts). For example, components, parts and sub-assemblies that can be either easily repaired or replaced with new ones for either Reusing or Remanufacturing (Hammond et al., 1998; Ijomah et al., 1999; King and Burgess, 2005; Sundin, 2004). According to Figure 3.5, the product development teams should ensure that during the incorporation of disassembly and reassembly mechanisms in the product design (Active Disassembly Research Inc., 2005). Moreover, while incorporating disassembly and reassembly mechanisms, as stated previously that not a single criterion of Tier 1 of MCHM should be violated, under any circumstances.

The concept of Modularity in product design permits the division of a system into its constituting and distinct system elements, namely sub-systems; sub-assemblies; components and parts (Sundin, 2004; Ijomah et al., 1999; King and Burgess, 2005; Hammond et al., 1998). For instance, an X-ray machine can be sub-divided into its constituting modules (system elements) as opposed to an intricately inter-connected components of a heart valve or a even a stent graft (Aguwa et al., 2010; Nair et al., 2003; Fenlon & Walton, 2000). The modules (or systems elements) can be interchanged and combined with (less or no-modification) to obtain product derivatives from a particular Platform Architecture (Aguwa et al., 2010; Chandrasekaran et al., 2004).

As observed in the medical device sector irrespective of class; the devices such as Heart Valves possess a low potential for modularity and end-of-life options as compared to X-ray machines and pacemakers that are composed of multiple interconnected system elements (Fenlon & Walton, 2000). The prospective users of

the MCHM model can choose to modify the project selection process to suit their own subjective requirements.

Also, whenever the company is unable to reconcile the end-of-life objectives with Tier 1 criteria, then by default the product should be considered for recycling (Weiss and Karwasz, 2005). Nevertheless, it is of utmost importance that the paradigm of modularity and platform-derivative approach should not be "misused" by launching multiple range of products with nearly cosmetic modifications (i.e. planned obsolescence) that although would increase the economic sustainability of the Medical Device company, while simultaneously jeopardizing the other two domains of sustainability (Packard, 1963; Fishman, Gandal & Shy, 1993).

The advantages of end-of-life, as stated by Sobelman (2008), is that for re-using the design by accessing the design archives by using specialized software tools ensures substantial savings in time and resources. For Example: Most probably, if a design is 20% new and 80% reused, then the testing and evaluation would be no more than 20%.

Moreover, Remanufacturing is known to preserve the embodied energy of the elements for their first life cycle. According to Lund (1985) a remanufactured product requires only 20-25% of the energy/resources consumed for its first life cycle, which begins from extraction up to disposal/end-of-life (Hauschild et al. 2005). Moreover, a comprehensive learning curve in product development can reduce the consumption of energy/resources even further (Lund, 1985). Furthermore, if the resources invested are optimized for utilizing the materials and elements for multiple life cycles is always preferred by Industry in terms of cost savings when compared to manufacturing the product from scratch up to recycling/disposal.

Also, Bras & McIntosh (1999) identified that product recovery by any one of the end-of-life options contributes to additional profits by cost savings and improvised understanding of the reliability and durability of the product. Therefore, further contributing to the learning curve of the Organization for

developing better products at a faster rate with competitive prices (up to 60% in some cases). Product Designers who intend to incorporate End-Of-Life options may have to choose product elements, materials; production methods and design candidates which although would last for multiple life cycles could simultaneously consume more resources and generate more higher emissions/waste usually in the first development and production cycle. For instance, certain robust reusable plastics or high strength alloys would require more non-renewable fuels such as coal and petroleum for their production; nonetheless these materials would survive for multiple life cycles and may consume only a fraction of resources for reuse or recycling. While, as stated in this example, the product elements or materials in subsequent life cycles are envisaged to consume much less resources. Hence bringing about an overall reduction is usage of resources and generation of waste.

Likewise, as explained using the first law of thermodynamics that energy and materials cannot be created or destroyed but can be transformed from one form (useful) into another form (recyclable or waste).

The second law states that more energy would be required for carrying out the transformation and therefore, low entropy materials that are procured in the beginning of the life cycle as starting elements, undergo significant modifications during the life cycle phases of production; distribution; use and disposal (Hauschild et al. 2005). As a result the entropy (which is denoted as disorderliness in this thesis) proportionally increases towards the end of the product's life cycle. Consequently, more energy is required to rectify the "high entropy material" (high disorder and low embodied energy) which is in the form of waste/ unwanted product to transform into a desired "low entropy material" (low disorder and high embodied energy). The disorder or entropy is highest for materials and products suitable for recycling. Similarly, the entropy is lower for materials and products suitable for remanufacturing and much lower for reusing. Thus, exemplifying the Stahel (1982) model for depicting End-Of-Life scenario.

Notwithstanding, the benefits of end-of-life, neither of the End-of-Life options is free from their own idiosyncratic challenges that range from access to expertise, technical infrastructure and resources to design related impediments for both the Remanufacturer and the Original Equipment Manufacturers (OEM). The restructuring of the conventional supply chain and logistics to a reverse logistics approach for "closing the materials loop" has been considered as one of the most severe stumbling block. As significant non-renewable resources are expended in transportation; recovering the product value and opportunity cost incurred while rectifying more damaged components as compared to components in better condition (Marques et al., 2004; Barker & King, 2007).

The impediment is further propagated by lack of assuring incentives and conflicts of interest with the Remanufacturer, specifically pertaining to the risk of losing foothold of the intellectual property to the other clients of the Remanufacturer and the loss of brand value as the "brand conscious" market may reject the product as "second hand". Nonetheless, the increasing awareness and sensitization of consumers towards Sustainability has diminished this 'second hand' drawback to a much larger extent. The demand forever increasing level of sophistication in medical devices in combination with competitive pricing results in a significant increase in structural complexity pertaining to the product design; development and compatibility/interdependency between the diverse product elements in terms of the product architecture.

These potential impediments towards attaining End-of-Life options are accounted into Tier 1 in the form of criteria such as Market Acceptance, Stakeholder Satisfaction and Competitive Edge. For instance, a product design which is able to attain regulatory compliance and remanufacturing; nevertheless, could become less competitive in the market and may not be accepted by the end-users. Consequently, the design candidate would be rejected and would undergo further iterations.

The fluctuations in the dynamics and logistics of the Value Chain Partners (e.g.: Increased prices of copper) of the Life Cycle and Stakeholders (e.g.: demand for

more eco-friendly products) results in uncertainty. The uncertainty is minimized by overcoming limitations posed by streamlining the access towards resources namely materials; expertise; tools and technologies (as mentioned in Section 3.3). This is achieved by establishing strong agreements between the value chain partners and stakeholders that have to be regularly honoured. Furthermore, the policies and legislations (e.g.: tax benefits and subsidies) in accordance with the company's business practices for continuous innovation are essential for overcoming the aforementioned sources of uncertainty.

Taking the discussion of uncertainty and complexity a step further is where a medical device company's commitment to its overall Sustainability is absolutely inseparable from its Risk Management measures (FDA, 2000). The degrees of anticipated risks are based on the magnitude of undesirable or uncertain events, which can further lead to other undesirable consequences, eventually threatening the welfare of the Organization and its stakeholders.

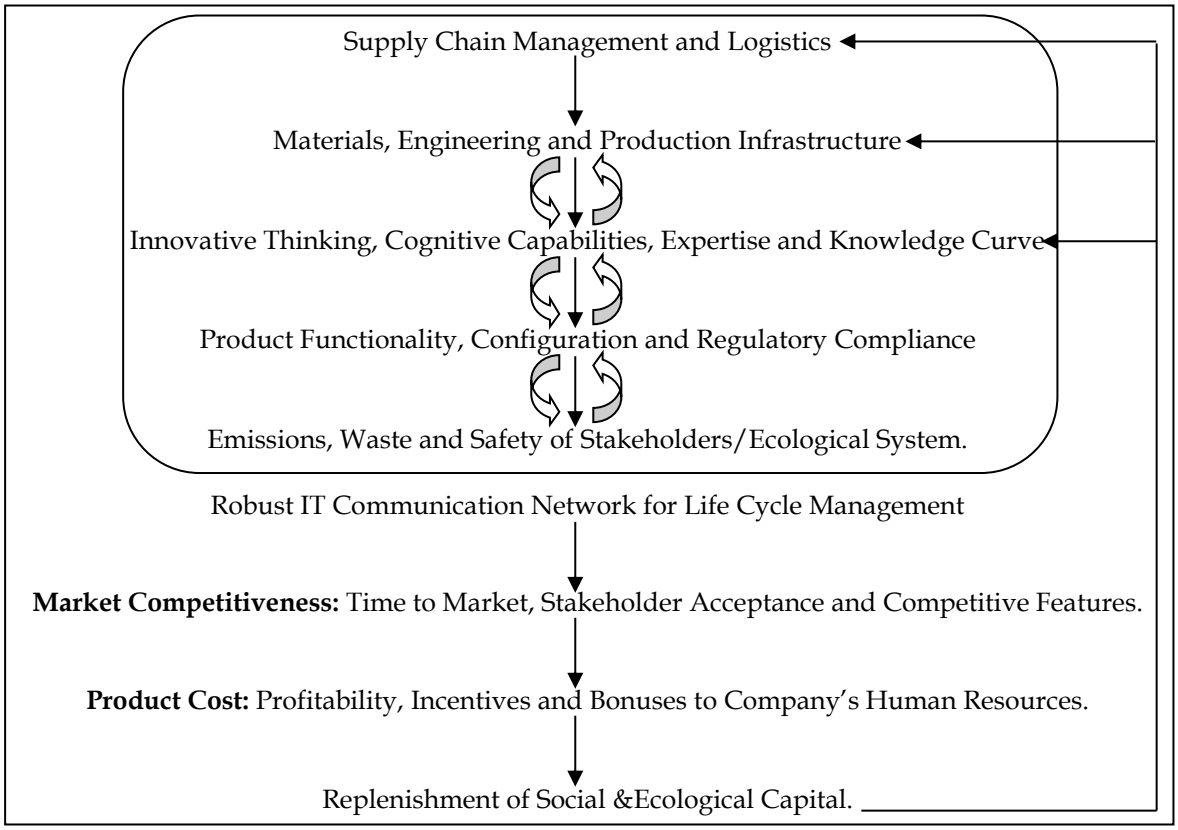


Figure 3.6 – Interrelation between Criteria of the Multicriteria Hierarchical Model

Therefore, the proposed MCHM does outline the co-relation between the criteria that are quintessential for ensuring sustainability in the first Tier in relation to the other two. Accordingly, the criteria in the MCHM are re-arranged to exemplify the inter-relations between them as shown in Figure 3.6. Moreover, through the inter-relations, the repercussions (or impacts) of any uncertainty or other unintended consequences can be traced throughout the Organizations' activities and its value chain.

The Figure 3.6 is able to illustrate the possible changes in the magnitude of risk from one criterion to another and provide a relatively in-depth insight to the user of the MCHM. Furthermore, in order to benefit from the proposed MCHM criteria inter-relations, the company is responsible to ascertain the sensitivity of the co-relation to compute the impact of any modification of one criterion on the rest. The company in order to do so can incorporate a well-known Systems Engineering based technique known as the Design Structure Matrix that explicitly outlines the 'extent' of interdependencies between various system elements (parts; components; sub-assemblies) of a product and various other business processes pertaining to product development <http://www.dsmweb.org>.

The product development teams can accordingly devise suitable product designs which are adaptable; product development approaches and commercialization strategies which are most suited for addressing the interdependency of the outlined criteria in Figure 3.2 and Figure 3.6. Moreover, the rectifications required towards the later stages would be comparatively less expensive and less probable (Malhotra et al., 1996, Trotta, 2010).

The extent of risk is closely dependent upon the project complexity encountered during product development and the effectiveness of the expertise possessed by the product development teams under the aegis of the senior management of the company. The importance of the interdependences and interrelations will be discussed in the design optimization section in the subsequent chapter of this thesis.

The criterion of Competitiveness basically encompasses the company's ability to deliver highly cost effective products within the suitable time frame into the market, which would further satisfy the end-user and patient requirements. Competitiveness also accommodates the company's ability to be flexible and leverage negotiations with its value chain partners in order to significantly reduce the product development cycle time. The aptitude to be competitive is by virtue of a strong and disciplined project management and operations strategy which can continuously identify, capture and leverage their knowledge resources of the company (and its collaborators) so as to devise the most suited products/services for their desired market. In order to do so, the company needs to closely study the trends of its target markets and build an inference so as to mobilize all of its resources as outlined in Section 3.3 of this Chapter. The criterion of Competitiveness is closely related to every other criterion of the proposed MCHM. To summarize in one sentence, the model demonstrates a strong alignment between the Upper Management; Product Development Teams and the Technological Infrastructure of the medical device company.

The success of a product development endeavour elicits a higher degree of assurance in terms of product quality, optimal resource consumption and reduced development cycle time by implementing a sound and redundant project management methodology. The project management approach with suitable templates should clearly define the list of deliverables in accordance with the stakeholders' requirements (Jerrad et al., 2008; Wiegers; Davis, 2002; Sutcliffe et al., 2009). Moreover, the strategic goals and business processes have to be aligned without stifling innovation by incorporating a certain degree of flexibility within the Organization. During the execution of the deliverables, the product development teams have to conduct their due diligence for each deliverable and for their co-relation with other deliverables in order to establish a proactive risk management approach. Moreover, sourcing the appropriate human resources in terms of skills and knowledge as well as providing access to effective training programs for improving useful tacit and explicit knowledge is also considered as a key driver for success.

The company must possess the relevant expertise and infrastructure to leverage "Knowledge" as a vital driver for innovation and development. Robust communication coupled with strong leadership and answerability is instrumental to coherently articulate the project activities. Meanwhile, the project management should encompass the marketing strategy as a part of its executive agenda to obtain feedback from stakeholders and value chain partners at every critical stage for a "go/no-go" decision as outlined in section 3.5.2 of Project Selection via MCHM.

The stakeholder involvement aids the development teams to identify areas of improvements and/or rectification early on and deploy operations for ensuring adherence to the desired objectives at an early stage (Trotta, 2010; Sutcliffe et al., 2009). Thus, avoiding expensive end moment modifications; nevertheless, the company's expertise and process flexibility should permit later stage modifications without undergoing detrimental economic consequences. For Example: A modification in product specification, just one month before launch could be resolved inexpensively, if the company has tools and expertise to establish a strong co-relation between their design and production facilities with a high product-production process flexibility to incorporate any anticipated alterations which were accounted during the product conceptualization phase (Yang et al., 2006).

Finally, the company should always bear in mind its economic objectives would be satisfied in terms of its access to credit lines and frequency of cash flows only through successful product development endeavours reinforced by stakeholder's satisfaction (Malhotra et al., 1996).

For implementing any of the End-Of-Life options it is imperative to determine the threshold limit of the Reliability of the Product and each of its elements (Anityasari and Kaebernick, 2008). Anityasari and Kaebernick (2008) devised such a methodology to aiding manufacturers to minimize the risk of disassembling products that may possess minimal or no reusability. Moreover, their approach could assist engineers in identifying the most appropriate take-back time of the

product in addition to selecting the most suitable end-of-life option for products with less known reliability. The authors recommend manufacturers to select a suitable reliability threshold limit during product design phase, which is compatible with the Tier 1 criteria, and also ascertain a suitable degree of trade-offs between the warranty cost and remanufacturing cost. Furthermore, the products recovered for the end-of-life option (which may or may not possess a lower degree of reliability) can also be considered for secondary markets as proposed by Gallo et al. (2010). For Example: A computer robustly designed with extended durability for military use, can be remanufactured and sold to the low durability computer market. The PUSH (namely technology) and PULL (market) dynamics have to be balanced with the supply-chain of the products submitted for an end-of-life option.

Meanwhile, during the product development endeavour the development teams will require an adjuvant analysis methodology to support the proposed MCHM for addressing synergies and trade-offs that would be less exhaustive compared to Systems Thinking Approach. One such analysis method is the Markov Decision Process and Sloan (2006) devised a decision making model based on the Markov Decision Process to assess the trade-offs and engage in a fruitful debate between the environmental, legal end-of-life options, safety, reliability, failure penalty, device cost and financial viability. The methodology enables the decision maker to conduct rough-cut analysis and confirm his/her intuition to ascertain the indifference point between an end-of-life device and a new device. For Example: Class I items such as Syringes (High Risk) that are less capable of being re-sterilized and Class I items such as Saw Blades that can be reprocessed. The methodology would assist the device manufacturer to propose a suitable price and contribute to the savings of the medical practitioner with respect to the reimbursement policy.

With reference to the criterion of reducing overall emissions and waste throughout product life cycle of a product designed for a single (No end-of-life) or multiple life cycles (with end-of-life) is evaluated by conducting a thorough life

cycle energy analysis. Boustani et al. (2010) conducted life cycle energy analysis pertaining to the utilization phase and end-of-life options for common residential appliances, namely refrigerators, dishwashers, and washing machines. Consequently, Boustani et al. (2010) deduced that the remanufacturing end-of-life option as theoretically identified earlier by King et al. (2006) by using the principles of Thermodynamics is in fact a net-energy expending end-of-life option. Furthermore, Boustani et al. (2010) recommend that global organizations (E.g.: UNO) and Policy Makers of developed as well as developing nations provide incentives to OEM for incorporating end-of-life options so as to be cost effective for the customer and other stakeholders (including the value chain partners).

These constraints for developing an interdisciplinary product with its adjuvant services need to be addressed in order to provide a desired combination of features to a variety of target market segments. Consequently, the parameters such as cost; quality; reliability; environmental impact; end-of-life can be simultaneously improved and optimized until the Pareto Optimal Frontier is reached. The aforementioned frontier is a limit wherein an improvement in one parameter worsens the other and consequently, beyond this frontier trade-offs have to be initiated (Zhao et al., 2010). To resolve such challenges Zhao et al. (2010) have used a genetic algorithm in conjugation with a multi-attribute utility model for a case study in personal computers to determine the Pareto Optimal Frontier with respect to price; environmental impact; choice of an end-of-life option; number of life cycles; take-back time and reliability to meet the dynamically changing needs of divergent markets. Furthermore, once the Pareto optimal frontier is ascertained with reference to certain criteria pertinent to the medical device and the company's objectives and regulatory obligations, the frontier can also act as a starting point of innovation in the sources of limitations outlined in Section 3.3 of this Chapter.

3.6. Concluding Points

The decision modelling approach towards the incorporation of overall sustainability within the early phases of product development is crucial to

minimize expensive modifications in the downstream segment of product commercialization. Moreover, such an exhaustive modelling approach requires being in a coordinated framework to connect with Business Process Operations and Design Engineering activities. As a result, a medical device company always desires a simplistic and a comprehensive decision model.

The medical device companies are advised to venture beyond the bare minimal sustainability basic stakeholder safety and ecological compliance to encompass additional degrees of stakeholder welfare and substantial decrease in emissions/waste. In certain cases, companies who have invested in their stakeholders' welfare and the environment by virtue of renewable energy projects and conservation of natural resources such as water have substantially contributed to the income distribution of the region, which is known to further improve the economic growth.

The approach of delivering the utility (the desired effect) of a medical device, in contrast for the actual physical good. This strategy of Product-Service System (based on Systems Engineering) would have to accommodate a more modular structure for easier assembly, disassembly and even End-of-life options. As a result, not all types of medical devices that range from heart valve to wheelchairs can be considered for the PSS method. Even though savings is cost and energy/materials could occur by the PSS and end-of-life options, they may also occur their own opportunity costs and fewer acceptances by the market/stakeholders. Furthermore, the medical device company should bear in mind the basic limitations it would encounter in terms of time, skills/knowledge of human resources, engineering tools, material properties, finance and regulation. These limitations may also pose an impediment for a medical device company to re-organize its value chain partners (suppliers, distributors and manufacturers) to counter uncertainties and mitigate undesired risks.

This chapter illustrates the role and importance of an Enterprise subscribing to a simplified multicriteria decision modelling approach, namely MCHM that is an extensive revision of the Analytical Hierarchical Process. It is imperative for the

decision model to be an integral segment of the Business Process Management and Engineering Process Frameworks in an Enterprise. The review of previous investigations in the domain of Decision Modelling and Sustainability, including the other multicriteria methods have been discussed with respect to their limitations, especially in their ability to address complicated scenarios that entail multiple stakeholders and a diverse set of criteria for overall sustainability. Thus, justifying the motivation to substantially redefine the Analytical Hierarchy Process, without eliminating the core concept of hierarchical arrangement. As a result, the proposed MCHM can be used to eliminate certain criteria that are irreconcilable with the most crucial criteria for a medical device to provide bare minimum sustainability to the company and its stakeholders.

The interconnected nature of the criteria in the MCHM would enable the product development teams to define the sensitivity values of one criterion over the other and in cases of undesired circumstances would be able to trace to the source. As a result, enabling sound risk evaluation and planning of mitigation measures throughout the life cycle of the product.

In the subsequent chapters, the role of MCHM in medical device development would be discussed in detail. This would be materialized by virtue of being included in a Multifaceted Framework that consists of a wide spectrum of technical tools and conceptual approaches for product design and development.

Chapter 4

Product Development Approaches in conjugation with Decision Modelling for Medical Devices Design

4.1. Introduction

This chapter contains a detailed discussion on a wide spectrum of product development approaches that are utilized by the industry. These product development approaches encompass various types of product life cycle management in order to attain sustainability. Moreover, these conceptual models are required to be integrated with technical tools for design, engineering and production in a seamless manner for streamlining both product development and commercialization. Therefore, this chapter explores the opportunities for incorporating the Multicriteria Hierarchical Model (MCHM) during the design phase of the product under development so as to enable the decision makers to select/reject suitable product configurations.

Section 4.2 would discuss in detail about the contemporary product development approaches with their shortcomings, followed by a review of the computational tools that play a crucial role in materializing the product development deliverables into a robust product and the recommended approach to incorporate sustainability within product design. Meanwhile, Section 4.3 provides a detailed discussion of the proposed Multifaceted Framework and the role of the MCHM onwards Design Optimization. Furthermore, the method to evaluate the framework would be discussed in Chapter 5 and the outcomes of the evaluation are discussed in Chapter 6.

4.2. Sustainable New Product Development

4.2.1. Review of New Product Development Methodologies

The significant feature of any Product Development Model is to outline the role of various drivers, factors, players, tools and methodologies and their corresponding interdependencies throughout the product life cycle (Suomala, 2003). The objective of these product development models is to enable the product development teams to gain a reasonable insight into the critical interwoven intricacies of their organizations' alignment with its sub-divisions, strategic business units (internal/external) and value chain partners.

Product Development Models act as the initiation step for a thorough readiness assessment of the Organizations' resources for launching a robust product/service in coordination with other comprehensive decision models. The goal is to ensure that the appropriation of the resources is executed in the most effective manner to ensure the best interests of both the shareholders and stakeholders. As the models represent a layout of the most essential resources (technical, non-technical and human), especially the product development tools. Therefore, it is important for the company to harmonize the developmental activities of its products and services that entail a substantial degree of interdisciplinary engineering, as correspondingly each discipline possesses its own synergistic and conflicting idiosyncrasies.

The role of Product Innovation is quintessential for the upholding an Organization's competitive edge in its desired markets and also acts as the modality to address the needs and welfare of its stakeholders. A products' performance is complemented by the service it provides in synchronicity with a wide spectrum of services that actively support the product throughout the life cycle (e.g., the maintenance, billing & payments and take-back). Therefore, Kindström & Kowalkowski (2009) recommended a strong harmonization between product development and its complementary services.

The project deliverables vary from stage to stage of the product development process (Krishnan & Ulrich, 2001). For example, the variation could be in the functional reliability in the feasibility phase of the product development process and the entire product life cycle. This can be further explained by co-relating the functional reliability with the importance of the raw material yield during the extraction phase as well as variation in product quality during the production phase. Mallick and Schroeder (2005) proposed an integrated conceptual framework to elucidate the complex relationships between the diverse set of metrics considered during product design (Finger & Dixon 1989a and 1989b), production (Krishnan & Ulrich 2001) and marketing activities (Griffin & Hauser 1996) and their overall influence on successful interdisciplinary Product Development (Tatikonda & Montoya-Weiss 2001).

Once the Medical Device Company acknowledges the acute inter-relations between the product development criteria and metrics, then it is incumbent upon the company to devise a long-term sustainable business strategy. Vickers and Boyle (2008) advocated the application of scenario network mapping to chart out the present and future trends of the desired markets. The scenario network mapping is envisioned to assist companies to devise roadmaps for a business horizon that comprises of decades, instead of years. The goal is to minimize unpredictability associated with new to the world and radical innovations that are further founded on the advancements of interdisciplinary research.

It is important for the product development teams to address the dynamics of the on-going business trends (e.g.: regulatory modifications and customer preferences). As a result, the product design would undergo numerous re-designs that would range from incremental to major modifications. This would compel the development teams to incorporate a substantial degree of operational and design flexibility in order to address the prospective dynamics and unexpected outcome of events throughout the product life cycle. For instance, the design should be robust enough to sustain its structural integrity despite unexpected fluctuation in raw material supply.

Since the growth of the Industrial Age, the world has experienced an exponential increase in resource consumption, especially non-renewable which is much larger than the rate of replacement by renewable resources within the regenerative capacities of the ecological dynamics (Daly & Cobb, 1989; Goodland, 2002). The impacts of a resource intensive economy on the ecosystems and socio-economics engender a series of undesired fluctuations in its dynamics (Hauschild et al., 2005).

Moreover, the rise is interdisciplinary dimension of modern products and services continue to unearth other limitations in the previously described new product development approaches. As a result, the product development approaches require a substantial evolution for a company to adopt in order stay competitive. McCarthy et al. (2006) published a report with multiple case study inferences to reinforce their perspective on New Product Development, as a process that is governed by the fundamental underpinnings of Complex Adaptive Systems. In their study, they propose that the diverse product development processes are composed of systems whose elements (known as agents) are interconnected to a certain extent and also function as independent decision-making points. Moreover, the rules, interactions, overlaps, feedback loops and outcomes of these agents result in non-linearity of the product development endeavour. These paradigms are not explicitly identifiable within the contemporary linear product development models. In addition, these quintessential axioms of complex adaptive system that comprises of adaptability, flexibility, informality, feedback and autonomy are known to promote innovation; thus contributing to the company's future (Clark & Fujimoto, 1991; Dougherty, 1992; Griffin, 1997).

Concurrently, Alexandre et al. (2003) devised a hierarchical framework that co-relates product development approaches and its corresponding technological and scientific origins, respectively. Moreover, the role of society with the stakeholder institutions and corresponding ecosystems play a strategic role in the success of the product development endeavour by materializing these scientific discoveries and technologies. The framework highlights the role of explicit and latent needs of the stakeholders while engaging cross-functional developmental activities for designing products and their respective variants. The lower tier of their

hierarchical model entails the knowledge domain, followed by the 2nd Tier of functionality and efficiency. The 3rd tier is comprised of technology capability to devise building blocks for designing a product or a service. For example, a cardiac pacemaker requires a small sized power supply, miniaturized electronic circuits and biocompatible electrodes. Therefore, technologies pertinent to these sub-systems have to be robust in nature with a higher degree of functional reliability. Similarly, these sub-systems should be fortified by the mandatory industrial quality assurance standards such as ISO, IEC, FDA, and others. The final uppermost tier comprises of a spectrum of products and services requirements that satisfy the stakeholder requirements, in addition to the concerned customers and end-users. The study developed by Alexandre et al. (2003) ultimately concludes that factors and behaviours that lead to any form of disobedience of the hierarchical model would eventually lead to a risk of high failure. Meanwhile, continuous improvement of the model would enable the medical device company to strategically allocate its limited resources to reap successful products and services. To clarify further, the hierarchical structure of the MCHM as discussed in Chapter 3 is quite unique compared to the hierarchal structure of product development proposed by those authors.

Every product development endeavour is fundamentally based upon the utilization and accessibility of resources namely in the domains of expertise, human labour, tools and techniques, monetary and materials (including energy resources) (outlined in Section 3.3 of Chapter 3). A self-sufficient organization or organizations in joint ventures can carry out the utilization and accessibility with each other forming an extended enterprise (Dyer, 2000; Jagdev & Browne, 1998). Accordingly, Barragan et al. (2003) have devised a four step decision making process for implementing informed decisions pertaining to sourcing their resources in a business environment wherein product life cycles are demanded to be short and product complexity is desired to be higher than its preceding generations to address the dynamically changing needs of a globalized market. This further compels organizations to engage in developmental and sourcing partnerships with institutions across the world so as to guard existing markets

and aggressively enter new markets. Barragan et al. (2003) recommend the product development teams to closely associate the financial metrics and the factors governing stable and long term competitiveness, not to mention the overall sustainability. Therefore, it is important for the product development teams, in coordination with other functional areas of the company, including procurement, human resources, engineering and production be simultaneously engaged in the finalization of sourcing strategies. The sourcing approach is recommended in the form of three edges of an equilateral triangle, namely, product architecture knowledge, business process management and supply chain coordination. The collaborations could range from short-term contracts, call options, long-term contracts, joint developments, partial or complete ownership. The increasing degree of complexity in today's products and services compels medical device companies to source product development expertise in entirely new areas of knowledge in accordance with enhanced access to all forms of resources in order to accelerate the time to market. Moreover, companies are recommended to engage in a slow transformation from their operational approach to a more strategic approach towards product development.

During the transformation towards a strategic approach for sourcing, the company would be in a position to attain its sustainability objectives by persuading its value chain partners (or supply chain partners) to closely consider their stakeholders simultaneously during the planning and implementation phases of their business practices. The company should acknowledge the regulations for promoting ecological considerations (e.g.: ROHS; REACH; WEEE) and communicate them accordingly so as to establish itself as a member of a larger social-ecological-industrial system. The "best practices" of supply chain activities have to be reconfigured concerning the depletion of natural resources and the ecological impact of globalized industrial activities. Accordingly, Pagell et al. (2005) these "best practices" could be Mass Customization, Large Scale Outsourcing, and Modular Product Design for incorporating End-Of-Life options, Dispersed Global Manufacturing and Sourcing, Collaborative Partners for Design and Development. The reconfiguration would entail learning, implementing

previously acquired knowledge and adaption of business processes (Hart, 2005; Purser, 1995; Shrivastava, 1994a, 1995b).

It is highly recommended for companies to collaborate with research institutions (private/public) or other companies to pursue innovation in new sustainable technologies and renewable sources of energy/materials (Massachusetts Institute of Technology, 2013 <http://web.mit.edu/newsoffice/2013/mit-eni-renew-energy-partnership-0213.html>)

Despite the availability of various renowned product development tools that are theoretical (e.g.: Stage Gate, QFD), mathematical (e.g.: Complex Theory) and technological (e.g.: Toyota Manufacturing Method). Some of the commonly encountered problems in product development are enumerated as follows:

- Marketing failure up to 90% and above
- Budget and timeline failures up to 70% and above.
- The above two coupled with several re-plans and reorientation of resources.

Although, the product development teams are aware of the pre-existing tools and techniques namely Stage-Gate, Design for Six Sigma, Toyota Product Development Systems, Open Innovation and Outcome based Development, they need to ask themselves the fundamental questions about the applicability of these tools and techniques pertaining to their specific scenarios to prevent further loss in performance. In order to benefit from any of the existing or newly introduced tools for product development, the medical device company should understand its shortcomings originating from its own expertise and ability to organize and utilize its resources effectively. Furthermore, the medical device company should incorporate better guidance coupled with a well-defined focus towards a certain target market and the ability to incorporate desired level of flexibility pertaining to scope of the product development activities and the scale of commercialization (Malhotra et al., 1996). These endeavours should be supported by a robust and efficient risk contingency plan in conjugation with the willingness to learn at a

faster rate than their industrial contemporaries. For example, a product development team dedicated to developing a new pacemaker should possess substantial willingness and expertise to incorporate additional features that deliver a higher degree of cost effectiveness to its end-users. In addition, during the design phase the team needs to account for a production method that can scale up significantly in a short period of time to address growing market needs. The product development teams which account for the most precious resource for a medical device company require their adequate supply of 'organizational fuel' comprising of team development; motivation; communication; training and conducive culture to promote innovation. Mr. Parendo Perry of Perry's Solutions (2011) stated that critical thinking and rational approach towards product development demands an in-depth understanding of the conceptual frameworks in order to elucidate the co-relations and interdependencies between the diverse vital facets of an organization and its product development infrastructure. This approach would ultimately result in shortening the timelines as opposed to directly engaging tools and techniques for obtaining a myopic and short-term problem solving options <http://www.perryssolutions.com/index.php>.

Human and knowledge resources are the vital drivers for innovation in a medical device company. Moreover, social cognition acts as a vital methodology for comprehending human social behaviour in order to investigate the mental processes that occur during interaction between people and systems. Accordingly, Akgu et al. (2006) investigated the role of socio-cognitive theory of learning within product development teams and their organizations that influence the success of new product development endeavours. Moreover, Akgu et al. (2006) devised an iterative process model for assessing the team learning phenomenon that includes the core components of social cognition namely, information acquisition, information dissemination, information implementation, unlearning, thinking, intelligence, improvisation, sense-making and memory. The investigation concluded that team intelligence resulted in a positive impact on the team information processing which further stimulates a rise in product development performance.

The life cycle perspective illustrates the co-relation of various facets of product development. In order to address sustainability oriented business practices, the product development endeavour does require interactions between the various life cycles (Labuschagne & Brent, 2005), namely project life cycle, product life cycle, asset life cycle and process life cycle. For example, during the product development stages in which the prototypes are being evaluated using a certain manufacturing technology or machine. The same technology/machine could be also applicable for the industrial scale production process. This situation demonstrates the interdependency and interaction between production life cycle and project life cycle (e.g.: product design) with the asset life cycle (e.g.: machining tools) in terms of optimum conditions or declining conditions of the asset. Likewise, would be in the case of production process life cycle that varies from prototype to final commercial product.

Sustainability oriented product development and commercialization, from a life cycle standpoint, starts with Life Cycle Design and Engineering (Herrmann et al., 2007), follow by Product Life Cycle Management and finally Product End-Of-Life Management (Ohlendorf, 2006). These three Life Cycle approaches require robust communication and consistent coordination of engineering and business processes. Herrmann et al. (2007) have devised the Braunschweig Framework of Life Cycle Management that is inspired from the ideas of the Viable System Model and the "concept of integrated management". The framework proposes a systemic and life cycle oriented framework to deliver a comprehensive perspective on products and their corresponding processes.

The Viable System Model entails normative (regulatory and legal requirements), strategic and operational management. The normative and strategic management are the basis for governing the constraints for the operational management. Engineering and management activities, in every phase of the product life cycle, lead to the commercialization of the product. This is accomplished by the support of structures that are governed by the behaviour and expertise of the senior management and its associated personnel (Akgu et al., 2006). There are diverse set of interactions between the normative, strategic and operational management

dimensions in coordination with the life cycle phases of products, processes and assets. Moreover, the spatial (size and intensity of tasks), organizational and temporal (time) separation of the personnel associated in the product development endeavour poses a significant challenge for the streamlined execution of the life cycle phases.

Synergies have to be ascertained and exploited, while conflicts have to be resolved and optimized during the integration of diverse life cycle perspectives of each system element and paradigm (e.g.: people and processes) of the medical device company. For example, the primary product of an automobile manufacturer is a car that is designed and produced by the manufacturer within its production life cycle, after the development cycle has been successful. The manufacturer also uses a secondary product namely a machine tooling unit for the production of the primary product that is present within its own usage life cycle. The production life cycle of the car [product] and the usage life cycle of the machine-tooling unit [asset] are further dependent on the life cycle of the production process, which also has a beginning and end [process]. Therefore, the three intersect and exhibit the functional and organizational interdependencies. The changes in the regulatory framework would demand rectifications in all the three life cycles. Furthermore, to incorporate those modifications, the usage life cycle of the machine tooling unit and the effectiveness of the process life cycle should be consistent with the new regulations.

4.2.2. The Role of Computational Modelling Tools in Product Development

The innovations in the domain of devising modern interdisciplinary and robust product developmental models have to be complemented with more technical methodologies that embrace scientific principles and mathematical models (Dankwort et al., 2004). The objective of acknowledging the design engineering and modelling facet of product development is to both qualitatively and quantitatively illustrate the potential outcomes for a given developmental approach.

Computational simulation and modelling tools have been extensively utilized in design intensive engineering activities. The interdisciplinary nature of certain medical devices that needs to satisfy stringent regulatory requirements for which certain advanced computational tools and modelling approaches play a crucial role in shortening the developmental cycle. For instance, pertaining to the utilization of Finite Element Analysis (FEA) for design optimization of the leaflet size and geometry of a bio-prosthetic tissue heart valve in order to attain the desired blood flow hemodynamic with long lasting durability (Denton & Ford, 2009). The bio-prosthetic tissue valve was identified to be more biocompatible with improved hemodynamic activity and low incidences of thrombosis. Nevertheless, this valve was not as durable as mechanical valves. Therefore, an optimal design structure was required for minimizing the limitations without compromising the benefits. The FEA involved subjecting the design of the bio-prosthetic tissue heart valve to various forms of loads in order to simulate the product performance in its actual environment of operation. The FEA entails a complex methodology of points and grids called nodes and meshes, respectively. Each mesh contains material and structural properties that are further programmed to illustrate the reactions when subjected to certain loading stress conditions. The concentration, arrangement and multitude of nodes are distributed in the design according to the anticipated stress levels of that region. For instance, the regions of the design expected to encounter significant stress would be densely populated with nodes as opposed to the regions with lower levels of stress. The FEA in the case of the bio-prosthetic tissue heart valve was equipped to evaluate the leaflet geometry, tissue thickness, leaflet mismatch and consequences of non-concentric valve deployment and fluid structure interaction analysis to elucidate the long-term results as a result of fluid flows. The FEA simulations enables the designers to gain an in-depth in-sight into the crucial failure modes and durability of the proposed design recommendations by evaluating varying magnitudes of the in-plane and compressive leaflet stresses, conduit stresses, deformation under loading and magnitude of suture forces. As a result, FEA was also considered for determining improvised design

recommendations. The valve was designed in ProE 2.0 and the finite-element models were generated using HyperMesh, (Altair HyperWorks <www.altairhyperworks.com>) in combination with the Abaqus standard version 6.5-3 as a general-purpose nonlinear solver. The run times were approximately 1.4 hours on a 64-bit Linux 2-node cluster.

To exemplify further from a pragmatic standpoint as the Product Development Teams rely on sophisticated computational tools including Finite Element Analysis and Computational Fluid Dynamics, which can extensively impact the flow and timing of the development activities, in addition to the no. of re-designs required to clear the validation phase. Accordingly, Isaksson et al. (2000) have devised a mathematical approach using Signal Flow Graphs in order to compare alternative computational simulation strategies with respect to the impact on the project lead time, activity cost and project success probability. As knowledge of utilizing computational tools is insufficient without incorporating a modelling and simulation strategy that further could be sourced from the company's knowledge infrastructure, project team involvement and third party consulting services. The computational simulation activity provides a more realistic insight concerning the definitive capabilities of the organization as a whole and identifies the occurrence of threatening weak links in the developmental process. Consequently, a medical device company should not only know on "how" to conduct computational modelling but also "how best to conduct computational modelling".

In addition, to mathematical techniques such as Signal Flow Graphs there are other known approaches such as Data Envelopment Analysis (DEA) which is a linear programming methodology to measure the efficiency of multiple decision-making units (DMUs) in an organization that entails a multitude of processes with their own characteristic inputs and outputs (Chiang et al., 2008). Similar to the Signal Flow Graphs, this mathematical approach leaves as much as less room for dependency on the experience and intuition of the product development teams, which is unfortunately prone to subjectivity and errors in terms of schedule overruns and wastage of resources (Issakson et al., 2000).

Another step further would be in the case of Bayesian network that is a probabilistic graphical modelling approach that represents a set of variables and their probabilistic dependencies between various facets of the Product Development Process. For example, effectiveness of computational modelling tools and project lead times (Jensen, 1997). This approach is able to represent complex relationship amongst various elements and is able to emulate human reasoning (Ren et al., 2007).

From a Systems Engineering viewpoint of devising co-relation between various system elements to develop Products and Services, Andersson et al. (1998) have stated that 'A problem in systems engineering is a deviation between the arbitrarily little known system of objectives and a chosen arbitrarily vague object system, linked with the partially unknown operating system from objectives to object.' Likewise, Albers et al. (2005) have proposed a unique problems solving approach within the domain of Systems Engineering, which is titled as SPALTEN -methodology (i.e. to split, decompose) of problem solving in Product Development. The SPALTEN -methodology attempts to evaluate the problem with respect to the problem type, the boundary conditions, situation, time, person, information and complexity. The evaluation based on the SPALTEN -methodology is carried out in accordance with the scope of objectives and the impacts of various activities on the stakeholders and ecosystem. Moreover, the SPALTEN -methodology considers the actual state (final system to be defined) with the target state (object system to be achieved) and the operating systems (pathways involving labour, materials and actions to transform actual state to target state).

The systems elements are required for being modelled in order to simulate the performance of the product design candidate devised by the development teams. Nevertheless, unlike the computational simulation conducted in Finite Element and Fluid Dynamics that is far more exhaustive in nature, the product architecture simulation delivers insight on the coherent functionality of the pertinent system elements, which eventually builds into a complete System. During the conceptual design stage, the geometric, parametric and procedural information are not easily

available. Therefore, Wyatt et al. (2009) identified only those modelling languages with the ability to provide a schematic component layout to illustrate the parameters that embody Product Life Cycle (Subrahmanian et al., 2006). Moreover, Wyatt et al. (2009) evaluated the capability of various product architecture-modelling languages (e.g.: Bill of Materials, SimuLink and MOKA) to address various life cycle objectives that include environmental compliance, logistics and assembly. For example, to address the life cycle objective of "Assembly", the chosen metric was Boothroyd-Dewhurst Design for Assembly (Boothroyd-Dewhurst Inc. <http://www.dfma.com/>) and the data items of the metric were the "parts geometry" and "parts weight". Therefore, the ability of SimuLink, MOKA and Bill of Materials to provide the necessary information on the product's "part geometry" and "weight" was evaluated and compared. Wyatt et al. (2009) concluded that the MOKA Modelling Language was much more comprehensive than its predecessors that could accurately incorporate up to 30% of the Life Cycle Objectives (MML Group for MOKA, 2002).

4.2.3. Methodologies to incorporate Sustainability within Product Development Process

The success of the product development endeavour is a result of a substantial degree of coherence between the diverse set of methodologies and tools.

Throughout the success of all the interdisciplinary engineering industries exemplifies the decisive role of 'lean approach' towards Sustainable Product Development. The well-renowned and proven effectiveness of the lean approach enables the top management to institutionalize 'lean' throughout the company. The commitment of a medical device company to opt for Lean Product Development approach would accomplish the Total Quality Management objectives to minimize waste and optimize consumption of resources. Thus, promoting overall Sustainability by gaining significant savings in financial and non-financial resources (Aras Corp. <www.aras.com>). The lean approach is required to be all-pervasive throughout every stage, value chain activity and development process. Moreover, the development teams have to commit to

unlearning old practices for applying new ones in order to initiate a bottom-up incorporation of lean product development strategy. As a result, the Lean approach is known to be a simple, non-intrusive and straightforward process that aligns itself with the on-going product development activities (e.g.: Designing) and product development processes (e.g.: Product Quality Planning).

The organization can combine other tools and approaches to complement the lean product development approach, namely, New Product Value Analysis, Team Dynamics, Value Engineering, Design for Six Sigma [DFSS], Design for Manufacturability/Design for Assembly [DFM/DFA] and Root Cause &Fault Analysis (source). The goal is to ensure smooth transition from one development stage to another by virtue of effective articulation of the business processes and their corresponding activities.

With the goal of reconciling Lean Product Development and Sustainability, medical device companies can adopt the seven eco-principles enumerated by the World Business Council for Sustainable Development (WBCSD). These principles advocate reduced consumption of material and energy for commercializing products and services; minimize disposal and utilization of toxic waste; increase the incorporation of renewable resources (materials/energy) and opt for end-of-life opportunities in product design (DeSimone & Popoff, 1997; Trotta, 2010).

The feasibility evaluation during design related activities are able to unearth the relevant conflicts, synergies and contradictions. Consequently, as discussed in previous chapters, the renowned Theory of Inventive Problem Solving (TRIZ) elucidates 39 sources of contradictions. For example, when a company decides to increase the number of functions in a device results in multiple components. Thus, adding to the weight, while sustainable product development recommends lower weight of the product to save resources during production/transportation (Fitzgerald et al., 2010; Trotta, 2010). Such challenges are usually encountered during Product Development that is resolved by incorporating the pre-defined 40 inventive principles identified and proposed by the inventors of the TRIZ methodology. Product development teams are advised to tailor the 40 inventive

principles subjectively for each project in order to resolve sustainability related conflicts for enhancing the sustainability quotient of their products and services. Moreover, Trotta (2010) identified a suitable combination of the pertinent WBCSD principles for each of the 39 contradictions that would be encountered during any Sustainable Product Development endeavour. Similarly, product development teams can scout for various patents and research publications to determine suitable solutions in the domain of product design, materials and engineering methodologies for substantially modifying the knowledge and implementing them in their design process, accordingly. This approach is commonly known as Design-by-Analogy as compared to Case Based Reasoning that utilizes previously acquired experience (Fitzgerald et al., 2010; Ghazalli & Atsuo, 2009).

The product development teams require a robust infrastructure of software and hardware tools in combination with an information communication system for materializing the design strategies and objectives by virtue of concurrent engineering. Consequently, Manufacturing Process Management (MPM) is a methodology that enables effective communication between the stakeholders and value chain partners, namely product designers, engineers, contract manufacturers and suppliers. The MPM embodies the concept of concurrent engineering and allows an organization to document the product development (Computer Aided Design [CAD]; Computer Aided Engineering [CAE]; Product Data Management [PDM]) and manufacturing process (Computer Aided Manufacturing [CAM]; Manufacturing Resource Planning [MRP]), for regulatory requirements and the implementation of a lean product development approach. Furthermore, MPM allows the product development organization to automate the various design and process modifications changes in collaboration with Product Life Cycle Management and Knowledge Management approaches for adapting to a dynamically changing scenario which is characteristic of any modern product development endeavour (Fortin & Huet, 2007).

The computational tools that are utilized to design the structure and geometry (CAD), evaluate from a virtual standpoint (CAE) and plan the production assemblies (CAM) are vital for product development, in order to proactively

address prospective challenges and inefficacies within the product design that may lead to any negative repercussions for the company and its stakeholders (Werner et al., 2004; Schweiger, 2006).

The integrated utilization of CAE-CAD is known to deliver more savings in both time and financial resources by accomplishing a more robust product prototype. A thorough assessment of the integration reveals that 70% of the life cycle cost can be identified by only 20% of the product knowledge and reducing the time needed for capturing product knowledge with a significant magnitude of user friendliness (Schweiger, 2006).

Once the preliminary concept of a product is subjected to product designing, which generates design files (a virtual product) with data/information and knowledge concerning the volumes and geometries, materials and manufacturing processes. The Life Cycle Analysis carries out the environmental impacts of the design. Furthermore, in order to initiate Life Cycle Engineering activities for improvising the sustainability quotient of the product, it is essential to develop a methodology that combines Life Cycle Assessment Tools with Computational Modelling Tools (3D CAD/CAM) with EcoDesign guidelines. EcoDesign guidelines are basically a collection of best design practices. In addition, EcoDesign contains a database of various ecological questions with its relative answers for improvising the impact of the product undergoing design and analyses. In this approach, the environmental compliance parameters can be merged with the computational design approach. Cappelli et al. (2006) proposed such a novel approach to integrate EcoDesign and Life Cycle Assessment into a Virtual CAD Framework.

Filho et al. (2009) have recommended some EcoDesign methods and tools to aid the product development teams:

a) Environmental Design Industrial Template (EDIT) is a software that addresses the economics and product design for analysing the effects of a product's design for any one of the end-of-life option.

b) Environmental Design Support Tool (EDST) evaluates products design with respect to environmental sustainability, namely material selection, recyclability and disassembly analysis.

c) Green Design Advisor evaluates products based on number of materials, mass, amount of recycled material, toxicity, energy use, disassembly time and end-of-life disassembly cost.

d) Method to Assess the Adaptability of Products (MAAP) evaluates product's conformity at assembly, maintenance, and repair, upgrade and remanufacture processes.

4.2.4. Significance of Knowledge Systems and Management in Product Development

When the designing and manufacturing activities are poised for integration, the product development teams could potentially encounter knowledge gaps pertaining to the diverse technical and engineering sectors, which are characteristic to a certain product design or production method. For example, designing a novel syringe and simultaneously opting for a newly developed plastic injection moulding methodology could pose an impediment to the company in terms of the design engineers lacking thorough knowledge of the injection moulding process capabilities. Furthermore, the modifications in the organizational structure which may have to be implemented for augmenting the competitiveness of the company, in addition to accommodating new technologies.

Therefore, the presence of a robust knowledge management infrastructure comprising of a knowledge repository containing previously stored knowledge that has been captured, stored, subjected to continuous evolution and made accessible throughout the organization, irrespective of the software platforms.

One of the contemporary approaches, namely Expert systems and Knowledge Based Systems, contain previously stored knowledge in the form of IF and THEN statements. Moreover, these Expert Systems have been utilized in numerous engineering applications ranging from identifying and planning inspection schedules for component production to train technical personnel in the domain of

design and evaluation. Similarly, conducting automatic re-meshing of a design mesh structure during finite elements analysis (Cakir, 2006). In simple words, Expert Systems are an artificial intelligence based tool to emulate human-like decision making using previously stored knowledge. Similarly, Dwivedia et al (2003) proposed the development of knowledge based engineering module for diagnosing defects in the casting approach of manufacturing and the evaluation of defects through a non-destructive testing method. In addition, Venkatachalam et al. (1993) proposed a Knowledge Based approach to Design for Manufacturability.

Medical devices, as stated previously, are the culmination of a diverse engineering and scientific disciplines with their own pertinent design and production approaches. As a result, the design and production methods possess their own specific knowledge domains that are further subjected to continuous evolution. Thus, indirectly resulting in knowledge gaps between various disciplines as outlined in the example of a new injection moulding technique and syringe design. A design engineering team well versed with contemporary injection moulding techniques would encounter knowledge gaps, if a new generation injection moulding technique would be incorporated into the production process. In this scenario, the process engineering team would possess an upper hand in the recently updated knowledge domain of injection moulding.

Moreover, these expert systems have been utilized to generate recommendations for both evaluation and improvisation of a given design proposed by the design engineering teams. The recommendations are generated by virtue of the production, design and operations rules stored in the expert system that actively participate in the verification and validation of the proposed design.

Meanwhile, when concurrent design engineering and feasibility evaluation activities are carried out, substantial amount of knowledge is generated during the "hand-off" between the development teams pertaining to the CAD-CAM or CAD-CAE interfaces. This is attributed to their specific files characteristics that are required to undergo a certain degree of transformation to be accessible for the subsequent computational activity. The transformation steps require specialized

knowledge (both tacit and explicit) from the engineers, which is quite challenging to store as well as standardize (Deng et al., 2002; Lee, 2005; Wheelwright & Clark, 1992). Therefore, Knowledge based Engineering (KBE) is incorporated by devising automated/semi-automated software applications for standardizing and automating routine engineering design activities. The goal is ensure that the captured and stored knowledge is re-usable (Chapman & Pinfold, 1999; Kulon et al., 2006). The software applications for KBE tools are devised through the codification of tacit and explicit knowledge using JAVA and C++ (Chapman & Pinfold, 1999; ElMaraghy, 2009). Furthermore, the KBE can be coupled with a geometry engine to enable automatic generation of product concepts in terms of computational models of Computer Aided Design (CAD) for virtual and real prototyping (Kulon et al., 2006). Moreover, KBE is beneficial for larger product development organizations which engage in a multitude of product development activities which are further composed of millions of parts with close tolerances, designed and validated by product development teams distributed globally (Corallo et al., 2009; Lee, 2005; Lee et al., 2005).

The product development teams must scout for other known barriers due to variations encountered in a globalized product development scenario, namely, Data Exchange Standards, Engineering Drawing Symbols, Measurements and Units, Design Software Differences and variations, Operating Systems and Programming Languages (Hu et al., 2006).

4.2.5. Significance of Interoperability between Computational Methodologies

The tools, systems and methodologies utilized during product development should demonstrate a high degree of interoperability (ability to work together) amongst each other. In order to promote enhanced interactivity among various systems and tools engaged in design, development, marketing, production and supply of a medical device. Interoperability provides a significant visibility in cases where seamless interaction between team members throughout the enterprise and the collaborative partners is desired. The utilization of Java as a universal Web programming language and Common Object Request Broker

Architecture (CORBA) as a platform-independent middleware are also essential key components of the collaborative production management (CPM) architecture (Vogel, 2001).

CORBA is devised by Object Management Group's (OMG) open vendor-independent architecture and infrastructure for which computer applications function in synchronicity over a wide array of networks. Moreover, using the standard protocol IIOP, a CORBA-based program from any vendor would be applicable, irrespective of almost any computer, any operating system, any programming language, and any form of network. CORBA is able to integrate various computational and non-computational machines from a diversified range of vendors, which spans across mainframes, desktop computers, real-time systems, and hand held devices and embedded systems. Accordingly, it is the middleware of choice for large sized enterprises and especially for servers that require numerous clients with high hit rates and coupled with higher reliability; scalability and fault-tolerance capabilities of performance (Object Management Group < http://www.omg.org>).

Poor interoperability between various computational design and software based management tools usually result in excessive financial losses (Szykman et al., 2001). While these challenges are being resolved during various product development activities, the evolution of computational tools into its next generation versions are required to provide representations that permit information exchange through direct electronic interchange in a distributed product development environment.

4.2.6. Advantages and Challenges in Customization of Computational Modelling Languages

The computational tools also posses their own share of challenges and disadvantages in addition to the issue of interoperability. Alongside, due to the complexity and the expertise intensive nature of the computational tools, physics and engineering based analysis poses an impediment for the Product Engineers to analyse their product designs. Therefore, the tools have to be customized with

features to permit integration into the product design activities for faster and more accurate analysis. Tikare et al.(2005) referred that although the Computational tool customization allowed product engineers to cost effectively analyse their designs from a engineering and physics standpoint, it was later uncovered that the generality of the models to simulate diverse set of problems was compromised. Moreover, the customization in itself consumed significant monetary and material resources, including man-hours. Thus, the engineering and management should jointly approve the customization approach after thorough assessment in order to justify the expenditure.

The availability of the most compliant computational tools, experienced development teams, most effective materials and reliable technologies do not necessarily assure that the projected product development results would be materialized. The reason being that the limitations of each of these crucial facets could fall into lengthy development cycles.

The limitations of the vital facets of a product and its development path are enumerated in detail as follows:

I] Computational Tools

i) Interoperability between various Computational Tools (Szykman et al., 2001)

ii) Inability to accommodate every life cycle objective (Wyatt et al., 2009).

iii) Complexity, that requires advanced expertise, may require capital-intensive customization for user-friendliness. (Tikare et al. 2005)

iv) Significant manual intervention maybe required in the steps of "Meshing" and "Geometric Processing", as their automation is identified to be extensively complicated. (Shimada, 2011).

II] Characteristics of Materials (Long, 2008)

- Usability in prototyping, production (Batch and Mass) and during Scale-Up.
- Functioning and Compatibility with Other Materials.
- Easy retrieval for Recycling and Remanufacturing.

- Satisfy Multiple Criteria related Performance, Environmental, Safety and Reliability Requirements of Multiple Life Cycles.

III] Production Machinery Considerations (Kumar & Suresh, 2007**)**

- Tolerances
- Complexity of the Machinery Layout
- Reliability: Operational capability, maintenance, up gradation, up time and downtime, efficiency.
- Flexibility levels for various capacities/volumes and product types.
- Ability to accommodate reverse logistics for end-of-life options namely re-use, recycling, reconditioning, remanufacturing.

Only those Organizations who committed to innovate on the frontiers of the aforementioned challenges in concurrence with their stakeholder welfare would lead in comparison to their competition. The subsequent sections would discuss the role of the proposed MCHM of Chapter 3 in Design Optimization during the Product Development Process.

4.3. Multifaceted Framework for Sustainable Medical Device Development

4.3.1. Conceptual Underpinnings of the proposed Multifaceted Framework for incorporating Sustainability in Medical Devices

Medical device companies need to look forward for incorporating modified versions of well-established product development tools to establish a decisive knowledge curve and stay ahead of competitors. These product development tools include but are not limited to Lean Manufacturing, Design for Six Sigma and Current Good Manufacturing Practices and Product-Process Flexibility (Kadamus, 2008). Furthermore, the synchronicity of these conceptual tools with their technical and engineering counterparts, in terms of computational and machinery is of paramount importance for the success of product development endeavour.

The relevant information is compiled into the pre-existing knowledge systems and databases by way of Knowledge based Engineering (KBE) (Corallo et al., 2009). The KBE captures tacit as well as explicit knowledge and provides crucial assistance during the concurrent design and engineering. In this segment the principles of TRIZ, Taguchi, Design by Analogy and Case based reasoning would be implemented to identify the best suitable solution for addressing synergies and trade-offs during the design phase (Xiong & Sun, 2006).

An iterative process of concurrent engineering design and optimization is conceptualized. This iterative process involves manufacturing process management, which co-relates product design with production feasibility. The product design segment within the multifaceted framework comprises of computer aided design and engineering tools. These design-engineering tools are operated using a high performance-computing infrastructure (or supercomputing) to conduct more design iterations within a short span of time. Meanwhile, the concurrent design and engineering segment chiefly entails the role of an Expert System conjugated with the MCHM for selecting suitable design candidates of the product during the design optimization process. The design candidates would be selected on the basis of the adherence of the design with reference to Tier 1 and the desired level of compliance with the chosen criteria in Tier 2 and Tier 3.

The Expert System in conjugation with the MCHM plays a pivotal role in optimizing the product design with reference to a wide spectrum of constraints (e.g.: lower emissions) and objectives (e.g.: higher reliability for multiple life cycles) during the Multidisciplinary Optimization procedure. In each of iteration, the resultant design is evaluated on the basis of its 'Value' (SAVE International <*www.value-eng.org*>). The 'Value" is defined by the design candidate's profitability, emissions/waste generated, resources consumed, knowledge generated and customer satisfaction in accordance with regulatory compliance. Moreover, the value is also determined by the contribution towards the Tier 2 and Tier 3 criteria as well (Hede et al., 2011). The Optimization process is rooted within the conceptual approach of the Systems engineering based Design Structure Matrix (<http://www.dsmweb.org>), for identifying various degrees of

interdependencies between the various sub-systems of a medical device and their corresponding components, parts and sub-assemblies.

The synchronicity of all the design iterations and life cycle management activities is carried out by a robust information and communication technology infrastructure (SIEMENS <http://www.plm.automation.siemens.com/en_us/>).

The quintessential paradigm of overall Sustainability as explained in Chapter 2 and Chapter 3 spans across both a macro-level (e.g.: social structures and ecosystems) and micro-scale (e.g.: mining of copper and its material properties) issues. The objective behind any sustainable product design activity is to encompass both ends of the spectrum to a desired limit at which the synergies/conflicts between the company's resources can be effectively addressed. Therefore, the product is considered as the source of the critical tangible impacts onto the three domains of sustainability within and outside the organization (Sutcliffe et al., 2009).

Furthermore, the pragmatic constraints surrounding the product development teams, range from convoluted legal procedures for attaining regulatory compliance to limited time availability for studying the market dynamics. The proposed conceptual multifaceted framework would only provide a guideline for the company to re-configure its product development strategy to address the constraints of its external business environment. The ultimate goal is include as much as overall sustainability as possible without compromising any of the necessary requirements to address stakeholder welfare outlined in Tier 1 of the MCHM.

4.3.2. MCHM in Product Design and Optimization

As discussed in Chapter 3, the conceptualization of the Multicriteria Hierarchical Model (MCHM) is based on the hierarchical nature of Analytical Hierarchical Process (AHP). Consequently, the aim of this sub-section is to propose the role of MCHM in product design optimization which is envisaged on similar lines of AHP participating in design optimization activities as investigated previously by other researchers (Wang et. al., 2010; Jia et al., 2010).

Ghazalli & Atsuo (2009) discussed the role of an AHP model in the selection and rejection of candidates for the remanufacturing of a certain automobile component. This is one of the few cases wherein AHP has actively participated at the structural level of the configuration of a product. These authors discussed the development of a computer aided evaluation system that utilizes case based reasoning coupled with an AHP model which is codified within the computer based system using object oriented C#. The goal of their research was to evaluate the prospects of remanufacturing for any given automobile components/parts by comparing the configuration of the part under consideration with reference to other automobile parts documented in a company's product database.

The remanufacturing process usually entails the disassembling of the product, followed by inspection, cleaning, replacing or repairing worn out parts and re-assembling to be returned to the market (Sundin, 2004). The users of the computer aided evaluation system have to feed the information of the part/component to be remanufactured followed by the evaluation of the part/component with respect to various characteristics (or criteria) including wear-out-life and technology cycle. These criteria constitute the AHP Model. The values of the evaluation results are compared to reference weights of the same characteristics (or criteria) in the AHP model. In order to enable the comparison more effectively, the computer aided evaluation system also utilized an Artificial Intelligence Tool and Nearest Neighbour Algorithm to scan through the product database for determining the most relevant candidate for remanufacturing.

Similarly, Singh (2006) investigated the application of group technology and pattern recognition using C and objected oriented technology to evaluate existing systems elements (parts, components, sub-assemblies) in a company's product database and co-relate similarities to a new system which is undergoing development. Singh (2006) utilized a binary conversion and template matching method coupled with Analytical Hierarchy Process for enabling the searching of suitable system elements from the company's database. Meanwhile, the sorting procedure was conducted by using a ranking based evaluation approach based on a comparative index.

As discussed in Chapter 3, in which AHP has been conjugated with fuzzy logic for a wide variety of applications, AHP has also been investigated in the domain of design optimization. Moreover, the incorporation of Fuzzy Logic has proved to be effective in both design optimization as well as decision-making. For example, Wang et al. (2010) investigated the structural parameters of the XK717 CNC milling machine for which the design variables were identified by the Taguchi Method (Fowlkes & Creveling, 1995), followed by finite element method to determine the X, Y, Z displacements and the first three natural frequencies. The Fuzzy AHP was incorporated with the relevant evaluation criteria to deduce the scores for conducting the design optimization of the structural parameters in accordance with the displacement and natural frequencies. Accordingly, the volume power of a diesel engine was evaluated and the pertinent structural parameters were optimized using an equivalent fuzzy logic AHP Model (Jia et al., 2010).

In contrast to the aforementioned research endeavours, which only focus on the design related specifications of the product under consideration, the approach of design optimization for a medical device proposed in this chapter actively involves project management facet of product development in close coordination with the exhaustive list of interconnected technical tools. The proposed multifaceted framework eliminates the additional barrier of designating scores/weights to each criterion and directly engages in the design optimization by using Multi Disciplinary Optimization. In Section 3.5 of Chapter 3 in which each criterion of the MCHM was envisaged to be co-related to a set of parameters/specifications with their "maximum achievable and minimum acceptable" values. Moreover, the multifaceted framework aims to resolve potential design related contradictions and impediments by subscribing to the conceptual approaches of TRIZ; Case based Reasoning and Design by Analogy (Fitzgerald et al., 2010; Ghazalli and Atsua, 2009; Khomenko & Ashtiany, 2007). The stated problems solving techniques would provide insights to the engineers to define the most suitable configuration and then execute an iteration of optimization followed by evaluation and further modification in a similar manner.

The proposed approach is more pragmatic in nature as it encompasses various social sustainability criteria and aligns with the Total Product Life Cycle development approach recommended by the FDA and other pertinent regulatory bodies (Parametric Technology Corporation (PTC), 2008 <http://www.single-sourcing.com/products/value/3988_PLM_QMS_WP_EN.pdf>).

4.3.3. Structuring the Multifaceted Framework

In comparison to the previously stated research investigations, in which score based Analytical Hierarchy Process has been used for conducting Design Optimization, the proposed conceptual Multifaceted Framework causes two distinct advantages.

Firstly, the MCHM discussed previously, is an active participant in the design optimization procedure by exemplifying the conflicts and synergies. In addition, the proposed framework would access the previously stored knowledge curve for the advancement of the development endeavour. Secondly, the proposed framework is pragmatic in nature suited for an industrial product development and commercialization environment by virtue of its ability to be easily customized. The proposed framework consolidates a wide spectrum of theoretical methodologies and well-known engineering systems used by both academia and industry (Figure 4.1.).

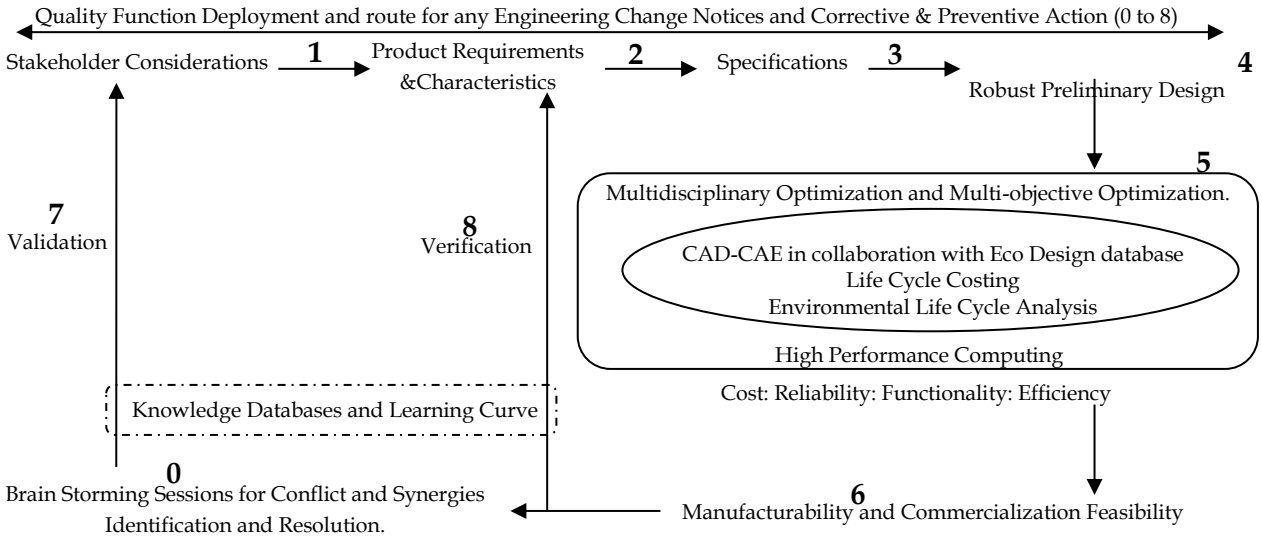


Figure 4.1 – Proposed Multifaceted Framework

Founded on the principles of Quality Function Deployment (<www.qfdi.org>), the stakeholder considerations have to be translated into product requirements to address the needs of the organization and the stakeholders. The product requirements are further translated into specifications that are designated by their "minimum acceptable and maximum achievable values", as discussed in Chapter 3. The range of values would aid the Product Development Team to perform the "Goal and Scope Definition" after every design iteration.

The paradigm of "Goal and Scope Definition" would direct the Project Engineers and Managers to arrive at the most 'optimal design' of the Medical Device that would satisfactorily attain a desired level of environmental compliance, product performance, manufacturability, safety & regulatory compliance and economic gain. Nevertheless, during the iterations, the Engineers and Project Managers would be made aware of the prospective feasibility of the device which would further facilitate them in implementing informed decisions for either continuation or termination of the design candidate undergoing optimization.

Simultaneously, during the identification of Stakeholders' considerations up to Product Specifications, the Project Managers and Engineers should actively scout for pertinent prior art in the form of research papers and patents. The inundating task of identifying pertinent prior art searching can be alleviated by using suitable Neural Network Systems (Trappey et al., 2006). Neural Network Systems are capable of complex pattern recognition between inputs/outputs and adaptive learning. Thus, it is a suitable tool for searching pertinent prior art from a plethora of research literature and published intellectual property.

The utilization of Theory of Inventive Problem Solving (TRIZ) and Design by Analogy coupled with Case based Reasoning is considerably supportive for identifying and addressing the underlying conflicts during product design (Fitzgerald et al., 2010; Ghazalli and Atsua, 2009).

The identified knowledge in the form of literature should be transformed into 3D/2D CAD Models using Optical Character Recognition Software under the close supervision of qualified and competent Design Engineers. The newly

identified, documented and codified knowledge should be added to the existing knowledge database that contains previously stored design and engineering knowledge of the Organization (and its collaborative partners). Moreover, during the Design and Engineering Phases, the knowledge from the database would be continuously accessed for standardizing and/or automating routine tasks. Knowledge Based Engineering approaches enables the synchronization of Computer Aided Design and Engineering (CAD/CAE) Activities in concurrence with the pre-existing knowledge (Corallo et al., 2009; Schut and van Tooren, 2007).

The aforementioned set of planned activities would result in a robust preliminary design, which would be subjected to various constraints namely materials availability and their properties (Carlos et al., 2005), cost analysis (Hart, 2010) and environmental compliance of waste produced/emissions released using Life Cycle Assessment (Gaha et al., 2011).

The engineering design approach of Multidisciplinary Optimization (MDO) utilizes "Optimizers" to resolve problems and conflicts pertaining to the various constraints, objectives and specifications that arise out of the interactions between diverse engineering and scientific disciplines (Robledo et al., 2011; Schut and van Tooren, 2007).

The Multidisciplinary Optimization (MDO) approach in this multifaceted framework is recommended to subscribes to the concept of a Design Structure Matrix (<http://www.dsmweb.org>) to identify the 'appropriate and optimal' values of the pertinent specifications of each component in order to ensure the desired level of environmental compliance, product performance, manufacturability, safety and regulatory compliance and economic gain. The economic gain is a critical factor for the growth of the organization and its contribution towards the social capital (Tier 2 and Tier 3 of Figure 3.2 and Figure 3.6).

Incompatibilities between systems and tools are well expected. Accordingly, Gaha et al. (2011) recommend the utilization of an Application Programming Interface of a geometric modeller of a computer aided design tool. For example, when the

design engineer intends to conduct environmental impact analysis of the CAD model of the product under design. The role of the Application Programming Interface would be to extract the product data and automatically transfers to the desired application/tools for environmental impact analysis. This leads to saving the time required for carrying out environmental impact assessment and other subsequent iterations. Moreover, the formats incompatibility and absence of a common format is no longer an impediment for data and information transfer. Consequently, the product designer is less dependent on additional specialized environmental expertise for conducting his design optimization iterations and analysis.

In order to obtain an "optimal" solution towards the Device Design, the MDO Approach, incorporates the technique of Topological (Surface) and Shape (structural) Optimization (Cascini et al., 2007). Topological Optimization determines the optimal material distribution within a given design space by modifying the apparent material density as defined by the design variable. Whereas Shape Optimization identifies a suitable shape that satisfies the stated list of constraints and minimizes a certain cost function. The cost function denotes parameters whose values have to be minimized as opposed to utility function that needs to be maximized. The design domain is further subdivided into finite elements and the optimization algorithm alters the material distribution within the design space at any iteration in accordance with the objective and constraints defined by the Project Managers and Engineers. The optimization algorithm determines the shape and the material density distribution within the given design domain in order to minimize, maximize or improvise the objective function (i.e. the Evaluation Parameters) while satisfying the Constraints. The Shape and Topology Optimization results in a new set of values for the specifications of the device to address the diverse set of objectives and constraints. The goal of the optimization approach is to determine the best suitable design or even the best possible compromise for satisfying a diverse set of constraints and objectives.

In this Chapter the utilization of Multidisciplinary Optimization is depicted to be conducted concurrently with the TRIZ-Design by Analogy-Case based Reasoning

to determine the 'best geometry' as opposed to only a MDO based 'Optimization' (Cascini et al., 2007; Fitzgerald et al., 2010; Ghazalli and Atsua, 2009).

The intensive design activity should be complemented with robust prototyping techniques and preliminary evaluations to conduct Verification (with respect to desired specifications) and Validation (with respect to stakeholders' requirements). These two qualification activities would entail lab, as well as field-testing, followed by recording the results in the knowledge database to be re-used in the subsequent design iterations.

The on-going 'MDO' design iterations of the robust preliminary design would also be subjected to inputs from the Eco-Design Database to increase the environmental sustainability quotient of the design (Capelli et al., 2006; Filho et al., 2009). During each of design iteration conducted for reducing the environmental impact, it is further recommended to consider the Environmental performance indicators (EPIs) as a measure of the current or past environmental performance of an organization (Jasch, 2000). One of the main strengths of the proposed framework is the potential use of benchmarking within the sector (Tyteca et al., 2002). One of the main weaknesses of EPIs is that they are often only collected for aspects on which data is readily available (Olsthoorn et al., 2001).

Meanwhile, the facet of manufacturability of the device would be governed in coordination with the Manufacturing Process Management (MPM) (Fortin and Huet, 2007; Qi et al., 2004). The Corrective and Preventive Actions (CAPA) and Engineering Change Notices (ECN) that are implemented after 'validation' of the Device Design (Design Master Record, Design History Record, Design History File) are routed through the MDO based 'Optimization' Step and the MPM sequence (Matlis, 2007a; 2009b).

The FDA during the approval stages requires the following documentation which reside in their respective separate and standalone information systems:

•Design History File (DHF) contains a compilation of records that describe the design history of a finished device. The DHF information resides in Computer Aided Design (CAD) and Product Development Systems (PDS).

•Device Master Record (DMR) contains a compilation of records containing the procedures and specifications for manufacturing a finished device. The DMR information resides in Document Management, Product Development and Manufacturing Specification Systems.

•Device History Record (DHR) contains a compilation of records that hold the production history of a finished device, also known as a Batch or Lot Record. The DHR information resides in device records, lot or batch records, equipment maintenance and calibration records and operator certification in Manufacturing Execution Systems.

These documentations are critical for knowledge capture/storage, production, validation and incorporation of corrective and preventive actions/ engineering change notices.

From a technological perspective, a MPM solution provides an effective bridge between the Computer-Aided Design/Product Data Management (CAD/PDM) and Enterprise Resource Planning/Manufacturing Execution System (ERP/MES) software in accordance with the Complete Product Life cycle Management (PLM). Post Design Phase, the Enterprise Resource Planning/Manufacturing Execution System (<www.iqms.com>) play a key important role in communicating and managing the various activities associated with the Product Life Cycle namely, extraction, production, distribution, use, disposal and end-of-life (Hauschild et al., 2005). The activities of the MPM are further promoted by the XML Interactivity between various systems for establishing a data-interchange mechanism that is compatible with Web-centric clients and servers. The XML software and network interactivity ensure a desired level of work package traceability (Design Modification Activities and CAPA/ECN) and Systems (Hardware and Computational Software) interoperability (Fortin & Huet, 2007; Qi et al., 2004). The networking and intercommunication of XML, in accordance with MPM for executing production and device integration activities, is known as Collaborative Production Management (Vogel, 2001).

The conventional practice of an MDO based 'Optimization' always implements the standard set of Optimizers. As investigated by Price et al. (2010), the Expert System can be considered as the chief optimizer in the MDO procedure. Moreover, Eldrandaly (2007) demonstrated the application of AHP based decision making in conjugation with an Expert System. Therefore, this research report recommends that the MCHM (which from Chapter 3 is inspired from the AHP methodology) could be programmed as a software application-using object oriented C language within an expert system (s) for orchestrating the Optimization procedure. As the Expert Systems decision-making is required to be based on certain fundamentals that could be provided by the hierarchical structure of the MCHM and the scored criteria of the second and third tier (Saaty, 2008). The hierarchical arrangement of these criteria and their scores would aid the "Goal and Scope Definition" at the end of each design iteration.

The product development teams need to determine the most suitable pathway to incorporate Life Cycle Analysis during the Design Optimization Phase. One known method is to combine with the Computational Aided Design Tools (Cappelli et al., 2006; Gaha et al., 2011). The other approach, investigated by Pineda-Henson and Culaba (2004) had devised a Green Productivity Analysis Methodology. In their methodology they combined Expert Systems with Life Cycle Analysis and Analytical Hierarchy Process for evaluating the environmental impact and productivity of engineering processes in the semiconductor assembly/packaging. The Green Productivity Analysis Methodology comprises of three key components corresponding to the software modules of a front-end database system, an embedded expert system or knowledge base and a Windows Shell program/interface program. The CLIPS (C Language Integrated Production System) Version 6.1, public-domain software was used as the expert system development tool. The Windows shell was codified in C language and further compiled using Visual C/C++. The objective of the windows shells program was to establish a linkage between the database system and the CLIPS expert system.

Additionally, the Artificial Intelligence tools suitable to the development teams' specific requirements can be considered to minimize any occurrence of expensive

errors arising out of inefficient decision making which is normally characterized by human intervention (Welle & Haymaker, 2011). The overwhelming weight of multiple iterations and calculations for an enormous collection of specifications, objectives and constraints is mitigated by the application of High Performance Computing to reduce the run-time during the Computational Aided Engineering and MDO activities (Kodiyalam et al., 2002). Finite Element Analysis, Computational Fluid Dynamics and Progressive Failure Analysis are the recommended CAE tools for evaluating the influence of various loading conditions on a wide variety of materials & their structures. These advanced computational tools enable product development teams to determine the specific load limits for a certain structure comprising of certain materials (Abumeri et al., 2010; Kodiyalam et al., 2004).

Before each simulation is carried out, it is recommended to employ mathematical programming methodologies, such as Signal Flow Graphs, which are in a position to predict the impact of a certain simulation strategy on the project timeline. The computational simulation is a time consuming activity and, accordingly, demands that the design engineers define a strategy of simulation and the scope of design evaluation including boundary conditions, during their modelling tasks. In order to decrease the timeline, the processing power of the Computing Systems could be raised or lowered for complying with the project deadlines (Isaksson et al., 2000).

4.3.4. Design Optimization Strategy and Evaluation of the deduced Design Candidates

In this chapter two broad defined strategies for conducting design optimization are proposed for the development of an interdisciplinary medical device. For either of the two strategies the values of the Reliability of Device performance and integrity play a decisive role. According to the first design strategy, the development teams are recommended to observe the following steps:

1) Identify the maximum achievable and minimum achievable values of the Reliability of the Device and its integrity against various loads (stresses and strains) throughout the life cycle.

2) From the literature and preliminary investigations determine the reliability values for the corresponding number of life cycles. For example, the reliability for 5 life cycles would be higher than the reliability requirements for one to two life cycles. Product Development Team Products have to account for the possibility that products with higher reliability may require more durable materials that may not necessarily be eco-friendly and non-toxic in nature. If there is no opportunity to switch to more sustainable materials and products, then the medical device company has to conduct its due diligence for obtaining the mandatory certifications and clearances. Moreover, multiple life cycles and high reliability materials could significantly add to the cost and may bring about future cost savings under favourable market conditions. Therefore, the development team should include their objectives of financial gain that are closely related to the social sustainability goals and the future expansion plans.

3) Identify opportunities for incorporating Modularity for a platform-derivative product development approach that can be reconciled with the requirements of disassembly/reassembly in the end-of-life opportunities (Chandrasekaran et al., 2004; Wyatt et al., 2009).

4) Subscribe to the aforementioned MCHM based Expert System Design Optimization Approach to investigate the optimum number of life cycles of a given medical device that sufficiently satisfies the Tier 1 criteria and is also modular in its configuration. If the Modularity is found to conflict with Tier 1 criteria, the designers can reduce the level of modularity either gradually or directly minimize it (refer Figure 4.2), depending upon the design idiosyncrasies of the medical device. This step would demand simultaneous engagement of project management, senior management and product development teams for communicating the results and decisions.

5) Preliminary investigation to confirm compliance with Verification (Product Specifications) and Validation (Value Chain Partners and Stakeholder) considerations. The regulatory bodies including FDA, ISO, REACH, ROHS and

WEEE are persistent about their compliance to safety and performance and not necessarily specify the compulsion to include the modular nature of a product.

6) Iteratively repeat steps from 1 to 5 to determine a list of numerous design candidates to be filtered further for finalizing the best suitable design.

The second strategy is to follow steps from 1 to 6 excluding the Modularity and/or End-Of-Life opportunities, as not all medical devices can be designed with high degree of modularity.

The design optimization procedure is known to yield a multitude of "most suitable design candidates" that would satisfy each criterion of the Tier 1 to a significantly large extent within the expected range of the assigned specifications. The business sectors of Medical devices have experienced fierce competition mainly characterized by shorter product development cycles and price. These are the 2 desirable attributes from the viewpoint of a patient and his/her medical healthcare providers. Consequently, the medical device company needs to launch the most effective and competitive device in the target market. As a result, generating more than one effective design candidates is beneficial in the long run for competitiveness and knowledge growth. Nevertheless, the numerous design candidates (which have already cleared Tier 1 criteria) have to be subjected to a filtration process that selects only 10% of the total no. of candidates generated during the design optimization process which score highest in each of the following ranks enumerated below.

The numerous design candidates which although satisfy each criterion of Tier 1 are subjected to an additional hierarchical arrangement of Tier 1 criteria to select the best few with the highest degree of compliance. The Magnitude of Degree is categorized as follows: High (>70%), Medium (50%-60%) and Low (20%-30%).

Figure 4.2 – Screening of Design Candidates during Multidisciplinary Optimization

In terms of Tier 2 and Tier 3, the companies can choose their own ranking approach, as these criteria are more optional in nature.

Rank 1: Safety; Human Factors/ Ergonomics; Regulatory Compliance; Acceptable level of availability and performance of the Total Product Life Cycle Management Systems. This level encompasses the key considerations of all the value chain partners and Stakeholders.

Rank 2: Modularity for Platform-Derivative Approach and End-Of-Life Options. The Modularity is categorized as high when more than 70% of the product can be disassembled into distinct system elements; Medium-Approximately 50%-60% of the product can be disassembled into a few distinct system elements while the other components and sub-assemblies cannot be broken down further. The lower degree of modularity is around 20%-40% of the product that can be disassembled into a few distinct elements in comparison to the majority of the 'un-dismountable' components/parts/sub-assemblies.

Rank 3: Lowest Environmental Impact. A comprehensive life cycle evaluation of the end-of-life reverse logistics and supply chain would be conducted to determine the "accurate reduction" in emissions/waste and socio-economic consequences to stakeholders. This rank also includes the performance and efficiency of waste management methods and emission control techniques (e.g.: adsorption; plasma treatment) (Pubule et al., 2011).

Rank 4: Faster Rate (i.e. speed) of Reimbursement by way of approved Payment Modalities from the Insurance companies and Medical Policies (Miller, 2007).

Rank 5: Higher degree of compatibility with the Value Chain partners namely Production, Supply, Distribution and End-Of-Life. The degree of compatibility is also evaluated on the extent of modifications required in the Total Product Life Cycle Management System for the proposed design.

Rank 6: Higher degree of Competitiveness and shorter time to market in comparison with other market competitors and product substitutes.

Rank 7: Higher degree of Aesthetic Appeal: The development teams can consult an expert for evaluating the aesthetic appeal or incorporate an artificial intelligence tool that verifies the proposed design candidates with reference to the previously stored design principles specifically promoting aesthetics (Catalano et al., 2002; Kaljun and Dolsak, 2011). The contradictions pertaining to aesthetics and product functionality cannot be resolved using TRIZ or any other method thereof as aesthetics is subjective from emotional; regional; temporal and cultural standpoints.

The criteria in Tier 1 are arranged in ranks only for the filtration of various design candidates and not for the decision modelling between medical device selections. Unless the decision-making is found to be more challenging than anticipated. Moreover, the financial gains and social sustainability criteria in Tier 2 and 3 can be considered for further screening of the 10% of the total number of candidates to finalize 2-3 best designs. This ranking methodology presumes the Collaborative Strength of the Team and their Expertise to be more than adequate for materializing the designs into a commercial product (Akgün et al., 2006).

4.4. Concluding Points

The chapter begins with the discussion of various conceptual product development approaches which have illustrated an extensive focus on long term planning, product configuration and its underlying technologies, suitability of these tools to a certain organization and flexibility within the value chain to adjust for uncertainties.

In this chapter the most important facet of non-linearity of product development and design is discussed. In addition, a brief outline of the various technical tools in design, engineering analyses and product development planning are discussed. Moreover, the critical role of identifying, storing and ensuring the accessibility of engineering and non-technical knowledge is ascertained to be crucial for adhering to the project timelines. Similarly, product development teams have to define an engineering analyses (or simulation) strategy to ensure that the evaluation of the virtual product is more comprehensive without expending excess of time and resources.

Notwithstanding, the advantages of customizability of the proposed multifaceted framework for a wide array of medical devices, the Product Development Teams would have to manually assign the values to each specification for every criterion. The arduousness of the customizability is governed by the complexity of the device that may or may not relevant to the classes of the medical devices. Nevertheless, as discussed previously, Knowledge Based Engineering applications can be incorporated for automating unproductive repetitive tasks.

The proposed multifaceted framework has been devised by considering the critical role of the MCHM for product design optimization by conducting an exhaustive literature research and validation by expert opinion. Furthermore, the literature review reveals that the coordination of a multitude of technical tools and computer-based systems could elucidate conflicts in terms of their data formats and programming structures.

The objective of this chapter is to demonstrate the active participation of the MCHM Design Optimization Procedure. This further justifies the revision of the conceptual structure of the AHP as proposed by Saaty in the 1990s (Saaty, 1990).

Chapter 5

Research Methodologies

5.1. Introduction

This chapter outlines the research methodologies utilized for evaluating the models and frameworks discussed in Chapter 2, 3 and 4. The models and frameworks as discussed previously are devised for incorporating social, economic and environmental sustainability within in product design.

Different sources of data were used in order to enhance validity and reliability of the case studies and expert interviews (Yin, 2003). Data was crosschecked by using the results of the survey and of the interviews. Several on-site visits were undertaken during the research. Some of the visits took place before and others after the interviews.

This chapter also discusses the research proposition that forms the fundamental basis of the proposed models and frameworks. This discussion of research methodologies with reference to the research propositions illustrates the goal of the thesis with a higher degree of clarity.

Section 5.2 discusses the structuring the of various research methodologies adopted in this thesis, followed by Section 5.3 which outlines the case study approaches and the type of interview method chosen for addressing issues pertaining to overall Sustainability in medical device development. Meanwhile, Section 5.4 outlined the Analytical Hierarchical Process (AHP) decision modelling approach and pair-wise comparison technique in detail (Saaty, 1990a; 2006b; 2008c; 2009d). The goal of the pair-wise comparison in this thesis is to only capture the insight and tacit knowledge in product development and decision making of experts from Academia and Industry with reference to various economic scenarios

(ranging from Keynesian to Free Market Capitalism) (Wapshott, 2011). The reason for using pair-wise comparison solely for capturing the insight and tacit knowledge for product development is to incorporate them within the case studies. Moreover, as in any of the case studies discussed in this thesis does not have any specific alternative to be chosen in comparison to a set of alternatives. As a result, certain facets of AHP based decision modeling such as consistency ratio/index would not be given much importance. Moreover, the criteria chosen for pair-wise comparison would be solely from Tier 2 and Tier 3 which are entirely optional in nature and their inter-relations would be governed by the product configuration, the capabilities and resources accessible to the medical device company and the economy of the geographical location in general. For example: In certain business scenarios, end-of-life options may contribute to additional employment; nevertheless in certain countries the economic policies may or may not provide subsidies for such end-of-life options and in certain circumstances neither of the end-of-life options may bring about any savings in emissions/costs to the company.

5.2. Defining the pathway of the Research Methodology

The decision modelling approaches and product development methodologies discussed in Chapter 3 and Chapter 4 would constitute as an important facet of business management practices to enable the finalization of important decisions. Previously conducted research investigations for evaluating various approaches pertaining to business management practices, such as Malmi and Ikaheimo (2003) combined case studies and interviews. Meanwhile, Szychta (2002) included fieldwork research using up to around 290 questions in combination with interviews. Similarly, Roslender and Hart (2003) conducted a series of semi-structured interviews in two organizations prior to their field study.

Moreover, unstructured and semi-structured interviews have been regarded as reliable sources of information and knowledge for delivering a profound insight on the theoretical propositions of a research endeavour in order to enable any

form of course correction. The same approach can be considered for validating the data collected by previously conducted field research (Patton, 1990).

Frequently, quantitative and structured methods are popular amongst economists (Meredith et al., 1989) and production operations management researchers (Westbrook, 1994). Notwithstanding, the facet of criticism; wherein many experts sometimes argue that quantitative approaches are retrospective in nature, unless real-time analyses is conducted. Meanwhile, the approaches of case studies with questionnaires and interviews attempts to validate the theoretical underpinnings of the proposed framework and models discussed in this thesis. However, the evaluation methods are prone to suffer from short sightedness and a narrow-minded viewpoint during the planning of case studies and interviews/questionnaires. Therefore, for each case study the scope has been adjusted accordingly, to determine the prospective actions an Enterprise can implement for increasing the degree of overall sustainability.

5.3. Introduction to the Case Study Method

The case study approach can comprise of single or multitude of cases. Even if one can generalize from a few cases or a single case, a multiple case approach would broaden the scope and strengthen the validity of propositions outlined in this thesis. The propositions that will be discussed in this chapter specifically have been ascertained by virtue of extensive literature review and preliminary interviews with experts from academia who had previous experience in a industrial environment.

Yin (1994) attempts to differentiate between literal replication and theoretical replication in which cases are structured to corroborate with each other on the propositions. The literal replication is meant to produce similar results while theoretical replication is aimed at obtaining different results for anticipated reasons.

As case study approach has an exploratory facet to it and accordingly, it is challenging to determine the most suitable theoretical foundations to guide the project, even before data collection commences. Therefore, the units of analysis in

a case study in this thesis are the models outlined in Chapter 3 and 4, which would be evaluated in more than one Enterprise that develop and/or manufacture medical devices ranging from Class I to Class III.

The enterprises were selected on the basis of their size and include SME (Small and Medium Enterprises) and large sized enterprises. Similarly, the size of the enterprise is considered crucial in order to gain an insight into the constraints they encounter in terms of financial, knowledge, material and technical resources (and other resources in Section 3.3 of Chapter 3). These constraints govern the ability to incorporate sustainability within any medical device across various classes.

Furthermore, the quality of the case study design is of utmost importance as the activity itself. The four tests are outlined as follows in Figure 5.1, which includes construct validity, internal validity, external validity and reliability. Yin (1994) proposes the users to address these four tests throughout the case study process, beginning from design, data collection, and data analysis and reporting.

Tests	Case study tactics	Phase in research activity
Construct validity	- use multiple sources of evidence - establish chain of evidence - ensure that key informants evaluate the draft of the case study report	data collection data collection composition
Internal validity (only for causal inferences)	- conduct pattern matching - conduct the construct of the explanations - conduct analysis with respect to time-series	data analysis data analysis data analysis
External validity	- use replication logic in multiple-case studies	research design
Reliability	- use case study protocol - develop case study data base	data collection data collection

Figure 5.1 – Facets to ensure Quality in the case study design (Ying, 1994)

In social research methodologies where case study method is utilized regularly, the construct validity is defined as the extent to which the case study user can legitimately draw inferences after implementation of his/her propositions and theoretical constructs.

On the other hand, external validity is based on the degree to which the experimental results of a particular study (and its pertinent contexts) are applicable (or possible to be generalized) to other situations. Usually causal inferences (i.e. cause-effect based inferences) are applicable in terms of their external validity, as they can be considered across a wide spectrum of circumstances, which are quite unique compared to the conditions, which the study was previously conducted. The loss in external validity can occur, when the previously conducted study 'may' have been carried out in small samples with very specific contexts (such as geographical locations and specific cultures) that do not possess any relevant commonalities to other situations. For example: The market acceptability of a car design suited for customers in the Nordic region that resonates with their culture may not be easily extrapolated (or applicable) to customers in South America. As both these regions have different socio-economics and cultural differences.

The internal validity is the extent to which the cause-effect inferences based on a certain scenario in a case study are valid. In simple words, this means the validity of studies (and also the inferences) that intends to establish a certain cause-effect relationship. The facet of reliability can simply be understood as the validity of the propositions and case study methods employed by the user.

The thesis favours the use of expert interviews and opinions to ensure that the case study design entails a substantial degree of quality as per the aforementioned tests.

According to Figure 5.2, the four types of the case study are outlined as follows:

- Type 1 - The study of a single case for a single unit of analysis under review;
- Type 2 - Study of a single case for multiple of analysis under review;

• Type 3 - Study of various cases for a single unit of analysis under review;

• Type 4 - Study of various cases for multiple units under review;

In this thesis more than one case is considered in terms of multiple enterprises and the units under review are also more than one (Type 4). The units under review are the models and frameworks ones mentioned in Chapter 3 and 4 namely, multicriteria hierarchical decision model (Figure 3.2 in Chapter 3), the project selection approach using the multicriteria hierarchical decision model (Figure 3.4 in Chapter 3), multicriteria hierarchical decision model pertaining to the end-of-life options (Figure 3.5 in Chapter 3) and the multifaceted model (Figure 4.1 and 4.2 from Chapter 4).

	single-case designs	multiple-case designs
Holistic (single unit of analysis)	TYPE 1	TYPE 3
Embedded (multiple units of analysis)	TYPE 2	TYPE 4

Figure 5.2 – Classification of case study types (Ying, 1994)

5.3.1. Data Analysis

The qualitative aspect of the data analyses during case studies would occur in accordance with the cognitive skills and analytical abilities of the researchers who conduct the case studies and the respondents who have participated in the case studies, respectively. The reason is that the description of the units of analyses and the scope of the case study needs to be well addressed by both parties by virtue of reliable data collection approaches. These data collection approaches would be discussed in detail in subsequent sections. This would also enable in presenting relevant and valid conclusions.

According to Yin (1994), the objectives and structure of the case studies are based on the following research propositions of this thesis which are in accordance with the analysis and review of the pre-existing literature:

•The opportunities to include social, economic and environmental sustainability are dependent on the design of the medical device(s).

•The ability to include social, economic and environmental sustainability is dependent upon the learning curve, accessibility to material resources and financial capital of the Enterprises.

•The presence of essential regulatory, social and economic policies poses either a barrier or promoter for incorporating social, economic and environmental sustainability within medical device design.

These aforementioned facets are responsible for shaping the data collection procedures and also directing the case study. The objective is to capture critical data and ignore irrelevant details that do not corroborate with the visible and tangible outcomes. For instance: minor factors such as strained employer and employee relations although can derail major projects, but enterprises are capable of solving such internal conflicts within themselves in order to adhere to the project deliverables/deadlines. The relation between the factors stated in these propositions and the causality with respect to incorporation of social, economic and environmental sustainability is conducted during the data collection procedures.

5.3.2 .The Research Process in the Case Study

According to Saunders, Lewis and Thornhill (2007) the research process that precedes the case study activities starts with the definition of the subject of the case study. This is further followed by clarifying the structure of the topic (or subject) to define clear objectives. The motive of the case study approach in this thesis is to evaluate the prospects of effectively incorporating the social, environmental and economic sustainability within design of the medical device. In order to strengthen the fundamental concepts of sustainability within product development and product design, a thorough literature survey was conducted which comprised of corporate newsletters, peer reviewed published research papers, book chapters, technical articles written in renowned magazines, such as Medical Device and Diagnostics Industry <www.mddionline.com> (Saunders, Lewis & Thornhill, 2007). Moreover, a few preliminary unstructured interviews were conducted with academicians in the area of product development research, decision modelling and medical devices to gain further insight on the resource based constraints to incorporate overall sustainability. Similarly, the major technical/non-technical challenges were also ascertained during unstructured interviews to address and incorporate overall sustainability within the design phase and the product development process as a whole across the Organization and its stakeholders. The motive was to structure a consistent approach for conducting a series of case studies and evaluating multiple units of analyses.

As mentioned by Yin (1994) the case study approach is most appropriate when the user has limited control over the on-going circumstances within the situation and cannot really influence the behaviour of the events/variables associated with the causalities. However, some critics point out the lack of rigorous approach within this method and the vulnerability to incorporate biases, despite the advantage of the flexibility to suit the context of the case under consideration.

The approach of case study is always governed by the type of research questions/propositions, the ability of the investigator to influence/control the

events under investigation and the ability to co-relate to on-going events in comparison to historical events.

Case studies are also categorized according to following manner:

•Descriptive: These types of case studies are intended to characterize or portray certain situations/events.

•Explanatory: These types of case studies are considered for creating causality relationships between variables under consideration.

•Exploratory: The case studies with a motive to comprehend the events/circumstances-taking place.

The case studies that were conducted include a combination of all three aforementioned categories. Consequently, on the basis of the propositions, exploratory facet is first actualized which is followed by the explanatory phase of determining the causality between various variables to corroborate with the propositions while simultaneously characterizing the enterprise under consideration to modify the interview structure, accordingly.

5.3.3. The Application of Case Study

As recommended by Yin (1994) a multitude of facets are to be accounted for structuring a case study. The motive is to articulate a logical framework between empirical data, research questions and conclusions by virtue of a sound methodology.

The facets are as follows:

•Propositions and assumptions on which the research questions are defined.

•The objectives that are to be addressed within the case study.

•The unit(s) of analysis.

•The logical connection between the empirical data and the propositions/assumptions.

•Criteria to interpret the findings.

Furthermore, a case study permits the users to opt for multiple sources of evidence and methods of analyses for corroborating the propositions (better known as data collection). These methods of analyses range from empirical documentation, records/files, questionnaires, interviews, observations, direct participatory observation and assessing physical artefacts of projects under development or completed (Yin, 1994).

In this thesis, no one particular method of analysis is considered advantageous over the other. On the contrary, all of these approaches are complementary to each other. During the case studies it is observed that each medical device of every category has its own particular design architecture for a specific physiological function in accordance with the Enterprises' engineering and business management capabilities. Therefore, more than one method of analysis was considered necessary within the case study approach (Yin, 1994).

Moreover, the procedures for collecting evidence and empirical data were conducted independently under the guidance of authorized representatives of each Enterprise. They (the authorized representatives) include but are not limited to research and development directors, engineers, scientists and business managers. The experiences and opinions were noted with reference to their product development processes. This approach was adopted so as to benefit from the expert advice of the Enterprises' learning curve without allowing any cognitive biases of the members of the Enterprise to interfere with the analyses (Hilbert, 2012)

5.3.4. Interviews as a critical component of the Case Studies

In this thesis interviews have been considered to play an important role in case studies (Yin, 1994). The three main categories of conducting interviews are as follows (Patton, 1990; Saunders, Lewis and Thornhill, 2007):

a) Informal conversational Interview

The interview questions are defined during the case study with specific reference to the Enterprise and its Medical Device. As a result, the interview becomes more relevant and is able to determine many more factors that lead to the development

of the medical device and opportunities for including sustainability from a viewpoint of solving technical/non-technical contradictions specific to the Enterprise's Device. The major drawback is that there are too many people to interview and ultimately data organization becomes increasing challenging.

b) Interview guide approach

The interviewer has a pre-defined script after thorough literature survey and probably other unstructured interviews. The context of the enterprise and the medical device under consideration can be maintained and gaps can be easily determined in order to modify the script accordingly. Despite the advantage of systematic data collection, if the interviewer makes adjustments within the script then there are chances of substantially different responses. Therefore, it is essential for omission of unnecessary details and questions during interviews to maintain the context of the propositions to be addressed.

c) Standardized open-ended interview

The questions are open ended in nature and are pre-defined by the interviewer. The respondents perceive flexibility to answer the questions based on the context of their Enterprise and medical device under consideration. As a result, the responses can be more comparable. Nevertheless, additional flexibility to fit the context of the Enterprise and the specific device under consideration is substantially limited, especially in the case of medical devices when each Class has its own diversity and is in turn manufactured by a wide spectrum of market players with each having their own specific uniqueness to enhance overall sustainability.

d) Closed quantitative interview

The set of pre-defined questions are presented to the respondents who choose the appropriate responses from a list of options. Even if the data analysis and comparability is simplified, the flexibility and contextual understanding are dramatically limited. However, the interviewer can easily include specific experiences of the respondents and ask additional sub questions around the main

question under discussion without making the interview too open ended and unstructured.

In this thesis an 'Informal conversational Interview' was adopted for the case studies in the Enterprises that developed and/or manufactured medical devices. In addition, a 'closed quantitative interview approach' based on a questionnaire was also considered for the multifaceted framework, as described in Figure 4.1 and 4.2 of Chapter 4.

The reason is that the design optimization approaches and product development activities vary in diverse circumstances and hence additional feedback was obtained from the survey respondents. The questionnaire for the multifaceted framework (Figure 4.1 and Figure 4.2) is mentioned in Chapter 6 and was emailed to around 10 experts who have substantial experience in product development and design engineering. The questionnaire was followed by a 1 hour long distance interview and notes were made and re-confirmed by emailing the respondents to prevent any erroneous comprehension due to the disparity in area of expertise between the interviewer and respondent(s).

The questionnaire had multiple-choice options of either YES/NO for questions that discuss the validity of combing a few engineering and management elements during design optimizations. Similarly, the options of Low/Medium/High were provided for gaining insight into the feasibility of the combination of engineering and product development elements. To explain in simpler terms, engineering element can include design engineering tool (computer aided design) and product management element could also be total product life cycle management system.

Hartley (1994) also concurs that interviews are an effective method to gain a detailed insight from the most crucial resource of product development, which are better known as Human Resources for who justify the utilization of various product development tools and the customers for whom the products are primarily devised. The face-to-face or long distance interviews permit the interviewer to perceive the pragmatic realities pertaining to product development. For instance: The recent financial crises of 2008 resulted in many companies opting

for redundancy. This resulted in a few employees were made to accommodate the workload of the employees whose jobs were either outsourced or terminated. Consequently, the respondents who had an exhaustive list of responsibilities found it challenging to adhere to the hours decided for the long distance interviews.

5. 4. Analytical Hierarchical Process

5.4.1. Introduction

The multi-criteria hierarchical model that is discussed in detail in Chapter 3 and Chapter 4 is based on the fundamentals of Analytical Hierarchical Process. This section of the research methodologies discusses the decision modelling approach of Analytical Hierarchical Process (AHP) which has been at the centre stage of this thesis for inclusion of Sustainability related criteria into product design.

In this chapter, the pertinent criteria of the following paradigms are arranged in a hierarchical manner: Product performance (in addition to stakeholder safety) with environmental compliance and bare minimum profitability (in Tier 1), economics of the business sector that enables the implementation of the model (in Tier 2) and the social impact of the business with its commercialized medical device (in Tier 3).

The concept of sustainable medical device is sub-divided into constituent criteria. This simplifies the problem for examining each criterion with respect to other criteria. Although, accounting for sustainability related criteria one cannot presume a reductionist approach as sustainability is to be considered from a holistic standpoint (Hermele, 2009). On the other hand, a holistic approach would demand the decision modelling approach to be more exhaustive in nature and during the product development endeavour certain crucial criteria (from all three domains of sustainability) are capable of exerting a substantial impact (positive/negative) onto overall sustainability (Hede et al., 2011). These crucial criteria can enable the user to derive a single overall priority index for every option (or alternative) under evaluation (Hemphill et al., 2002).

Consequently, in this chapter a methodology for decision modelling using AHP based approach is discussed with the allocation of weights to enable prioritization of pertinent criteria in Tier 2 and Tier 3, after the most dominant and crucial criteria are finalized and incorporated within Tier 1. The assignment of weights and pair-wise comparison would not be done for Tier 1, as each criterion in Tier 1 is non-negotiable.

The Tier 2 and Tier 3 would encompass the conventional AHP decision modelling approach. Moreover, not a single criterion from Tier 2 to Tier 3 could be included in product design if it cannot be reconciled with any one criterion of Tier 1. A more detailed discussion has already been included in Chapters 3 and 4.

For the pair-wise comparison method the following criteria were selected:

End-of-life and Modularity (Tier 2)

Employment (Tier 2)

Income Distribution (Tier 2)

Housing (Tier 3)

Community welfare (Tier 3)

Business Growth from Tier 3 to represent both Mergers & Acquisitions and Corporate Expansion.

Market Share (Tier 3)

The other criteria in Tier 2 and Tier 3 from Figure 3.2 of the MCHM which denote an increasing degree of cost effectiveness from Tier 1 to Tier 3 and an increasing degree of commitment towards renewable resources/reduction of emissions and waste was recommended by the Experts from Academia and Industry, who also participated in the pair-wise comparison procedure.

For the criteria in Tier 2 and Tier 3 the pair-wise comparison procedure from the AHP process has the following steps:

1. Identification of sustainability criteria that are dependent on the Tier 1 criteria. For instance: The modular approach towards product development and end-of-

life are dependent upon the product design and its ability to adhere to regulatory compliance.

2. The chosen sustainability related criteria are arranged into the hierarchy of Tier 2 and Tier 3 in accordance to their ability to influence the near future continuation of the enterprise and long-term growth plans, respectively. For instance: End-of life is located in Tier 2 which would immediately impact the product performance and the company's sales while the plans for corporate growth are placed in Tier 3 as they are pertinent to long term growth strategies.

The objective to arrange the pertinent criteria in the aforementioned form of hierarchy is to illustrate that the stakeholders should accept a medical device with bare minimum profitability for the developers/manufacturers on which additional degrees of overall sustainability can be established. Moreover, without these two critical criteria as outlined in Tier 1, the other criteria in Tier 2 and 3 such as long term corporate growth would be counter intuitive and futile in nature.

3. The assigning of numerical weights and pair-wise comparison of the criteria mentioned in Tier 2 and 3. The scores were assigned based on their relative importance between two criteria at a time based on the Saaty (1980) scale in Table 5.1. The assigning of numerical weights involved interviews with a total of 7 experts. During the interviews, the pair-wise comparisons between the outlined criteria in the two tiers (Tier 2 and 3) were discussed and simultaneously, the experts revealed their opinions as well as experiences pertaining to sustainability and product development. A pair-wise comparison of one criterion with respect to other criteria is determined to be more objective as opposed to subjective judgments on only a single criterion under consideration. As considering only one criterion for evaluation would entail an experts' biases and even preclude a more holistic approach with reference to other criteria (Hilbert, 2012). Meanwhile, comparing one criterion with all other simultaneously would transform the expert interview sessions into a more exhaustive form, which may lead to confusion between the interviewer and the expert. Therefore, comparing one criterion with

the other at a time followed by trying to co-relate with other criteria as well was identified to be more convenient for both the interviewer and the experts.

4. The scores are aggregated and the relative weights on each hierarchical level are analysed.

5. Evaluation of the consistency of the collected data from the experts after aggregation.

6. In contrast to conventional AHP related applications; there are no options or alternatives that would be evaluated in terms of the hierarchical structure of the proposed multicriteria hierarchical model (MCHM) in this thesis. The MCHM that comprises of Tier 1 as the critical tier and Tier 2/3 would select and reject suitable design candidates during product development and product design process for which consistency index/ratio may or may not be applicable. The goal of the pair-wise comparison is to capture tacit knowledge and insight from the Experts pertaining to product development. Furthermore, the criteria in Tier 2 and Tier 3 are also optional in nature.

7. The 'Informal conversational Interviews' that were more semi-structured addressed the following two issues:

a) The pair-wise comparison between various criteria in terms of their ability to influence each other. For instance, whether growth in market share could also bring about increase in the hiring practices of the company. Similarly, whether adopting end-of-life options may or may not increase the hiring in the company.

The experts were not asked to assign any numerical value to the ability of one criterion to influence the other during the pair-wise comparison between two criteria at a time. The responses were collected in the form of short notes, which would be discussed in Chapter 6.

b) The diverse economic circumstances in which the relations between criteria during pair-wise comparison can undergo substantial changes. For example: If the medical device company is based in Sweden, where the social safety net in terms of healthcare and unemployment benefits is larger than the United States.

As a result, the disposable income tends to be higher and the medical device company can focus on increasing the market share and look forward for corporate expansion which would eventually bring about job growth and other forms of technology transfers for social benefit (Krugman, 2012).

The responses were collected in the form of short notes, which would be discussed in Chapter 6.

The goal is to determine the role played by diverse socio-economic circumstances based on the degree of Government presence in regulating the financial markets and providing social welfare. To illustrate further, the experts were requested to provide their feedback on the pair-wise comparison between two criteria with reference to the socio-economic scenario in Sweden, where the government has a dominant role in the economy, while United States government has a much lesser role in the economy and the government in Portugal holds a position which is between United States and Sweden. The countries namely, Sweden, United States and Portugal were given as examples to exemplify diverse socio-economic circumstances.

Furthermore, as the interviews were 'informal and conversational' in nature is the reason for not defining a script for the interview which lasted for around 30-40 minutes. Instead of the script, the questions were spontaneous in nature but were based on the guidelines from 1 to 7 outlined for the pair-wise comparison.

The advantage of AHP based decision modelling technique is to evaluate various candidates in terms of a wide spectrum of coherent or conflicting criteria by virtue of pair wise comparison of each criterion with respect to the other. Similarly, candidates or alternatives could be evaluated on the basis of the numerical value for each criterion they address in the Tier 2 and Tier 3 of the MCHM. This approach results in ranking of various candidates to enable the user of the MCHM to select the most suitable alternative (Rogers, 2001). For instance, Figure 3.4 in Chapter 3 illustrates the ability of the MCHM to select suitable projects for further development. Meanwhile, the ranking based elimination of various design candidates during the design optimization phase as discussed in Chapter 4 and

illustrated in Figure 4.2 is not related to the pair-wise comparison method. However, the MCHM can function similar to an AHP decision modelling approach solely on the choice of the user of the MCHM in terms of Tier 2 and Tier 3.

The AHP approach on which the MCHM is based utilizes the hierarchical arrangement of the criteria for exemplifying the overall objective of the decision making, while simultaneously accounting for a wide spectrum of criteria ranging from economic, social and emotional in nature. In conventional AHP, the objective is placed at the top, the criteria in the centre and the options at the lower level (Nigim et al., 2004).

The users either by themselves or in interactions with experts assign weights via subjective judgment to each pair-wise comparison of two criteria at a time. This is followed by computing the overall weight of each criterion and evaluating the level of consistency of the assigned scores (Hobbs and Meier, 2003)

Greening and Bernow (2004) have stated that the major impediment in the AHP decision modelling is to obtain a consensus based agreement between various decision makers and their biases/experiences, which is shown to substantially affect their judgment. However, studies such as Wu et al. (2007) and Liang et al. (2006) state that the AHP decision modelling process is a systematic and numerical approach that incorporates the subjective evaluation of all decision makers into account for selecting the final candidate. Moreover, Zhong-Wu et al. (2007) considered the AHP technique to be simple in comparison to their other multi criteria counterparts for quantitatively evaluating non-quantitative criteria.

In this thesis, the impediment pertaining to ensuring a consensus between various Experts is less relevant because the pair-wise comparison approach has been used only for capturing tacit knowledge and insight. Moreover, the tacit knowledge and insight disseminated by the Experts is relevant to the specific contexts which could be pertinent to certain circumstances which occur during the development of medical devices

5.4.2. Description of the AHP process

The hierarchical structure of chosen criteria to devise the AHP decision modelling approach was devised by Saaty(1980). An example of this hierarchical structure is denoted in Figure 5.3.

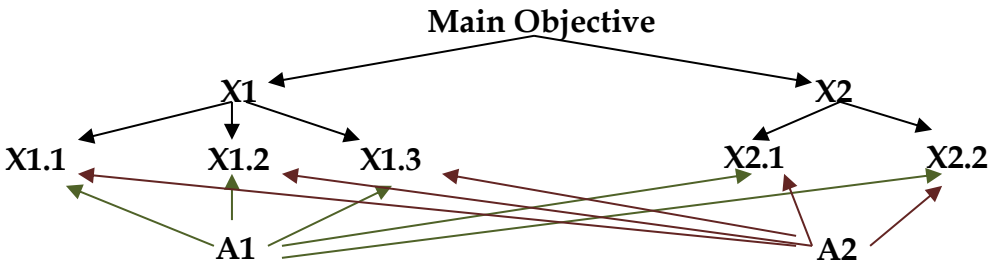


Figure 5.3: Analytical Hierarchical Process

Hon et al. (2005) have described the key steps for decision modelling by the AHP approach which are: building a matrix of pair-wise comparison, the eigen values followed by the eigenvector calculation and reviewing the consistency of the matrix and ultimately the normalizing the weights of the selected criteria. The process can be resumed as follows:

1. As stated the previously the objective, criteria (and sub-criteria) and candidates are located in their respective hierarchical positions. The hierarchy is represented by the illustrated figure; wherein X1 and X2 are two criteria, X1.1, X1.2 and X1.3 are the sub-criteria associated with X1 and X2.1, X2.2 are the sub-criteria associated with X2. The alternatives are designated by A1 and A2.

2. Pair-wise comparison is conducted as follows: Elements, X1.1, X1.2 and X1.3 are compared pair-wise with respect to their importance towards X1.1 (from the X1 criterion) and using Saaty scale presented in table 5.1. The process is repeated at each level until the final top level of the hierarchy is attained. This step also includes the calculation of consistency ratios of the matrix judgment to confirm that the assigning of scores is consistent in nature.

In Table 5.1 the numbers (9; 7; 5; 3; 1) represent values of pair-wise comparison situations when A is compared to B, the comparison of B with respect to A would

be the reciprocal value (1/9; 1/7; 1/5; 1/3). For example: When A is compared to B and if A is strongly more important than B then the score is 7. Accordingly, the score of B with respect to A would be 1/7.

Table 5.1 – Saaty (1980) Scale of assigning weights on the basis of pair-wise comparison.

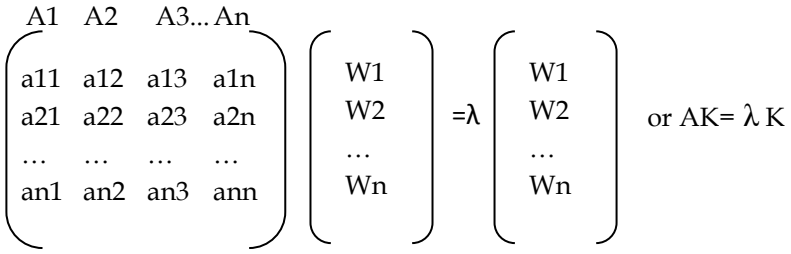
Score	**Pair-wise evaluation**
9	A is absolutely more important than B
7	A is strongly more important than B
5	A is strongly important than B
3	A is moderately more important than B
1	A is equally important than B
1/9, 1/7, 1/5, 1/3,1	Reciprocal values

In the matrix representation, as illustrated in Figure 5.4, when a criterion is compared to itself the score is usually 1. This means that result the diagonal, which corresponds to each and every criterion being compared to its own self, is scored as 1. The scores below the diagonal of unity are reciprocals and hence judgments pertaining to the upper region of the triangle, which is right hand side above the diagonal, are to be considered for evaluating the alternatives (Kablan, 2004).

The AHP decision modelling approach is based on the eigenvector analysis technique mentioned in Kablan(2004) and is denoted in the matrix for criteria C1, C2,…..,Cn. The numerical values assigned to aij are as per Saaty scale illustrated in the previous Table 5.1 'A' is the consistency matrix of the judgments and Saaty's (1980) method would enable the users to calculate K (the vector of weights) which is the principal right eigenvector of the matrix A.λ max is the highest value of the eigen value of matrix A and Z is the identity matrix and K is the eigenvector. When the pair-wise matrix is perfectly consistent then λ will correspond to the equal number of alternatives under consideration (n). The consistency index (CI)

and the random consistency ratio (CR) are computed according to Kablan (2004) and as indicated in Figure 5.4.

The Random Index is the average value of the Consistency Index for random matrices using the Saaty (1980) scale, which is further based on Forman's (1990) random indices. Moreover, Saaty (1980) only accepts a matrix as consistent if and only if Consistency Ratio < 0.1 (Alonso & Lamata, 2006).



$(A- \lambda \max Z)K=0$

$CI= (\lambda \max-nZ)/n-1$

$CR= CI/RI$

Figure 5.4 – Matrix approach towards Analytical Hierarchical Process (Forman, 1990; Saaty, 1980; Alonso & Lamata, 2006)

The consistency ratio provides an insight on the consistency of the matrix with reference to a purely random matrix. The values of the random index are obtained from published tables for every size of the matrix, n (n is also the no. of criteria). When the consistency ratio ≤0.10 the decision makers pair-wise comparisons are considered consistent (Kablan, 2004; Lee et al., 2007; Zhong-Wu et al., 2006; Hon et al., 2005).

5.4.3. A simple explanation of the AHP process and computation of the consistency index

Figure 5.5 represents the computation process of AHP after collecting the data from the pair wise comparison, for an example with 3 criteria (N=3).

Criteria	A	B	C	Nth root	Priority Vector (PV)
A					Nth root of A/ Total Nth Root
B					Nth root of A/ Total Nth Root
C					Nth root of A/ Total Nth Root
SUM	SUM A	SUM B	SUM C	Total Nth Root	Total adds to 1.
SUM*PV	(SUM A)* PV of A	(SUM A)* PV of B	(SUM A)* PV of B		

Figure 5.5 – Simplified explanation of Analytical Hierarchical Process

The required steps can be described as follows:

Step 1. The pair-wise comparison starts from each row from left hand side towards every criterion on the right hand side mentioned in the columns. (Direction denoted by the bold arrow ⟶ pointing towards the right).

Step 2. The values in each row are multiplied (A v/s A, A v/s B and A v/s C) and the cube root is computed. This is because n=3 (as in no. of criteria) so nth root is cube root.

Similarly, the pair wise comparison is conducted for B and C from their respective rows.

Step 3. The numerical values of the nth root are added together (denoted by the block arrow pointing downwards ⇩).

Step 4. The values of each nth root for each row is normalized i.e. the value of each nth root of each row is divided by the total sum of all the nth roots. As a result the normalized value of all the nth roots would total to 1. This is similar to the concept of a % percentage, but only without the changes in decimal place by multiplication of 100. The normalized values are also known as priority vector (PV).

Step 5. The numerical scores in each column (starting from A) from top to down are added to compute SUM-A. This SUM-A is multiplied by the priority vector (or

normalized value) to obtain a SUM*PV value for A. The direction is denoted by the square dotted arrow pointing downwards ⇣)

The SUM*PV of A and B and C are added up to obtain λmax.

Step 6. The consistency index is calculated by the following formula: (λmax-N)/(N-1).

Step 7. The consistency index divided by the random index presented in Table 5.2 (based on the number of criteria) gives the consistency ratio.

Table 5.2. – Random Index with respect to the number of criteria (Forman, 1990; Saaty, 1980; Alonso & Lamata, 2006)

N (number of criteria)	Random Index (RI)
1	0.00
2	0.00
3	0.58
4	0.90
5	1.12
6	1.24
7	1.32
8	1.41
9	1.45

If the Consistency Ratio (CR) <0.10, the experts' pair-wise comparisons are considered to be relatively consistent. Meanwhile, if the Consistency Ratio (CR) > 0.10, the experts have to be consulted again for their pair-wise comparisons and the source of inconsistencies have to be identified.

The AHP technique is suitable in situations where multiple diverse criteria are to be considered for decision-making (Liang et al., 2006). The diversity can range from economical, social, emotional and technological in nature to name a few. The simplicity coupled with the concept of prioritization. Moreover, the quantitative

scale permits mathematical calculations of the prioritization for obtaining a single overall index to denote the justifiability of an alternative under consideration. In previous research endeavours, AHP has been considered for group decision-making in combination with the Delphi approach (Lai et al., 2002). The AHP method does deliver insight into the conflicts between various experts who participate in pair-wise comparison, which would eventually govern the consistency ratio, and the judgments.

5.4.4. Advantages and limitations of the AHP and incorporation of enhanced flexibility in MCHM.

The AHP technique is suitable in situations where multiple diverse criteria are to be considered for decision-making (Liang et al., 2006). The diversity can range from economical, social, emotional and technological in nature to name a few. The simplicity coupled with the concept of prioritization. Moreover, the quantitative scale permits mathematical calculations of the prioritization for obtaining a single overall index to denote the justifiability of an alternative under consideration over other alternatives that are being evaluated similarly. In previous research endeavours, AHP has been considered for group decision-making in combination with the Delphi approach (Lai et al., 2002). The AHP method does deliver insight into the conflicts between various experts who participate in pair-wise comparison, which would eventually govern the consistency ratio, and the judgments.

The MCHM as discussed is based on the conventional simplified AHP approach, as defined by Saaty (1980). The MCHM as discussed in Chapter 3 is to act as an effective mediator between the Engineering and Project management activities of medical devices. For instance, while the senior manager can define corporate growth strategy for the company, the project manager can use the MCHM for selecting the most suitable medical device for development.

The arrangement of criteria of the MCHM, as shown in Figure 3.2 and Figure 3.6 of Chapter 3 denotes a network which resonates with Saaty's (1990a; 2006b) Analytical network Process (ANP). The ANP also uses a pair-wise comparison to

illustrate the inter-dependency between various criteria in order to choose the most suitable alternative. This structure is unique in comparison to AHP; wherein the criteria are considered independent of each other. As discussed in the previous section of this chapter that the criteria are usually interrelated and the context of the co-relation between the criteria change dramatically for various types of economic structures and geographical locations. Therefore, the senior management can implement suitable business strategies based on this decision model in order to reduce the overall ecological and negative social impacts. The core purpose is to avoid a situation wherein the company reduces the negative externalities at one end and eventually increase the degree of social/ecological externalities elsewhere.

The inter-connected framework of the MCHM resonates with the phenomena of complex adaptive system, in which systems continuously interact with each other by virtue of multiple feedback loops. In the case of a product development enterprise, such as an innovative medical device company, the continuous exchange and dissemination of information and knowledge leads to the commercialization of robust products/services at a much faster rate (Chiva-Gomez, 2004). The MCHM does not explicitly endorse any specific restriction on the inter-relations between the criteria. Furthermore, the MCHM prefers to preserve the aforementioned hierarchical structure in scenarios where irreconcilable conflicts arise out of the dynamic interactions between the resources as stated in Section 3.3 of Chapter 3.

The AHP approach considered in this thesis aims to coherently combine the experience and knowledge from the chosen experts (from academia and Industry) by utilizing the quantitative scoring scale devised by Saaty(1980). In contrast to the conventional approach of determining points of conflicts between various experts, the pair-wise comparison has been considered with respect to specific pertinent contexts, so as to alleviate the impediment of 'forcibly' reconciling conflicts via mathematical calculations which would eventually denote a single overall score without portraying the holistic picture of the situation on which the decisions are being made. For instance, in the experience of one expert, the introduction of end-

of-life options is more important than increasing employment in the company. The reason being that recycling, remanufacturing and reusing can increase employment in the company or with other collaborators who conduct end-of-life options. However, end-of-life is not necessarily a profitable or even an environmentally sustainable approach if excessive resources have to be expended in transportation and re-transforming them in a market that changes rapidly and dynamically (Nasr and Thurston, 2006). This is also the reason for the Tier 1 to contain the minimum degree of profitability and reduction of emissions/waste so as to ensure that when such aforementioned conflicts occur in certain specific situations for a medical device company, then more rational decisions can be implemented.

This implies that the scoring by a certain expert is relevant in one particular situation and becomes less relevant in another situation. Therefore, the goal is to articulate the inputs from the experts during the semi-structured interviews (or informal conversational interviews) based on the research propositions in Section 5.3.1 while conducting pair-wise comparison. This justifies the reason for not defining an interview script for the pair-wise comparisons.

The inputs provided by experts with respect to the specific contexts can act as a more suitable approach to address conflicts that arise while considering either two of more criteria between each other. Furthermore, these inputs would be incorporated during the case study activities, which have been discussed in detail in Chapter 6.

Furthermore, as discussed in the subsequent chapter that when the pair-wise comparison of the experts are discussed, a specific short note is mentioned on the relevant context with respect to more than one business and economic scenarios. For example: A medical device company in Portugal should focus more on employment than market share. An Academician from a Portuguese University mentioned this comparison, which was in reference to the on-going European Union financial crises. Because, in his opinion growth in market share eventually takes place when there is increase in disposable income of the population to

purchase goods/services, as this income is generated by virtue of employment or entrepreneurship (small-medium/large scale) (D'Alessandro et. al, 2009).

Therefore, the essential ingredient of flexibility is introduced in this proposed MCHM wherein the relevant contexts are mentioned so that the pair-wise comparisons made by the chosen experts can be considered across all types of medical devices companies (small/large) across various geographical and economic circumstances.

5.5. Concluding Points

In this chapter, the importance of case study method is discussed in detail with primary focus on expert interviews using 'Informal conversational Interview' process for conducting the case study and ensuring the quality of the design of the case study. Moreover, the case study method provides the freedom to the user to test and validate the propositions/frameworks in a 'real life setting' and determine the prospects of external validity of other case studies as well. The most critical point to be noted in this chapter and throughout the whole thesis is that the MCHM, which is based on conventional AHP, is applicable at the design/development phase of the Medical Devices, as opposed to choosing an off-the-shelf medical device available in the market. The selection of a suitable off-the-shelf medical device can be conducted if certain less relevant criteria are excluded; nevertheless the choice in this case is given to the user of the MCHM provided the regulatory compliance and bare minimum profitability are maintained.

Moreover, during the design/development phase the medical devices companies are bound to encounter a multitude of uncertainties at the socio-economic and business frontiers. As a result the proposed forms of flexibility provided by the pair-wise comparisons from the Experts coupled with short-notes from the interviews (in the subsequent chapter) are mentioned to mitigate the impact of such uncertainties. This is also one of the reasons for the pair-wise comparison method of the AHP decision modelling approach to be used for capturing insight and tacit knowledge pertaining to product development and not for selecting any

specific alternative over other alternatives for which aspects of AHP method such as consistency index/ratio become less relevant or even irrelevant.

The objective is to enable the users of the model to adapt within less time to their specific business and economic scenario within the design/development phase so as to prevent or minimize expensive corrections.

Chapter 6

Results and Discussion

6.1. Introduction

With reference to the decision modelling approaches and product development frameworks described from Chapter 2 up to Chapter 4 with their research methodologies as outlined in Chapter 5. This chapter reveals in detail, the outcomes of the discussed methodologies for evaluating the effectiveness of the proposed decision modelling approaches and product development frameworks.

This chapter commences with Section 6.2 that describes the pair-wise comparison of the criteria mentioned in Tier 2 and Tier 3 of the MCHM. The pair-wise comparison which was conducted by interviewing a total of seven Experts from Academia and Industry who not only assigned suitable numerical scores while comparing one criterion with the other criteria but also disseminated their own expertise as well as experience (including insights) towards incorporating overall Sustainability during product development.

On the other hand, Section 6.3 describes the results obtained from the another set of experts from Industry and Academia who provided their feedback by virtue of a 'informal conversational interview' and a structured questionnaire for evaluating the multifaceted model which illustrates the role of the MCHM in design optimization in coordination with a wide range of technical and non-technical tools. This was in contrast to an active application of the multifaceted model within the design engineering activities of a company engaged in product development. The reason for adopting the stated methods of evaluation is attributed to the availability of the time (at least 1 year) and the substantial reconfiguration of a company's design engineering process, which leads to undesired opportunity cost. Moreover, as many of the technical tools in

computational design engineering in conjugation with other technical tools such as production machinery and conceptual tools such as QFD <www.qfdi.org> have been well studied in both academic and industrial circles. Consequently, obviating the requirement of a detailed industry based evaluation. Furthermore, the objective of the thesis entails the evaluation of the MCHM (inspired from AHP) for conducting product development and even product design which beyond the conventional role of decision modelling.

Meanwhile, Section 6.3 describes the results from the case studies conducted within the 6 entities as mentioned in Chapter 5. The research propositions as outlined in Section 5.3.1 of Chapter 5 have been evaluated within the case study approach through interviews, questionnaires and in certain scenarios even by active participation. Furthermore, at the end of this chapter a 2 page note is mentioned which establishes the co-relation between the three sections of this chapter and the significance of the various techniques considered to evaluate the proposed decision modelling approaches and product development frameworks.

6.2. Pair-wise comparison of Tier 2 and Tier 3 of the Multicriteria Hierarchical Model (MCHM)

As discussed previously in Chapter 2 and 3, the three aforementioned domains of sustainability are inter-connected within each other. Therefore, assigning either a financial value or a numerical value for decision making has proven not only to be reductionist in nature, but even suffering from poor accuracy (Hermele, 2009; Jansen, 1992).

This impediment is the core justification for the thesis to adopt a more qualitative approach towards the pair-wise comparison procedure pertaining to the criteria outlined in Tier 2 and Tier 3 of the Multi-criteria hierarchical model (MCHM) which as mentioned in Chapter 3 and 4 is remotely similar to the Analytical Hierarchical Process (AHP).

The categorization of the pertinent criteria into three tiers with the primary tier being non-negotiable to which any or all criteria selected from Tier 2 and Tier 3 have to compulsorily satisfy. The product engineers and managers would

collaborate to ensure that the Enterprises' goals and stakeholders' requirements are incorporated within the design phase of the product. Moreover, the design optimization process that would generate suitable designs candidates as alternatives to which the MCHM would be used for further screening.

In this thesis, no particular case study (discussed in the subsequent sections) contains any design candidates for which the MCHM has been utilized for selecting a suitable design candidate. On the contrary, the feedback from the pair-wise comparison interviews conducted with 7 experts was utilized to guide the case study participants for incorporating overall sustainability within their product development process. The experts were consulted for assigning suitable scores for each pair-wise comparison, as mentioned in Section 5.4 of Chapter 5. The objective was to gain insight into their tacit and explicit knowledge of addressing circumstances pertaining to diverse business, technical and economic situations. For instance, developing advanced medical devices in geographical regions with diverse economic frameworks that range from a stronger presence of Government (e.g.: Sweden), medium presence of Government (e.g.: Portugal) and low presence of Government (e.g.: United States).

Therefore, the approach in this thesis is aimed at articulating the responses from the experts with reference to their pertinent contexts, especially when in certain economic and political circumstances; more than one criterion can be addressed simultaneously. For instance, as stated previously in Section 5.4 in Chapter 5, the end-of-life options can contribute to increased employment in a certain business and economic situation and in another situation can prove to be expensive and even ecologically detrimental in nature (Nasr and Thurston, 2006). The MCHM, which is based on a modified version of a conventional AHP, is envisioned to address more dynamic circumstances between the aforementioned domains of Sustainability. As a result, the focus (or the importance) on the consistency ratio has been kept at the bare minimum in this thesis is solely because the pair-wise comparison method is to gain insight into the product development expertise of the experts with respect to diverse business scenarios and economic circumstances. The other reason for the consistency ratio to be less significant is

because the product development teams can opt for either one or more of the criteria mentioned in Tier 2 and Tier 3 of the MCHM. While in conventional AHP the consistency ratio requires all the mentioned criteria and sub-criteria to be considered. The calculations of the consistency ratios have been mentioned in the subsequent sub-sections but their importance is kept at a bare minimum.

Furthermore, the conventional AHP does not explicitly account for the inter-dependencies between various criteria, unlike its Analytical Network Process counterpart. However, the principle of prioritization which is essential for the medical device development with simultaneous consideration of bare minimum overall sustainability (as in Tier 1 of the MCHM) is the key principle attribute for which a modified version of a conventional AHP has been proposed in the form of the multicriteria hierarchical model (MCHM) (Saaty, 1990a, 2006b). Moreover, as every criterion in the MCHM is interrelated with other criteria; nevertheless certain criteria exert a stronger influence on the fate of the medical device company and the other criteria. As a result, the most crucial criteria outlined in Tier 1 are imperative for any of the other criterion in Tier 2 and/or Tier 3 to be successfully materialized. This justifies the MCHM to be organized into three tiers. For instance, a medical device that is modular in nature (Tier 2) and profitable (Tier 1), but does not attain regulatory compliance (Tier 1) would never be allowed to enter the market. Thus, incurring substantial financial losses for the company who develops/manufactures it, as product design can incorporate both regulatory compliance as well as being modular in nature.

The stated approach of articulating the responses via interviews from the experts is envisioned to provide flexibility into the MCHM to be applicable to a diverse range of socio-economic circumstances (e.g.: Sweden and United States). Moreover, such an approach also delivers an additional benefit of minimizing conflicts between the socio-economic circumstances by expounding the underpinnings of the three domains of sustainability and enabling the senior management in collaboration with the product development teams to chart out suitable business and product development strategies.

6.2.1. Evaluating the validity of the MCHM: Informal Conversational Interview approach

The chosen experts represent both academia and industry for the Tier 2 and Tier 3 pair-wise comparison interviews. The experts approved the three-tier structure and in addition recommended an increasing degree of Cost Effectiveness and lowering of the overall Environmental Impact from Tier 1 onwards up to Tier 3.

During the interviews, all the Experts unanimously agreed that the product design configuration, accessibility and attributes of the listed resources (Section 3.3 in Chapter 3), product commercialization strategies and current economic scenario (such as Keynesian Economics v/s Free Market Economics) as discussed by Wapshott (2011) would define the success or failure of the Enterprise to accomplish its desired objectives.

Further literature review on the AHP revealed that utilizing a fuzzy logic approach towards decision modelling in AHP has proven to be substantially successful, especially in cases that involved selecting suitable business processes for reverse logistics and supply chain distribution for Remanufacturing (Hummel et al., 2002; Nukala and Gupta, 2005). However, when compared to the current economic and business environment that entails dynamic exchange of information with relatively high uncertainty would eventually render the applicability of Fuzzy logic in decision modelling to become less effective (Siler and Buckley, 2005). Therefore, the justification of adopting regular human intervention for finalizing appropriate decisions is well founded, notwithstanding the utilization of improvised decision modelling tools.

6.2.2. Results from the interviews and pair-wise comparisons

As illustrated in Figure 6.1, the academicians (Experts 1 to 4 and 7) prioritized End-of-life (EOL)/Modularity; Employee Welfare and Contribution to Income Distribution of the Stakeholders in contrast to investments in Community Welfare Programs, as they envisioned their chosen criteria to eventually contribute towards overall social welfare and environmental stability. The justification stated by these experts was that employment and income distribution would increase the

purchasing power of the employees to further contribute to overall socio-economic growth, including housing (D'Alessandro et. al, 2009). Thus, further propagating the growth of commerce and business (Handler & Grossman, 2009). Almost all the experts from both academia and industry stated that end-of-life (EOL) options/modularity would eventually lead to increase in employment provided the cost model is optimized to not be more expensive and the resources expended for transportation and re-processing of materials should not have a detrimental ecological impact.

On the other hand, Experts from Industry (Expert 5 and 6) denoted a higher priority towards Corporate Expansion and Market Share, as in their opinion these two criteria would eventually contribute to the overall socio-economic development of the stakeholders, in terms of increase in employment and income distribution. Moreover, in the opinion of the Industry Experts the two aforementioned criteria namely, Corporate Expansion and Market Share would eventually entail Product Modularity and EOL options as one of the key business strategies (Wapshott, 2011). As a result, as EOL options and modularity eventually lead to employment and better ecological sustainability, while concurrently resulting as an outcome of a company's growth objectives is one of the major reasons for this criterion to receive a lower ranking by some of the experts from Industry.

Meanwhile, Community Welfare Programs received higher ranking than Business Growth/Market Share as the Experts from Academia argued in favour for the presence of social capital which is crucial for building up the economy as a whole on which corporate growth can occur (Wapshott, 2011).

Both, Academicians and Experts from Industry possess their own specific perspectives on the role of Business in socio-economics, product design and environmental impact. However, substantial insight can be gained from their diversified viewpoints, as the Experts from academia were providing their feedback with respect to the on-going EU economic crises. As a result, the focus was more on employment, housing, income distribution and end-of-life options.

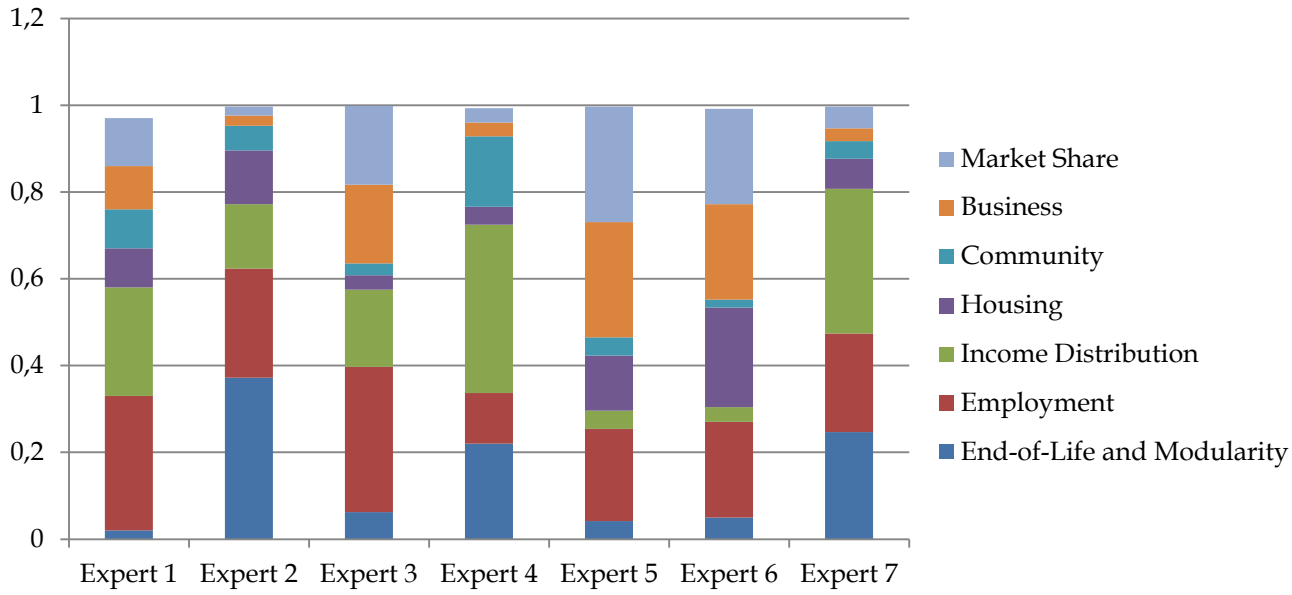


Figure 6.1 – Scores assigned by experts from academia and Industry during pair-wise comparisons.

During the interviews, one of the academic experts stated that Small and Medium sized Enterprises who develop medical devices usually focus more on growth in sales for a time of 5 years and later look forward for expansion. Meanwhile, large sized Enterprises opt for increasing market share and business growth (as well as diversification).

One of the academics expert stated that in countries such as Sweden and Denmark that have a stronger presence of Government in regulation of financial markets, healthcare, social programs and unemployment benefits. This is one of the reasons the companies operating in these geographical region are requested to report their corporate social responsibility activities (such as employee housing, income distribution and social activities). However, the respective governments do not define magnitude of socially responsible activities and the enterprises are provided with freedom to opt for any degree (even minimal) of socially responsible commitments. This is also one of the reasons, companies in these geographical regions prefer not to dedicate more priority towards socially

responsible activities owing to the substantial presence of the Government and the high quality of social welfare services they provide via the tax revenue (Krugman, 2012).

This situation is quite contrary to what is found in countries such as the United States, where the role of Government in the Economy, Financial markets and social programs is very small. This is also, one of the reasons large corporations in these nations are provided with tax benefits and other incentives in terms of access to easier credit for their corporate social responsibility endeavours.

For companies operating in geographical regions where the government has a stronger presence in economics and also encourages environmental sustainability, companies tend to lobby with the respective governments to implement legislation that favours more environmentally sustainable products. The reason being that fierce competition is originating from distant countries such as India and China is mitigated because the companies operating in these distant countries are known to externalize their social and environmental costs to increase their profits (Stiglitz, 2007). Furthermore, substantial quantity of non-renewable fuels is expended eventually releasing waste/emissions when material goods are imported from distant geographical locations.

The feedback obtained from these experts would be considered during the case studies, which are discussed in the subsequent sections of this Chapter.

6.2.3. Calculation of Consistency Ratio

This section illustrates the calculation of the consistency index as outlined in Section 5.4 of Chapter 5 and provides additional details on the numerical scores assigned by the experts from academia and industry.

Table 6.1. – Pair-wise comparison by Expert 1 from Academia

Criteria	EOL-Mod	Employ	Income	Housing	Community	Business	Market Share	Nth root	Weight
EOL-Mod	1	1/9(0.11)	1/3 (0.33)	1/7 (0.142)	1/3 (0.33)	1/8 (0.125)	1/8(0.125)	0.22	0.02
Employ	9	1	7	1/3 (0.33)	7	3	3	2.78	0.31
Income	3	1/7 (0.142)	1	7	7	4	4	2.3	0.25
Housing	7	3	1/7(0.142)	1	4	1/7(0.142)	1/8(0.125)	0.8	0.09
Community	3	1/7(0.142)	1/7(0.142)	¼(0.25)	1	5	5	0.87	0.09
Business	8	1/3 (0.33)	¼ (0.125)	7	1/5 (0.2)	1	1	0.89	0.10
Market Share	8	1/3 (0.33)	¼ (0.25)	8	1/5 (0.20)	1	1	1	0.11
SUM	39	9.778	8.989	23.722	19.73	14.267	14.25	8.86	1
SUMXWeight	0.78	3.03	2.24	2.13	1.77	1.4267	1.5675	12.94 (λ max)	
Consistency Index	12.94-7/6=0.99								
Consistency Ratio	0.99/1.32=0.75								

This expert from academia assigned lower ranking for end-of-life options and community welfare projects, while Employment; Income Distribution, Housing and Business Growth/Market Share have received higher ranking. Only when Business Growth/Market Share is compared with Community Welfare Programs is assigned with a lower ranking. Moreover, in the expert's viewpoint end-of-life can be accommodated as a part of Business Growth/Market Share and hence less importance was assigned to this criterion.

Table 6.2. – Pair-wise comparison by Expert 2 from Academia

Criteria	EOL-Mod	Employ	Income	Housing	Community	Business	Market Share	Nth root	Weight
EOL-Mod	1	7	4	2	6	7	8	4.07	0.372
Employ	1/7 (0.142)	1	8	9	6	4	5	2.76	0.252
Income	¼(0.25)	1/8(0.125)	1	4	4	7	9	1.63	0.148
Housing	½ (0.5)	1/9(0.11)	¼(0.25)	1	8	9	9	1.36	0.124
Community	1/6(0.166)	1/6(0.166)	¼(0.25)	1/8(0.125)	1	6	8	0.63	0.057
Business	1/7(0.142)	¼ (0.25)	1/7 (0.142)	1/9(0.11)	1/6(0.166)	1	1	0.26	0.023
Market Share	1/8(0.125)	1/5(0.2)	1/9(0.11)	1/9(0.11)	1/8(0.125)	1	1	0.23	0.021
SUM	2.325	8.851	13.752	16.345	25.291	35	41		
SUMXWeight	0.8649	2.230	2.035	2.026	1.441	0.805	0.861	10.262 (λ max)	
Consistency Index	10.262-7/6=0.543								
Consistency Ratio	0.543/1.32=0.41								

In contrast to Expert 1, this Expert has assigned a very high score for Modularity/End-of-life options, which is even higher than Employment owing to the perspective of the stated criterion would eventually contribute towards job growth. Similarly, EOL options/Modularity was higher ranked than Housing and Income Distribution. Meanwhile, similar to Expert 1 the Business Growth/Market Share was assigned a lower ranking compared to Community Welfare Programs even when this criterion received a lower ranking compared to other criteria. The reason is that these two experts argue in favour of the presence of social capital as a critical factor in economic growth.

Table 6.3. – Pair-wise comparison by Expert 3 from Academia

Criteria	EOL-Mod	Employ	Income	Housing	Community	Business	Market Share	Nth root	Weight
EOL-Mod	1	1/7(0.142)	1/7(0.142)	8	8	1/7(0.142)	1/7(0.142)	0.59	0.062
Employ	7	1	9	7	7	1	1	3.15	0.335
Income	7	1/9(0.11)	1	8	6	1	1	1.67	0.178
Housing	1/8(0.125)	1/7(0.142)	1/8(0.125)	1	1/7(0.142)	1	1	0.31	0.0330
Community	1/8(0.125)	1/7(0.142)	1/6(0.166)	7	1	1/6(0.166)	1/6(0.166)	0.26	0.0277
Business	7	1	1	1	6	1	1	1.7	0.1812
Market Share	7	1	1	1	6	1	1	1.7	0.1812
SUM	29.25	3.536	12.433	33	34.142	5.308	5.308		
SUMXWeight	1.81	1.18	2.21	1.089	0.945	0.9618	0.9618	9.1576 (λmax)	
Consistency Index	9.1576-7/6=0.3596								
Consistency Ratio	0.3596/1.32=0.272								

In this Expert's viewpoint, end-of-life options are not as important as EOL is a component of Business Growth/Market Share which in itself is considered equivalent to Community Welfare Programs. Meanwhile, Employment and Income Distribution is given a higher ranking. In contrast, housing is given much lower ranking as the Expert argued that social capital, income distribution and economic growth would eventually lead to growth in housing.

Table 6.4 – Pair-wise comparison by Expert 4 from Academia

Criteria	EOL-Mod	Employ	Income	Housing	Community	Business	Market Share	Nth root	Weight
EOL-Mod	1	9	1/9 (0.11)	8	1	7	7	2.31	0.22
Employ	1/9 (0.11)	1	1/6 (0.166)	6	1	6	6	1.2	0.117
Income	9	6	1	7	1	7	6	3.98	0.388
Housing	1/8 (0.125)	1/6	1/7	1	1	1	1	0.42	0.041
Community	1	1	1	1	1	6	6	1.66	0.162
Business	1/7(0.142)	1/6 (0.166)	1/7 (0.142)	1	1/6 (0.166)	1	1	0.33	0.0322
Market Share	1/7 (0.142)	1/6 (0.166)	1/6 (0.166)	1	1/6 (0.166)	1	1	0.34	0.033
SUM	11.519	17.498	2.726	25	5.332	29	28		
SUMXWeight	2.53	2.047	1.057	1.025	0.863	0.9338	0.924	16.901(λ max)	
Consistency Index	16.901-7/6=1.6503								
Consistency Ratio	1.6503/1.32=1.25								

This Expert from Academia also argues in favour of the role of social capital for a prosperous economy and hence has ranked Community Welfare Programs equal to other criteria and higher than Business Growth/Market Share. Similarly, Income Distribution has been given a higher degree of importance compared to End-of-life, as the former criterion generates the purchasing power of the consumers for sales of goods/services and the Expert considered EOL as a part of Business Growth/Market Share. Meanwhile, Business Growth/Market Share have consistently been given lower rankings.

Table 6.5. – Pair-wise comparison by Expert 5 from Industry

Criteria	EOL-Mod	Employ	Income	Housing	Community	Business	Market Share	Nth root	Weight
EOL-Mod	1	1/5	1	1/5	1	1/5	1/5	0.398	0.042
Employ	5	1	5	1	5	1	1	1.99	0.212
Income	1	1/5	1	1/5	1	1/5	1/5	0.398	0.042
Housing	5	1	5	1	5	1/5	1/5	1.2	0.127
Community	1	1/5	1	1/5	1	1/5	1/5	0.398	0.042
Business	5	1	5	5	5	1	1	2.5	0.266
Market Share	5	1	5	5	5	1	1	2.5	0.266
SUM	23	4.6	23	12.6	23	3.8	3.8		
SUMXWeight	0.966	0.9752	0.966	1.6	0.966	1.01	1.01	7.4932(λ max)	
Consistency Index	7.4932-7/6=0.0822								
Consistency Ratio	0.822/1.32=0.06								

Compared to Experts 1 to 4, the responses from this Expert from Industry were found to be consistent with the Consistency Ratio being lower than 0.10

From an Industry related Expert's standpoint End-of-life, Income Distribution and Community Welfare Programs are ranked lower compared to other criteria such as Business Growth/Market Share. The reason is that the aforementioned three criteria in the Expert's opinion are strongly related to the growth objectives of the Enterprise.

Table 6.6. – Pair-wise comparison by Expert 6 from Industry

Criteria	EOL-Mod	Employ	Income	Housing	Community	Business	Market Share	Nth root	Weight
EOL-Mod	1	1/6(0.166)	6	1/7(0.142)	6	1/8(0.125)	1/8 (0.125)	0.5	0.05
Employ	6	1	7	1	7	1	1	2.2	0.22
Income	1/6(0.166)	1/7(0.142)	1	1/7(0.142)	7	1/6(0.166)	1/6(0.166)	0.34	0.034
Housing	7	1	7	1	7	1	1	2.3	0.23
Community	1/6(0.166)	1/7(0.142)	1/7(0.142)	1/7(0.142)	1	1/7(0.142)	1/7(0.142)	0.18	0.018
Business	8	1	6	1	7	1	1	2.2	0.22
Market Share	8	1	6	1	7	1	1	2.2	0.22
SUM	30.332	4.45	33.142	4.426	42	4.433	4.433		
SUMXWeight	1.5166	0.979	1.12	1.01798	0.756	0.9752	0.9752	7.338(λ max)	
Consistency Index	7.338-7/6=0.056								
Consistency Ratio	0.056/1.32=0.042								

In the viewpoint of this Industry related Expert who has ranked Employment and Business Growth/Market Share higher compared to End-of-life, Income Distribution and Community Welfare. As in this Expert's opinion, End-of-life can be categorized as a part of growth strategy and not necessarily result in high employment and increase in employment generates more tax revenue and better purchasing power of the consumer for a prosperous economy.

Table 6.7 – Pair-wise comparison by Expert 7 from Academia

Criteria	EOL-Mod	Employ	Income	Housing	Community	Business	Market Share	Nth root	Weight
EOL-Mod	1	5	1/3(0.33)	3	3	7	7	2.5	0.247
Employ	1/5(0.2)	1	1	7	5	7	7	2.3	0.227
Income	3	1	1	7	5	7	7	3.38	0.333
Housing	1/3(0.33)	1/7(0.142)	1/7(0.142)	1	1	3	5	0.71	0.07
Community	1/3(0.33)	1/5(0.2)	1/5(0.2)	1	1	1	1/5(0.2)	0.42	0.04
Business	1/7(0.142)	1/7(0.142)	1/7(0.142)	1/3(0.33)	1	1	1/3(0.33)	0.31	0.03
Market Share	1/7(0.142)	1/7(0.142)	1/7(0.142)	1/5(0.2)	5	3	1	0.5	0.05
SUM	5.144	7.626	2.956	19.53	21	29	27.53		
SUMXWeight	1.2705	1.731	0.9843	1.3671	0.84	0.87	1.3765	8.4394(λmax)	
Consistency Index	8.4394-7/6=0.2399								
Consistency Ratio	0.2399/1.32=0.18								

Similar to this Expert's other Academic Experts has assigned End-of-life, Employment and Income Distribution with a higher priority in contrast to Business Growth/Market Share and Community Welfare Programs. The justification is also rooted in the role of social capital and safer environment, which would lead to a better community and prosperous commerce.

6.2.4 Concluding Points for Pair-wise Comparison

For a Medical Device Enterprise, the role of regulatory agencies, the economic policies of the geographical region, the business growth objectives of the Enterprise and the configuration of the device are crucial for the success/failure of the development endeavour. The device configuration on the basis of the resources would govern the inclusion of end-of-life options/modularity, profitability and opportunities to increase employment. As outlined during the pair-wise comparisons, Experts from Academia have reinforced their viewpoint on the crucial role of social capital in the propagation of a prosperous economy (Wapshott, 2011). For instance, better income distribution via improved wages for employees of an Enterprise and more opportunities of employment to be created by the Enterprise leads to sales of goods/services (Fishman, 2012). Meanwhile, the Experts from Industry stated that Business Growth/Market Share would eventually bring about better income distribution and employment opportunities for the benefit of the overall social welfare of the stakeholders; nevertheless they did not deny the role of a social capital necessary for the propagation of commerce but rather were in support of corporate related growth to materialize the socially relevant objectives.

6.3. Evaluating the role of Multicriteria Hierarchical Model (MCHM) in Design Optimization

6.3.1. Introduction and Recapitulation

The results discussed in this section are pertaining to the evaluation of the proposed Multifaceted Framework as discussed in Chapter 4, which involves the active role of the Multicriteria Hierarchical Model in design optimization with reference to a multitude of technical and non-technical tools.

The methodology defined in Chapter 5 utilizes the approach of 'informal conversational interview' and a structured questionnaire, in contrast to an active application of the multifaceted model in an industrial setting. The justification lies in the limitation of time for the implementation in order to validate the Multifaceted Framework at an industrial scale. On the other hand, the availability of academia and industry experts, who due to their in-depth experience can provide substantial insight on the conceptual validity of the multifaceted framework. Furthermore, as discussed in detail in this section, the effectiveness is subjective to specific design engineering scenarios and the product configuration, which is further based on the enterprises' obligations and ambitions.

The experts selected and contacted for the evaluation of the Multifaceted Framework were not the same as the experts for the pair-wise comparison.

Accordingly to Chapter 3, each criterion within the three tiers is comprised of one or more specifications with their "minimum acceptable and maximum achievable values". For example, the regulatory requirements for a pacemaker have to be functional for a minimum period of 2 years (minimum acceptable). Moreover, the medical device company's knowledge in engineering and materials sciences reveals that for a given set of materials and engineering design architectures, the pacemaker design can survive from 2 years to up to 5 years. However, the reliability engineering required for a 5-year operation life span would be more expensive and only a small segment of the market may opt for such a robust design (maximum achievable).

As a result, the product engineers and managers aim for obtaining the most optimal values of these specifications to at least attain a bare minimum magnitude of sustainability, in terms of environmental safety, obligatory stakeholder considerations and desired level of profits.

Inspired from previous research endeavours; wherein AHP has been utilized for design optimization of a product design and even programmed via object oriented C# language to select suitable candidates for product development or remanufacturing (Ghazalli & Atsuo, 2009; Singh, 2006; Wang et al., 2010). This thesis also studies the opportunity to incorporate the decision modelling approach of the Multi-criteria Hierarchical Model (MCHM) within design optimization activity that not only encompasses product specifications but also addresses stakeholders' considerations such as increase in employment (Tier 2) and Community Welfare (Tier 3) in terms of the profitability. The Figure 3.6 elucidates the role of product design with the utilization of resources (as mentioned din section 3.3 of Chapter 3) to gain profitability that can be further invested in building the company and the social capital for the stakeholders. The details are discussed in Chapter 3 with substantial focus on prior research endeavours and the novelty explored in this thesis.

The design optimization would actively involve a previously stored (and continuously updated) knowledge curve, close coordination of interconnected technical (e.g. Finite Element)/non-technical (e.g.: QFD <http://www.qfdi.org>) tools with the aforementioned problem solving techniques for resolving conflicts (TRIZ/Design by Analogy). The knowledge curve in this thesis is focused mainly towards knowledge based engineering tools and expert systems (Corallo et al., 2009; Price et al., 2010). Consequently, the proposed approach is substantially pragmatic in nature as it encompasses social criteria and aligns with the Total Product Life Cycle Development strategy recommended by the FDA.

6.3.2. Informal conversational Interviews with a structured Questionnaire

i) The role of experts and the structure of the Questionnaire

The experts were interviewed by the 'informal conversational interview' approach during the filling up of the questionnaire. The responses were collected by email and re-confirmed by a phone interview. Moreover, the responses from these experts have been coherently articulated with their specific contexts to determine the circumstances in which the proposed multifaceted model for design optimization using the MCHM approach would function effectively or encounter additional undesired impediments.

The objective of this research methodology is to validate the ability of the MCHM to actively participate in product design that is a key phase of product development (Trotta, 2010).

Some of the experts did express the inability of the questionnaire approach to precisely define the diverse circumstances and contexts in which a decision model can play the role of an effective design optimizer in complex engineering design solutions. Therefore, the coupling of interviews and questionnaires was considered to be a suitable approach to alleviate the disadvantages of the two techniques; wherein the questionnaire counters the less structured nature of the informal interviews and the interviews are able to capture the insight and tacit knowledge of the experts pertaining to design optimization activities at a industrial scale with reference to its technical as well as economic feasibility.

Furthermore, only 6 experts chose to answer the questionnaire and provide their feedback via interviews. In this case study, Expert 1 and 2 are from the same University (just like 5 and 6) and their responses were jointly approved for the questionnaire. Meanwhile other experts chose to discuss the multifaceted framework by reviewing the questions and accordingly, preferred to disseminate their insights throughout the interview process instead of filling up the questionnaire.

The questionnaire is outlined as follows:

QUESTION 1: In your experience can an Expert System incorporate a decision making model such an analytical hierarchy process that is a category of multicriteria decision-making?

YES or NO

If YES then how effective (increase in performance) would it be?

LOW [or] MEDIUM [or] HIGH

QUESTION 2: As each domain of expertise namely Design, Training, Operations Management and Logistics, Supply Chain and others would have their own corresponding Expert Systems. Therefore, is it possible to connect all these Expert Systems and by using a codified decision making model such as AHP effectively and moreover efficiently execute the Multidisciplinary Design Optimization Process?

LOW [or] MEDIUM [or] HIGH

QUESTION 3: How effective is an Expert System in Product Design in coordination with CAD/CAM/CAE tools?

LOW [or] MEDIUM [or] HIGH

QUESTION 4: How effective is an Expert System as an Optimizer for Multidisciplinary Design Optimization (MDO)?

LOW [or] MEDIUM [or] HIGH

QUESTION 5: Let us imagine that for the MDO of a cell phone that involves the corresponding learning curves or knowledge systems for Product Design for structural integrity of plastics, plastics processing, product design for structural integrity of metals and metals processing and so on so forth.

So is it possible for multiple Expert Systems and Knowledge Systems to act as an Optimizer for the Multidisciplinary Design optimization task?

YES [or] NO

If YES then how effective it would be?

LOW [or] MEDIUM [or] HIGH

QUESTION 6: How feasible it is to have an infrastructure with Expert Systems for acting as an Optimizer for the MDO process, coupled with other CAD/CAM/CAE tools and conducting environmental life cycle analysis using the SimaPro software (Pre Consultants BV <www.pre-sustainability.com>) and simultaneously conducting Manufacturing Process Management in order to confirm whether the product design is compatible with the manufacturer's production process?

LOW [or] MEDIUM [or] HIGH

QUESTION 7: Based on Question 6 would the inclusion of a High Performance Computing Systems (or better known as a Supercomputer) reduce the processing load of one or multiple Expert Systems?

YES [or] NO

If YES then how effective it would be?

LOW [or] MEDIUM [or] HIGH

QUESTION 8: Scale of funding that is needed for Question 6 and 7?

LOW a few hundred thousands USD$ [or] Medium 1-2 million USD$ [or]

High 3 million USD$ and above

QUESTION 9: Can Expert Systems be effectively combined with TRIZ (use neural networks for obtaining the right set of patents and research cases), Case based reasoning and Design by Analogy to govern Product Design?

LOW [or] MEDIUM [or] HIGH

QUESTION 10: In the above 2 situations how well does XML fare to satisfy needs of interconnectivity and interoperability?

LOW [or] MEDIUM [or] HIGH

The results of the questionnaire are summarized in Table 6.8.

Table 6.8. – Expert feedback for Multicriteria Hierarchical Model (MCHM) in Design Optimization

Question no.	Summary of the Question	Expert 1 and 2	Expert 3	Expert 4	Expert 5 and 6
1	Expert System and Decision Modelling	Yes, High	Yes, Medium	Yes, Medium	Yes, Low
2	Expert Systems with MCHM and Design Optimization	Medium	Medium	High	Medium
3	Expert Systems and Computational Tools	High	Medium	High	Low
4	Expert System in Design Optimization	High	Medium	High	Low
5	Multiple expert systems and knowledge systems in design optimization	Yes, High	Yes, Medium	Yes, High	Yes, Medium
6	Expert systems and a wide range of technical tools	High	Medium	High	Medium
7	Expert systems with supercomputers for design optimization	Yes, Medium	Yes, Medium	Yes, Medium	Low
8	Scale of funding for Q6 and Q7	High	High	Low	High
9	Expert systems and 10problem solving techniques	High	Medium	Medium	Medium
10	XML for interconnectivity and interoperability	Medium	Medium	Medium	Low

ii) Detailed responses by Experts 5 and 6 for each of the questions defined in the Questionnaire

Two of the respondents (who are Expert 5 and 6) as they belong to the same institution, which were interviewed chose to provide additional feedback for each of the 10 aforementioned questions, instead of only responding to the questionnaire.

For Question 1 they stated that Expert Systems are computer-based systems to emulate the decision-making ability of a human expert, while MCHM (a modified version of AHP) is a decision-modelling tool. Although, both possess some commonality on the frontier of decision-making, but are not necessarily the same. This implies that decision-making tools such as AHP always require inputs provided by experts. Therefore, they suggested utilizing the expert system to match the inputs provided by the experts during pair-wise comparisons. This approach can enable the MCHM to select the most suitable projects for further development (as mentioned in Figure 3.4 of Chapter 3).

Moreover, the effectiveness of a MCHM programmed within an Expert System does not necessarily prove to be the most accurate in nature. The Expert systems that match human decision-making are based on diverse preferences and personal differences of experts. Moreover, it is extremely difficult to predict human behaviour in various different circumstances under different contexts. Similarly, tools such as AHP and MCHM are subjective in nature and possess their own degree of effectiveness for certain situations.

For Question 2 and 3, they stated that the method in which these diverse tools and connected to each other by acknowledging their incompatibilities in terms of data formats and programming structures would define the effectiveness with respect to the volume of design activity and the available human/financial resources (Gaha et al., 2011).

In Question 4, for the use of an Expert System as an optimizer in multidisciplinary design optimization (MDO), they mentioned that in principle an expert system

was never designed to be an optimizer in the first place and it is used in the decision making process that governs the actual MDO process. Although, Expert Systems can be combined with Genetic Algorithms (GA) and Particle Swarm Optimization (PSO) for interactive optimization, but this would occur without the benefits of an interactive algorithm, as it would not be interactive anymore (Yahya, 2003).

With reference to Question 5, they approved the use of knowledge systems that are quite different from the fundamental framework of the Expert System. The knowledge systems have to be integrated for being considered as an optimizer and one cannot consider only parametric optimization, as these systems are required to modify the design that undergoes optimization.

Meanwhile, for Question 6, they stated that as the softwares for CAD, CAM and CAE are usually proprietary in nature and hence unless there are features to effectively connect or integrate these tools, it would pose a substantial challenge that could be mitigated by a Total Product Life Cycle Management System (Lee, 2005). Moreover, even for Question 7, they stated that maximum time loss occurs at the interface of these tools and unless they are resolved the inclusion of a supercomputer (or high performance computing) would not bring about any efficiency. Similarly, for Question 8 the costs would mainly depend on the number of proprietary softwares being used and the 'developers licenses' issued by the vendors of these software's and the extent of programming done by a project team who decides to implement the multifaceted framework would provide a more deeper insight on the cost structure.

For Question 9 they stated that case based reasoning and expert systems can be effectively combined for gaining an insight to make suitable decisions for the product design and architecture. A few researchers in the domain of TRIZ have devised a software application provide suitable combination of inventive solutions by virtue of the law of technical systems evolution and conflict resolution approaches (Russo et al., 2011).

For Question 10 in terms of interconnectivity and interoperability of XML, both the sender and receiver of information during design activity should probably use the same language and similarly, a file made in XML format would have to be transformed into a type of XML format which can be used in CAD tools (which is known as model exchange or co-simulation). They also recommended the use of Functional Mockup Interface for the stated recommendation <https://www.fmi-standard.org/>.

If a parametric optimization approach is desired then the optimization strategy should be incorporated within the AHP or MCHM Model in itself, provided the product design model remains the same throughout any iteration of the optimization process (Wang et al., 2010). As a result, for any iteration the designer would encounter a new Pareto optimal frontier with respect the resources stated in Section 3.3 of Chapter 3. On the other hand, Engineers can opt for a discrete optimization approach or machine learning or even artificial evolution (in terms of genetic programming and artificial neural networks).

iii) Feedback from other experts who chose to provide their feedback through the 'informal conversational interview' approach instead of responding to the Questionnaire

The proposed Multifaceted Framework and the included Multi Criteria Hierarchical Model have been subjected to both expert review and opinion from experts in both academia as well as Industry. The experts from Industry concurred with the authors for a ranking based elimination of the design candidates pertaining to the criteria in Tier 1 as outlined in Figure 4.2 in Chapter 4 (Hambali et al., 2009).

The Multifaceted Framework was evaluated by a total of ten Experts from both academia and industry combined who responded to the questionnaire and those who only chose to provide their feedback instead of responding to the questionnaire. To relieve the exhaustive level of complexity of the Multifaceted Framework, the experts from industry preferred the Engineering and Technology

Development Teams to direct the Product Design and Optimization under the supervision of the Project Management Team and Senior Management. The experts from the industry also highlighted that notwithstanding the anticipated budget of more than USD$ 3 million for implementing the Multifaceted Framework. The success is solely dependent upon the ease of integration with the Global Harmonization Task Force (GHTF) Requirements, Quality Management System (QMS) ISO 13485 and the Environmental Management System (ISO 14000) of the Medical Device Company <http://www.imdrf.org/>.

An interview with industry representatives in the domain of Product Life Cycle Management stated that the Total Product Life Cycle Management System is known to effectively communicate with the Quality Management System and similarly, interoperate with the Knowledge based Engineering Tools after integration (Bermell-Garcia & Fan, 2008). Therefore, any potential discrepancies would probably stem from the incompatibilities between the engineering tools. The experts who discussed the questionnaire have also confirmed this facet.

The experts from academia deemed the MCHM conjugated with Expert System to be an effective Optimizer. Nonetheless, the XML interconnectivity may not necessarily be able to support an exceedingly exhaustive design optimization endeavour, especially when more than one Expert System would be involved. This implies that the magnitude of design optimization required pertaining to the product configuration has to be appropriately finalized. Furthermore, the inclusion of Neural Networks for mining of prior art is considered to be capital intensive in nature and requires expert involvement for training for at least up to 6 months. Therefore, the proposed Multifaceted Framework is suitable for medical device companies with a substantially large R&D budgets substantiated by robust learning curves and advanced expertise in engineering and project management.

Moreover, the same academic experts stated that in scenarios of contemporary advanced engineering environments demand the inclusion of diversified domains of knowledge in technical and non-technical fields (including socio-economics, politics, and psychology. Thus, the nature of knowledge (especially non-technical)

and the intellectual process or activity undergoing codification in a Expert System would pose a major impediment for the Expert System to act as a successful Optimizer or even conduct decision modelling (Cowan, 2001).

The recommendation of the academic experts, who evaluated the Multifaceted Framework, stated that Expert Systems are beneficial to the design and decision modelling process. Nevertheless not without limitations, as the in cases of an exhaustive design engineering environment encountered in aerospace engineering, which may not be a commonly occurring situation in medical device development.

6.3.3. The Pragmatic and Creative facets of the proposed Multifaceted Model

The technical tools (such as CAD/CAE/TPLCM) mentioned in the Multifaceted Framework are well established in the Engineering Industry and its effectiveness is subjected to the volume of design optimization tasks and the complexity of the design. This is one of the reasons, why an Expert Opinion Approach using interviews and questionnaires was considered in this thesis to evaluate the proposed Conceptual Multifaceted Framework. The Experts owing to their in-depth experience pertaining to the feasibility and effectiveness of similar multifaceted frameworks are capable of providing valuable insight on the probability of success or failure, if an Industrial entity intends to implement a part or the whole of the proposed multifaceted frameworks.

Accordingly, for design optimization of more simplified medical device designs, the product development teams can incorporate existing computational design engineering tools, such as CATIA and ANSYS (Nandwana et al., 2010). Similarly, these design-engineering tools can be combined with decision modelling frameworks (such as AHP) for analysing and modifying product designs (Hambali et al., 2009). For example, Akarte et al. (1999) proposed a AHP and Fuzzy Logic approach for selecting a casting process which was also connected to a Computational Design and Engineering System for aiding the Engineers in evaluating product process compatibility and conducting design improvements,

simultaneously. Likewise, product development teams with smaller R&D budgets can consider the decision rules of the MCHM Model and incorporate them in their existing Decision Modelling Software with some customized modification, as discussed in Ghazalli & Atsuo (2009).

The most important facet stated by an expert in the area of new product development revealed that usually companies, who are either into development of Class 1 or Class 3 medical devices, usually do not engage in developing medical devices outside their specialty, especially if they are small medium sized enterprises. The justification lies in the pragmatic viewpoint that the technologies are entirely unique and specialized for devices that range from stents, syringes and pacemakers. On the hand other, large sized medical device companies possess substantial financial and non-financial resources, in terms of access of knowledge and material resources to reduce the time for attaining the learning curves necessary for economies of scale. The same expert revealed that owing to the financial crises, more medical device companies are focusing towards their economic growth and much less on environmental sustainability.

The goal of the multifaceted framework is to evaluate the effectiveness of the MCHM and its ability to go beyond conventional decision modelling into design optimization at a comprehensive scale. Ultimately, it is concluded that the MCHM is most effective as a conventional decision-modelling tool for selecting suitable projects and even solving conflicts within product design as opposed to playing a critical role in design optimization.

6.4. Analysis and Discussion of the Case Studies

In this section containing case studies a wide range of technologies ranging from polymers, biodegradable and long term implants and Systems that comes in contact with body fluids/tissues. As the sector of medical devices are undergoing a continuous evolutionary pathway owing to the rapid growth in other sectors of science and technology. Concurrently, in this section each case study would assign

the term "Entity" for either an Enterprise(s) or a Person(s) with whom the case study was conducted.

6.4.1. Case Study 1

a) Brief Description of the activities

Entity 1 provides consulting services in the area of novel innovations for enabling companies to identify grant opportunities and obtain funding for their projects. The services provided by them mainly include the preparation of grant applications, forming consortia with a project management framework and writing reports to public institutions in the areas of research and innovation policy.

In addition, Entity 1 is based in Western Europe at a public funded University specializes in product development services ranging from concept development to engineering design analyses to clinical trials and regulatory documentation/ approvals. Concurrently, Entity 1 provides services in strategy consulting for its clients to attract more investment for their new medical device ideas by virtue of their strong network of suppliers and associates which are positioned as the key decisive factors for their continuing success. Some of their products are surgery via low frequency electromagnetism and intraocular implants.

b) Reasons for selecting Entity 1

Entity 1 was defining a concept of a Class 1 Medical Device that enables easier storage and dispensing of medication for elderly patients.

c) Activities conducted during the case study

An informal conversational interview by telephone and email was carried out with the proprietor of Entity 1. The conceptual validity of the multi criteria hierarchical model (Figure 3.2 of Chapter 3) formed the core subject of the discussion with respect to Class I to Class III medical devices as outlined in Chapter 2.

On the other hand, active participation during the conceptual development of the Class I Medical Device had occurred at the premises of Entity 1 for a period of around 30 days. Concurrently, the consortium of project partners was undergoing finalization. The delay was due to the less responsive approach by one of the key project partners. As this particular project partner comprised of only 4 individuals and was addressing a multitude of other project commitments simultaneously, leading to a lower degree of efficiency.

The 1st month period was utilized for identifying suitable components for the Class 1 Device and validating the incorporation of certain product characteristics, such as additional cost benefits and modularity that would enable easy assembly and remanufacturing.

d) Outcomes of the case study

Entity 1 concurred with the fundamental structure of the MCHM (Figure 3.2 from Chapter 3) to be categorized into primarily two major criteria of Regulatory Compliance and Business Performance with the inclusion of the most crucial criteria into Tier 1. Likewise, incorporating the Modularity and End-Of-Life criteria in 2nd Tier for resolving any irreconcilable conflicts between multiple criteria.

During the product conceptualization of the Medical Device activity at Entity 1 an attempt was made to eliminate barriers that could substantially delay the project and pose impediments for production as well as prototyping/testing.

Following are the challenges encountered in terms of fabricating the components for the Class I Medical Device for easier storage and dispensing of medication for elderly patients:

•The project partners intended to develop a medical device that was smaller than the existing large sized tabletop products available in the market. Moreover, for a smaller sized device to occupy lesser space on the table of the patients' room or ward, the mechanical components are required to be smaller in dimension.

However, there were only a few manufacturers in the neighbouring geographical location that could produce the desired components. This posed a significant impediment in terms of supply chain activities and its pertinent uncertainties to transport the final product to the desired destination.

•In terms of the design and fabrication of sub-millimetre (10^{-3} meters) and micron (10^{-6} meters) sized devices that act as sub-systems and components for larger systems in a relatively modular device architecture. The core challenge was to attain substantial reliability with economies of scale for cost effectiveness in a complex manufacturing set-up.

•The magnitude of high-speed precision control and degrees of freedom for movement are usually governed by tolerances and close contact by virtue of surface-to-surface interaction (and abrasion of parts). Thus, potentially leading to thermal instability that would further result in diminished reliability or even failure before the anticipated time period. The other impeding forces are namely electrostatic forces, surface tension, bonding and adhesive forces that are augmented by humidity and intermolecular Van der Waals forces that apparently become dominant at the micro scale (Hsu, 2005).

•Inclusion of multiple systems and sub-systems in a confined space, within the device architecture, to promote ease in manufacturing, assembly, repair/maintenance and fuel savings in transportation.

•The tools considered for process modelling and simulation for design, fabrication and assembly of miniaturized sub-systems have to address the scaling laws and in certain cases acknowledge the dimensions, methodology and robustness of the fastening materials. Likewise, would be the considerations of the material properties that would exhibit different behaviour (mechanical, metallurgical/chemical) from its macro-scale counterpart and hence would require revised versions of the design and simulation tools.

•A validated testing Protocol needs to be more comprehensive while designing and developing the sub-systems and their components. The axioms for validation

would include but are not limited to thermal shock, vibration, humidity and electromagnetic susceptibility.

The two figures below illustrate the striking similarities between Figure 3.2 and 3.6 of Chapter 3, which was modified to create Figure 6.2, as it specifically addresses the needs of the medical device under development.

Figure 6.2 is the proposed layout of the medical device under development to Entity 1 towards the end of the case study. The mentioned components were identified by literature survey.

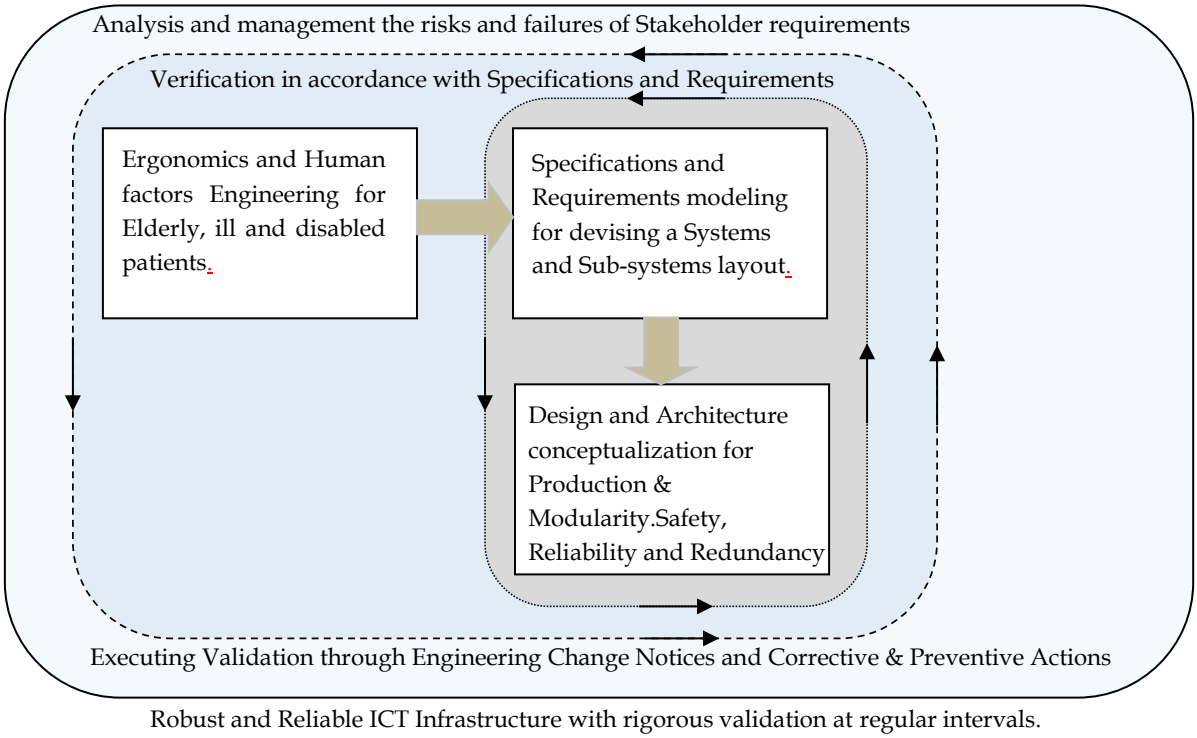


Figure 6.2. – The Strategy of Product Development

Meanwhile, Figure 6.3 is the proposed layout of the internal configuration of the medical device under development for Entity 1.

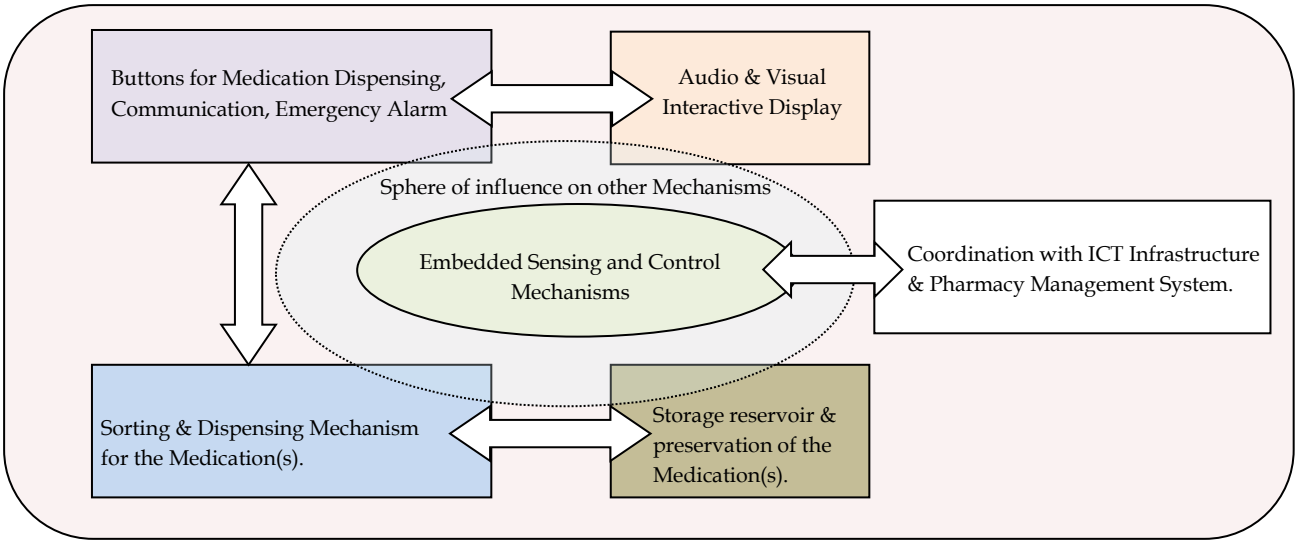


Figure 6.3. – The Internal Conceptual Layout of the Class 1 Medical Device for storage and dispensing of medication for elderly patients.

e) Concluding Points

The hierarchical arrangement of the aforementioned criteria in the MCHM (Figure 3.2 of Chapter 3) is validated during the case study by virtue of feedback from Entity 1 and the project partners for the medical device under development. This implies that the hierarchical arrangement is applicable to medical device development activities across more than one Entity.

The Western European Nations from where the Entity 1 and its project partners originate provides substantial support in terms of healthcare, which eventually acts as an incentive to drive down costs and look towards innovative technologies for providing a higher degree of cost effectiveness. In terms of addressing the first two research propositions mentioned in Section 5.3 of Chapter 5 within this case study, one of the project partners was a start-up firm comprised of members with not more than 5 years of experience after their respective undergraduate degrees. This is one of the reasons for this particular partner to require more time in finalizing the most suitable components with the lowest ecological impact and incorporating not more than a 30% opportunity for remanufacturing.

Furthermore, for the third research proposition, the Entity 1 was located at a publicly funded University. Consequently, the element of state sponsored research and development provides substantial alleviation of the cost intensive nature of developing engineering knowledge which can be further leveraged into new innovations and businesses that contribute towards society at large (Brodwin, 2012). It is essential to remind that a considerable degree of autonomy is also a critical factor to promote innovation without stifling creativity. Hence, the University has implemented suitable project control mechanisms to enable a reasonable government oversight for promoting research and development with a required level of accountability.

6.4.2. Case study 2

a) Brief Description of the activities

Entity 2 is a company that provides water purification solutions and is located at Western Europe. The founder and his members have around 20 years of experience in the Industrial sector of haemodialysis equipment.

The entity 2 develops, designs, manufactures and installs customer specific haemodialysis equipment at the clients' premises. Moreover, since the past 10 years Entity 2 has also been developing technical panels, which are required for is connected to the haemodialysis machines. Since then almost every year the company launches new products.

Entity 2 markets its products in the Western European region and in certain countries in Africa, including Angola, Morocco and Mozambique. Entity 2 participates in the annual conference of European Congress of Nephrology to interact with potential and existing competitors and end-users namely doctors, technicians and nurses.

b) Reasons for selecting Entity 2

Entity 2 develops and manufactures haemodialysis equipment and filters which are categorized under Class III Medical Devices because the instruments come in

direct contact with internal body fluids. Class III medical devices are critical for the sustenance of the life of the person to whom it is prescribed.

c) Activities conducted during the case study

Close observation of the product development process and the effectiveness of the three tiers of the multi-criteria hierarchical model were ascertained.

Firstly, the product development process at Entity 2 begins when a prospective customer initiates a request after which the management creates a cross functional team of employees from engineering, finance, marketing and competition analyses, regulatory and legislation compliance, testing/quality assurance and supply chain to define the product conceptualization and its components.

Secondly, entity 2 considered the involvement of suppliers at early stages to determine the deliverables and the delivery time to their client(s). For example, one particular client desired a technical panel made from Reinforced Plastic Fiberglass (RPFG) that was fireproof and ecologically safe. Unfortunately, few suppliers could provide this at a lower at the price acceptable to Entity 2 and their clients, as there was no substantial market demand for such materials. As a result, a different material with an acceptable cost and relatively higher ecological impact compared to RFPG was chosen. This situation proves the validity of the criteria mentioned in Tier 1, wherein the ability of the supply chain to provide the Enterprise with the materials desired by the market (or client specifically) is equally necessary for addressing the client's needs. The business collaboration was able to continue because the Entity 2 was able to reconcile this conflict by identifying a suitable material by a supplier for a desired price of the customer.

Thirdly, once the raw materials were finalized, a conceptual design with the cost structure (and selling price) was calculated in consultation with the marketing and sales department. Once the customer approved the preliminary plan, the prototyping activity was conducted in consultation with the client while simultaneously preparing operation manuals and technical drawings.

Fourthly, after development and fabrication (including testing and quality assurance) of the equipment's, Entity 2 sent the technical equipment's as ordered by the clients to their premises with the technical team of Entity 2. The goal was to reduce distribution costs and address the clients' requirements "on the spot" without involving any delays which would have occurred in the case of a third party distributor or maintenance team. This unique approach of personalized product development and installation has been the core factor in the high customer satisfaction and growth in business of Entity 2.

As mentioned in Tier 1 of MCHM in Figure 3.2 in Chapter 3, Entity 2 has adopted a much higher percentage of cost effectiveness and simultaneously adhering to regulatory, legislation and customer requirements (in addition to other criteria in Tier 1). Accordingly, Entity 2 was able to grow their business as mentioned in Tier 3 only by simultaneously adhering to Tier 1, which also includes making substantial profits without overcharging their clients.

Furthermore, the percentage of cost effectiveness as mentioned in Tier 3 was incorporated by Entity 2 in most of their products as they are able to address the markets' needs pertaining to low energy and water consumption. However, not much importance is given to recycling, reusing and remanufacturing. Entity 2 focused mainly on four factors namely, materials, energy, maintenance/repair and toxicity for conceptualizing their products and evaluating their life cycles, while concurrently adhering to legislation and regulatory compliance.

Meanwhile, the eco-friendly nature of the products developed by Entity 2 were not necessarily desired by their customers (as the costs could be higher), unless legislation demands it. Nevertheless, the trend towards more eco-friendly materials and products is slowly taking shape in the markets of their interest.

Also, during the discussion, the representatives of Entity 2 provided a list of factors that pose as an impediment towards incorporation of environmental sustainability:

i) The technical tools for evaluating environmental impact with in-depth analyses and incorporating environmental considerations by way of eco-design tools within the product design requires specialized expertise which is not easily accessible and can prove expensive if sought from external 3rd party consultancies.

ii) The training and implementation consumes time and in some cases disrupts the structure of the cross functional teams which are defined for each different projects. As a result, there can be multiple errors during implementation, selection and use of the tools. Moreover, the design tools were identified to be quite specific in nature and there was not any substantial clarity on the circumstances in which the tools could be more effective. Accordingly, the cost-to-benefit ratio towards the utilization of these tools was completely unclear.

This implies that the incorporation of any new tools for attaining a higher degree of sustainability is required to comply with the Tier 1 criteria of collaborative strength of the teams, the knowledge curve and the competitive time to market in terms of delays caused by any known/unknown factors that gives competitors a better head start.

These impediments are critical in nature because they tend to violate some of the most crucial criteria in Tier 1 of the MCHM, namely Collaborative Strength of the Team, bare minimum profitability and competitive shorter time to market.

Moreover, the product development experiences of Entity 2 have the following direct and inverse relations pertaining to various factors, which can be co-related to the hierarchical structure stated in the MCHM in Figure 3.2 in Chapter 3:

i) The clients determine the products' quality by the functioning role of the components of the products developed by Entity 2 and specifically focus on the ease of use as an important selection criterion.

ii) Clients prefer longer life spans with lower maintenance cycles coupled with minimal reduction in optimum performance. This includes lower consumption of energy and water. Moreover, the clients' negatively view the possibilities of

incorporating too many changes in the future that can occur in the name of innovation. However, they prefer to select dialysis products that are indeed innovative during their selection process. One major dilemma that Entity 2 observed is that due to the rapid growth in engineering and technology. This would enable stronger companies to innovate faster to address the markets' desires and occupy the market share of Entity 2 by leveraging the eco-design and life cycle analysis tools more effectively.

iii) Unfortunately, due to dialyses products are Class III medical devices that come in contact with the patients' body fluids, the clients negatively perceive any opportunity for recycling, reusing or remanufacturing in their application areas. Consequently, the inclusion of end-of-life options in Tier 2 (negotiable criteria) in MCHM is clearly justified.

This upholds the hierarchical categorization of the criteria in the MCHM, wherein stakeholder consideration in terms of safety and regulatory compliance gains priority, especially with respect to performance to longer life span and cross-contamination.

d) Outcomes of the case study

After analysing the product development process and the management strategies of Entity 2 it is possible to present some suggestions, namely:

1. Entity 2 should study the evolving trends of the market and start to identify suitable suppliers of new materials with lower ecological impacts and scout for some custom development opportunities to actualize economies of scale, in circumstances when the costs are substantially higher and undesired by the market.

2. The, Entity 2 could leverage their knowledge curve to devise products that are innovative and operate for longer life spans, due to the analyses of changing trends in the market coupled with their previous experience in customer requirements.

3. The information pertaining to the knowledge curve could be stored in easily accessible documents and computational design files. The company could also procure design engineering services from external parties for computational modelling of the dialysis filters and water purifiers in terms of its flow rate, water and energy consumption (Corallo et al., 2009; Yamamoto et al., 2009). However, Entity 2 needs to clearly define a trade-off between the investment required by these third party service providers and the return-on-investment (Vogel, 2005).

4. It was recommended to Entity 2 that the prototyping should be initiated while the product conceptualization and customer approval of specifications is under progress. As the previous learning curve of Entity 2 and moreover, the rate of technological innovation within the dialysis machines sector is not as rapid as nanotechnology and electronics. As a result, the Entity 2 can reduce the time taken to fabricate more effective prototypes within a short span of time and demonstrate to the client.

At the premises of Entity 2, the interviews and active discussions were conducted within a one-to-one interaction with the Lead Technical Representative. The goals of the interviews were to determine the effectiveness of the proposed MCHM. During the interview, the stated representative mentioned the utilization of a rather similar but less structured Decision Modelling approach as outlined in MCHM within Figure 3.2 to 3.6 in Chapter 3. However, the Design Engineers of Entity 2 could successfully incorporate Remanufacturing and Recycling within their product components, except the components such as dialysis filters, which come into direct contact with human blood. Moreover, owing to their growing business in developing nations, Entity 2 was able to gain a competitive advantage in terms of economies and scale in order to locally source the materials and components. This certainly contributed to a substantial level of social and economic sustainability. It is essential that sourcing locally and adopting end-of-life options reduces fuel consumption for transportation and saves additional resources that would have been expended in manufacturing from the extraction phase of the life cycle (Boustani et al., 2010; Nasr and Thurston, 2006).

Towards the end of the case study, the Engineers of Entity 2 have acknowledged the effectiveness of the MCHM as illustrated in Figure 3.2 to 3.6 and have chosen to incorporate the frameworks in its subsequent product lines.

e) Concluding Points

The recommendations enumerated in the previous section focus on the importance of the design phase and the learning curve for incorporating overall sustainability. Thus, addressing the first two research propositions of the thesis. Moreover, it is essential that regulatory agencies implement and enforce policies and provide incentives for the production low ecological impact materials. It is also important to note that advancements in dialysis technologies initially commenced in publically funded universities such as University of Glasgow and University of Giessen followed by commercialization by private entities, further fuelling more joint ventures between industry, academia and non-profits (<http://www.advancedrenaleducation.com>). Thus, proving the appropriate role of government and non-profit entities for stimulating innovation and economic growth (Brodwin, 2012).

6.4.3. Case study 3

a) Brief Description of the activities

Entity 3 was initiated in 2007 and develops innovative medical devices (mainly Class I and II) for patients undergoing physiotherapy and who require continuous health monitoring. The products are wearable sensors coupled with wireless communication that conduct many different functions such as electromyography (EMG), electrocardiography and monitoring respiration.

b) Reasons for selecting Entity 3

Entity 3 develops customized Class I and II Medical Devices. These devices incorporate a wide range of components made of plastic, electronics, metals and other non-metals, which are quite characteristic of most medical devices.

c) Activities conducted during the case study

After a detailed study of the product design and development process, recommendations were provided in terms of switching to materials with lower ecological impacts and reducing the quantity of material without compromising the structural integrity. Moreover, many inventive principles from TRIZ were recommended to reconcile conflicts that would arise from new materials with lower quantities so as to address more challenging circumstances in which the device has to operate (Fitzgerald et al., 2010).

d) Outcomes of the case study

Entity 3 had already finalized partners for distribution of products and personalized services for remotely and distantly located clients. Entity 3 attained roughly around 30% of cost savings and reduction in ecological impact when the Eco-Indicator 99 tool was adopted.

e) Concluding Points

The members of Entity 3 possessed qualifications and work experience pertaining to design engineering and wireless electronics. As a result, they could easily adopt the recommendations for the material, design and problems solving technique. These recommendations address the first two research propositions.

The environmental sustainability could be incorporated by virtue of reducing the material required and switching to more eco-friendly materials. However, this approach could conflict with the regulatory compliance requirements. For example, certain components were required by the regulatory agencies and hence could not be switched to different materials or even eliminated from design, even if they did not possess any operational functions.

During the case study it was discovered that the electronics components did posses their own ecological and social impact, despite the RoHS and REACH compliance (Eichstaedt, 2011).

Moreover, small and medium sized enterprises (and even some large enterprises) are not able to compel the suppliers of the electrical components, such as cables to incorporate a higher degree of overall sustainability, unless there are regulatory policies compel them to do so.

At the moment there are engineering processes to recover these minerals and metals from electronic waste, but unfortunately are quite cost intensive and are known to suffer from inefficiencies in terms of performance and consumption of resources (Cui & Zhang, 2008). Thus in certain circumstances acting counterproductive towards environmental sustainability.

Nevertheless, there have been two major initiatives known as GeSI(Global e-Sustainability Initiative)and StEP(Solving the E-waste Problem), in collaboration with United Nations and representatives from policy making and industries to promote responsible utilization of resources (United Nations University, 2009). This implies the critical role of policy makers and industry players collaborating with each other to actualize environmental sustainability. These initiatives aim to enable enterprises across different sizes and industrial sectors to recover precious metals and minerals from electronic waste and accordingly, become less dependent on unsustainable mining activity.

As discussed in previous case studies, the members of Entity 3 also had conducted the preliminary research work of their innovative ideas with close collaboration with Universities. A certain % of the funding was funded by grants from Government sponsorships.

6.4.4. Case study 4

a) Brief Description of the activities

Entity 4 is a physicist and a professor at a Western European University who specializes in the area of nanomaterials and smart polymers for developing sensing and therapeutic approaches for biomedical applications.

b) Reasons for selecting Entity 4

Advancements in regenerative medicine, medical devices and bioengineering require a more interdisciplinary approach by virtue of innovation in engineering and physics (Hassler et al., 2011). The expertise of Entity 4 is in physics, specifically in the domain of phase transitions of ferromaterials and similar materials thereof which enables Entity 4 to collaborate with scientists in polymers, regenerative medicine and medical devices. The potential in the expertise of Entity 4 has resulted in the development of biocompatible sensors/actuators for biomedical implants, which enables the user and his/her medical practitioner to monitor the performance of the patient and his/her implant. The ability of the MCHM approach to address product development and sustainability within polymers containing embedded sensors has been discussed in case study 3. However, case study 3 does not discuss implantable and biocompatible polymers for monitoring performance of patient and the implants. The reason being that the role of these embedded sensors are more critical for the patient's life and comes under Class III Medical Devices. In addition, within the domain of regenerative medicine itself, there are substantial advancements of embedded polymers with electronic sensors to stimulate tissue growth. Consequently, the inclusion of this case study in the thesis is of utmost importance.

c) Activities conducted during the case study

During the interview it was revealed that the most critical criterion of social sustainability in terms of patient and end-user safety are biocompatibility and very low costs. Thus, leading to a safer implantable device with minimal increase in the final selling price of the product/service.

Entity 4 discussed his research endeavours in the area of polymers with embedded sensors and actuators for biomedical implants in human bones. It was revealed that the electronic circuits which were printed onto the implantable biocompatible polymer and the electronic data acquisition systems were RoHS compliant (Source: INKtelligent printing® from Fraunhofer Institute for Manufacturing Technology and Advanced Materials <http://www.ifam.fraunhofer.de/content/dam/ifam/de/documents/IFAM-

Bremen/2801/fachinfo/spektrum/en/Produktblatt-2801-EN-Funktionsstrukturen-INKtelligent-printing.pdf>). This implies that the bare minimum sustainability has already been attained by default and without any conscious attempt towards incorporation. The same dilemma of case study 3 and 4 is encountered here as well in terms of increasing the environmental sustainability of these electronics components in terms of extracting the metals/minerals and reducing the ecological impact of the insulation materials (United Nations University 2009).

Furthermore, during the interview it was revealed that in many circumstances the sensing capabilities of printed electronics on biocompatible polymers is not as effective as silicon sensors. However, silicon sensors are not necessarily biocompatible and hence the research team of Entity 4 encapsulates the silicon sensors in a biocompatible polymer for incorporation inside an implant (Hijikata, 2012; Schmidt et al., 1993).

A project in tissue engineering and regenerative medicine by the research team of Entity 4 involved utilizing a biocompatible and biodegradable polymer with bone-like minerals and bone-differentiating stem cells to be incorporated as a bone implant for treating bone defects. The polymer was electro active in nature that responds to electrical impulses when mechanical pressure is experienced by the bone. Moreover, as the bone is a piezoelectric material and by the application of suitable pressure a electrical impulses are released which initiate mechanical changes in the electro active polymer which further continuously provides additional mechanical stimuli to the bone in order to increase the rate of regeneration (Shastri et al., 1998). Furthermore, the continuous periodic action of mechanical pressure and electrical impulses enhanced the proliferation and differentiation of bone-based stem cells that further reduced the time taken for healing. This tissue-engineering composite was successfully tested in animals.

d) Outcomes of the case study

The whole interview revealed that the social and environmental sustainability was automatically included by default by virtue of sound policies and the economies of scale of polymers/electronics technology brought about the cost effectiveness that resulted in a higher degree of overall sustainability.

The presence of a few inventive principles of TRIZ was observed in the tissue engineering composite. They were the periodic action of mechanical and electrical impulses (Principle 19) and the role of electrical fields (Principle 28) (Russo et al., 2011).

The principle of Preliminary Anti-action (Principle 9) was observed in terms of shielding undesired effects of silicon sensors by encapsulation in a biocompatible polymer. In addition, the printed embedded sensors/actuators provide a more convenient approach to measuring the performance of the implant and avoiding the use of inserting any probes into the region of the body that contains the implant. As such a rudimentary approach is ineffective and even hazardous to the patient's health. This advantage resembles the Principle 26 of Copying, wherein the function of the invasive probe was enabled onto the implant by virtue of the printed electronics.

In addition, Entity 4 evaluated the role of MCHM with reference to Figure 3.6 and revealed the degree of criticality in percentage of the pertinent criteria illustrated in the figure. Entity 4 also recommended to view the product development process of polymer composites in the following stages which is similar to conventional product development process (Ulrich & Eppinger, 2004):

Phase 0: Idea generation

Phase 1: Ideas and Opportunities screening

Phase 2: Exploration and Investigation

Phase 3: Concept Validation

Phase 4: Design and Process Validation

Phase 5: Industrialization

Entity 4 highlighted that the business structure and the engineering activities are substantially different from companies, which builds and integrates systems. This implies that the MCHM model is not completely suited for Enterprises that intends to develop a polymer composite with integrated systems. In addition, Entity 4 recommended that the MCHM approach of this thesis is more suitable for their clients who are Original Equipment Manufacturers (i.e. automobile manufacturers) or in simple words an automobile analogue to medical device manufacturers. As a result, this case study provides a unique perspective on the developmental challenges encountered by suppliers of sub-systems, components and materials for medical device development.

It was observed that as technology intensive markets to address ever changing consumer needs rapidly evolves. This resulted that the project timeline becomes critical. This creates a need for simpler and more comprehensive evaluation of project prospects and risks. Therefore, a tier 1 approach of a handful of criteria to immediately eliminate less promising ideas leads to cost savings in terms of man hours for evaluation. Moreover, Entity 4 concurred with the approach of conducting a preliminary investigation, as outlined in Chapter 3, in order to gain more in-depth insight into the success potential of the project and eliminates any biases based on personal experience and existing learning curves (Hilbert, 2012).

Furthermore, the inclusion of low cost and advanced polymer technologies with embedded sensors and actuators, which were a result of actualizing law of accelerating returns and globalization, has made it possible for regulatory policies to integrate bare minimum overall sustainability (up to tolerable levels) (Modelski et al., 2008). Entity 4 stated that the price is considered to be quite cost effective for a modern technologically advanced instrument that can enable development of a wide range of novel applications with very low costs. Thus, boosting the speed of research and development by creating more low cost prototypes for reducing the time for each developmental iteration and further contributing to costs savings.

It is also observed that the research team of Entity 4 adopted TRIZ inventive principles without any actual conscious attempt of incorporation. This could be attributed to the inventors and manufacturers of the electro active and biocompatible polymers. The biocompatible polymer, which provides the advantages of polymers without any health hazards, can be considered as an Inventive Principle Number 40 that is composite material.

e) Concluding Points

The case study revealed that the technologies and product development/design circumstances surrounding polymer composites with integrated systems is certainly unique from product development and design processes, which was encountered in other case studies in this thesis. As the role of physical chemistry and molecular chemistry plays a much stronger role, because chemical engineering processes are critical for the success and failure for integrating systems within these polymer composite matrices. Meanwhile, other cases usually procure materials and sub-systems from their suppliers and perform integration into a complete system or possibly engage in a joint development activity. Consequently, this case study delivers a unique insight towards the product development process of the suppliers.

After reviewing the history of electrical engineering and the innovations within this sector that pioneered technologies in electromagnetism and electronics/semiconductors which has eventually lead to materialize into the domain of printable electronics and fibber optics.

Some of the earliest advancements in electronics occurred in the 19th century from the endeavours of Prof. Ferdinand Braun of University of Würzburg and Mr. Jagadish Chandra Bose at University of Cambridge under Lord Rayleigh. Later for almost around 100 years of innovative efforts between public funded Universities and commercialization of novel technologies by private entities has resulted in substantial advancements with both economies of scale as well as scope (Fjelstad, 2010). For instance, low cost printing of electronics on a wide variety of substrates

including glass ad paper for a wide variety of application ranging from sensing to display.

As stated in the law of accelerating returns coupled with globalization of commerce and research endeavours has enabled the rapid growth of technology in the field of electronics to address growing needs in commercial, civilian and military sectors (Modelski et al., 2008).

In comparison, the advancement of fibber optics although started sometime in late 1960s within the private sector, namely MTI Instruments and has followed a similar curve as the printed electronics (Culshaw & Kersey, 2008). However, the scientific background of fibber optics dates from early 18th and 19th century by a plethora of independent inventors and physicists from public funded Universities. Consequently, supporting the hypotheses that the initial conceptual validation and proof of principle occurs usually within public funded institutions or non-profits, owing to enormous investments required in research and cost intensive instrumentation followed by transferring to the private sector for further development (Hayes, 2010).

These examples illustrate the role of appropriate government funding and involvement with reasonable oversight to avoid stifling of creativity and knowledge growth (Brodwin, 2012).

The history of Electroactive Polymers dates from the 19th century starting from Wilhelm Röntgen and until Electret discovered and commercialized the initial rudimentary version. In the 20th century various collaborations between public and private universities and corporations lead to additional advancements. Furthermore, since two decades substantial government carried out growth in technological improvements for electro active polymers sponsored institutions and non-profits until the spin-off company, which was launched, to commercialize the technology was acquired by Bayer in 2010. This further proves that leaps in technological advancements do require an appropriate support of publicly funded

institutions with considerable freedom to explore opportunities for commercialization.

6.4.5. Case study 5

a) Brief Description of the activities

Entity 5 is an orthopaedic clinic. The clinic provides advanced testing and training facilities for its orthopaedic patients by employing a professional team of doctors and nurses. The areas of therapy are Orthopaedics and Traumatology, Sports Traumatology, Physical Medicine, Rheumatology, Podiatry, Physiotherapy, Sports Physician Assessment, Testing Effort Cardio-Pulmonary, nursing and many more. Moreover, they provide their support to the professional and amateur athletes of their city's football club.

b) Reasons for selecting Entity 5

Entity 5 is an orthopaedic clinic that has developed in-house medical device and procured only fabrication services from an external engineering company. The clinic has been able to translate their impediments into a simple low cost solution by close cooperation with members of their clinic (Chatterji et al., 2008).

c) Activities conducted during the case study

The clinic has developed an indigenous Class I medical device after encountering challenges during the diagnosis of antero-posterior translation and rotatory laxity of the knee during magnetic resonance imaging. The device without inducing any injury to the patient's affected knee is able to position the joint to maintain the stressed condition for improvised diagnosis, which is provides accuracy than x-ray or MRI when the joint is more relaxed. A more effective diagnosis is desired because the pre-operative planning and post-operative care are critical for the patient's health (Espregueira-Mendes et al., 2012). Through the efforts of over 3-4 years, which involved 1 year of collaboration with a publically funded University, they have obtained a CE (Conformité Européenne <http://ec.europa.eu/enterprise/policies/single-market-

goods/cemarking/index_en.htm>) certification for their device. The device has been designed to be simple, accurate and reproducible in order to assist in analysis of the anatomy and the function of the knee that suffers from an injury.

During the research, it was revealed that the device was being developed in-house under the guidance of the orthopaedic specialists in collaboration with a few engineers from an engineering enterprise (while one biomedical engineer is an employee of the clinic). This means that the engineers could precisely gain an insight on the pragmatic requirements of the orthopaedic professionals in their environment of operation within the clinic. The device was under development in the clinic that leads to more frequent clinical trials and the safety of the patient was assured under strict supervision of the orthopaedic specialists by virtue of their extensive experience in healthcare. The close proximity of the biomedical engineer, the engineering company that conducts the prototype fabrication and the orthopaedic specialists played a critical role in reducing the development time. The proximity is not only with respect to location but also the awareness of diverse engineering, medical and scientific fields between the product development team members. Furthermore, the owner of the clinic has gained significant knowledge in mechanical engineering related fundamentals for orthopaedic applications and as a result can guide the development activity with more clarity and better focus.

The list of materials and their quantities were evaluated and, by using Eco-Indicator 99 tool (Pre Consultants BV <www.pre-sustainability.com>), was adopted to determine the most suitable materials from switching with the existing one.

d) Outcomes of the case study

After the analysis of the information and data obtained, and considered the literature review, some recommendations were provided. Firstly, to devise a project portfolio approach for future medical device development projects, which

illustrate the ability to share various technical and human resources and new knowledge (clinical and technical) that would be generated (Pacelli, 2004).

Secondly, the developmental costs for medical devices are usually high, even for a simple contemporary medical device. Consequently, 1-2 year collaborative projects with public funded universities to access young and enthusiastic talent in orthopaedic sciences and biomedical engineering. Even in cases where there are no public grants for such projects, the costs to hire students for preliminary investigation is much lower than hiring engineering design companies who may charge higher fee. However, the logistics of such activities need to be planned and executed efficiently.

After the Eco-indicator 99 analysis and discussion with the engineering partners of Entity 5 revealed that there are a few materials available, which possess lower ecological impact and provide similar mechanical properties with similar production costs. Meanwhile, materials with lower ecological impact and better mechanical properties were identified to have at least 80% higher production costs that were only justifiable in cases of economies of scale. Moreover, the existing material does provide the desired mechanical strength and flexibility to position the patient's leg during diagnosis. Thus, Entity 5 did not opt for switching to a material with lower ecological impact, and accordingly concurring with the three-tier structure of MCHM (Figure 3.2 in Chapter 3)

e) Concluding Points

This case study provides an insight on product development strategy where the factor of proximity of the project members, such as engineers, doctors and technicians dramatically reduces the time required for incorporating a wide range of human factor/ergonomics (Miller, 2007). The environmental sustainability aspect could not be considered in detail as the regulatory compliance requirements did not stress of a more ecological plastic as opposed to a material which creates a more functional device. This means that the Tier 1 of the

Multicriteria Hierarchical Model is maintained but without the bare minimum environmental sustainability.

Meanwhile, the social sustainability aspect can be acknowledged in terms of collaboration with Universities which results in exchange of knowledge and ideas, which results not only in better devices but even publications and patents (namely intellectual property). The close collaboration with University would also result in imparting pragmatic skills to young engineering and medical students to train them to work in real life environments.

The development of a simple low cost solution and the plans to sell the device to other hospitals would enable the purchasing clinics to provide more cost-effective treatment to their patients. It is important to note that not necessarily an external private medical device company could have provided the same advantage. As the developmental costs would have been dependent on the size of the company and the extra-cost in terms of lost opportunity to these medical devices companies.

However, smaller medical device companies could have provided a similar solution but the geographical distance and the lack of close relations with the members of the clinic would have caused some delays. Furthermore, if future medical devices are far more sophisticated that incorporates specialized components, Entity 5 may have to initiate a long-term university collaboration (with a certain % of government grants) and a external medical device company.

As encountered in case study 3, in terms of the role of policy for incentivizing more sustainable components for the medical device industry, is also applicable in this case study (United Nations University 2009).

6.4.6. Case study 6

a) Brief Description of the activities

A University professor from a public University in Western Europe established entity 6 in 2010 at the Entrepreneurship Incubation Centre of the same University. Entity 6 researched and developed novel prosthetics and orthopaedic devices.

Entity 6 was a result of research endeavours between researchers from Life and Health Sciences Research Institute located near the public University of the stated geographical location, School of Health Sciences and the Departments of Mechanical and Industrial Electronics of the stated University in collaboration with clinicians at the Hospital located near the public University.

Entity 6 uses a electro-mechanical platform using 3D design and modelling for designing and fabricating customized implants for correcting PectusExcavatum (a type of thoracic deformity in young children) by the Nuss procedure. This procedure entails using a video-assisted thoracoscopic surgery (VATS) technique to surgically insert a curved steel or titanium bar under the sternum to correct the deformities. The curved steel or titanium bar is structured by the patented technology developed by Entity 6 after a pre-operative Computerized Tomography scan of the patient's thoracic region.

The technology is in the form of a medical device comprising of pressure and strain sensors in a plastic enclosure with a brace to encircle the patient's thoracic region to obtain measurements for structuring the steel/titanium plate. Entity 6 has already filed for a few patents and is continuing their research for devising solutions in the areas of Pectus Carinatum, scoliosis and dental moulding.

b) Reasons for selecting Entity 6

Entity 6 develops both Class III and Class I medical devices and utilizes advanced computational modelling tools to address the specific needs of the patients in the most cost effective manner.

c) Activities conducted during the case study

During the interview, it was revealed that the plastic enclosure of the medical device comprises of a material that is extremely in low cost and is sourced from a distant supplier. Moreover, the material is the most ecological friendly in nature compared to other materials with similar mechanical properties. However, there are no opportunities for remanufacturing or reusing as the device comes in contact with the patients' skin and by regulatory compliance requirements cannot be used

for another patient. Moreover, the device is only composed of a few electronic sensors that are RoHS compliant.

d) Outcomes of the case study

After detailed analysis of the interview and feedback via email, it can concluded that the medical device has very limited components which prevents any opportunity for remanufacturing or reusing, even if the plastic enclosure cannot be reused. Moreover, the volume of sales is substantially low to justify a cost effective enclosure from a local supplier.

e) Concluding Points

The collaborative endeavours between publicly funded institutions and private entities has the potential to initiate many entrepreneurship ventures which address specific needs of the stakeholders of our society in the most cost effective manner. Although has RoHS complaint parts, the discussed medical device of Entity 6, does suffer from the same dilemma of social and environmental externalities as discussed in case study 3. (United Nations University, 2009) Likewise, when compared to other case studies, the product design does govern the magnitude of sustainability and also the presence of a robust knowledge curve. However, no substantial knowledge was required for assembling the medical device. Meanwhile, a few years were invested in the design/modelling procedures for analysing the thoracic region of patients suffering from Pectus Excavatum and assembling the machinery for structuring the metal implants in accordance with the patient's specific condition.

6.5. Co-relating the three sections of Chapter 6

This chapter discusses the research questions with reference to the proposed Multifaceted Framework and the MCHM by virtue of detailed interviews for pair-wise comparison of the criteria and case studies.

The second section of this Chapter pertaining to the prospective role of the proposed MCHM (Figure 3.2 in Chapter 3) to actively participate in design

optimization is assessed by virtue of interviews and questionnaires. It is concluded that the combination of design engineering tools and optimization approaches have to appropriately selected for conducting the desired degree of design optimization of a product. Moreover, using the MCHM for design optimization is envisioned to be suitable for only a limited extent; nevertheless, for more complex design scenarios which requires additional software/hardware tools would render the MCHM less effective and hence be more suitable for decision modelling in the conventional manner.

Meanwhile, the first and last sections are closely related. As discussed in the pair-wise comparison section in which 5 experts from academia prioritized End-of-life/Modularity; Employee Welfare and Contribution to Income Distribution in contrast to Community Welfare Programs. They justified their choice by envisioning that end-of-life options would contribute to sourcing materials/components from local suppliers and accordingly, this perspective concurred with the Entity No. 2 which end-of-life options were incorporated within the product design. Similarly, as per experts from Industry, Entity No. 2 expanded their market share in Africa by developing competitive products and incorporated economies of scale for which materials/components were again sourced locally. This implies that growth in market share and/or corporate expansion does eventually contribute to income distribution of stakeholders. Moreover, in the concluding points of Case Study No. 3 of Entity No. 3, the United Nations initiatives for recycling electronic waste by encouraging collaborations in the domains of policy and technology was envisioned not only for environmental sustainability but even for growth in employment (United Nations University, 2009). This further fortifies the viewpoint from the case studies ranging from 1 to 3 with reference to the critical role of Government Institutions and sponsorship of advanced research at its initial stages to ensure a more cost effective transition into the market economy by the private sector.

As discussed in Chapter 3 that the criteria in Tier 2 and 3 are optional in nature in addition to their interconnectivity. The consistency ratio of the pair-wise

comparisons was considered less important in comparison to the tacit knowledge disseminated by the Experts.

With reference to the research propositions in Chapter 5, the disparity in knowledge curve is clearly observable between Entity No. 3 and Entity No. 5 wherein Entity No. 3 was able to adopt newer material and modified design within a shorter time span compared to Entity No. 5. The reason for the disparity is attributed to the engineering related knowledge curve of Entity No. 3 in contrast to the orthopaedic science knowledge curve of Entity No. 5, in addition to the extensive dependency of the latter on an external engineering company. This impediment is present notwithstanding the advantage of Entity No. 5 that is an orthopaedic clinic wherein access to expertise in orthopaedic sciences, patients and instrumentation for treatment/diagnosis is readily available.

Chapter 7

Conclusions and Future Research

7.1. Introduction

This chapter outlines the conclusions of the proposed multifaceted framework, the Multicriteria Hierarchical Model and its associated frameworks in this thesis. The previous chapter of results and discussions disseminated a detailed comprehension on the effectiveness of the proposed frameworks and models within an Industrial environment, in addition to the applicability of expert's opinion within the initial phases of product development of medical devices.

Moreover, it is essential to articulate and coherently compile the outcomes of the research in this thesis so as to ensure that users of the proposed frameworks and models gain substantial benefits after implementation.

Furthermore, this chapter would also provide an insight to locate any potential shortcomings of the proposed frameworks and models during implementation in diverse product development scenarios.

Section 7.1 would outline the results and discussions with reference to the literature review and illustrate the contribution to existing literature of overall sustainability, decision modelling and medical device development. Meanwhile, Section 7.2 would mention the direction of future research for the discussed frameworks and models. Finally, this thesis does discuss the cultural paradigms and philosophical underpinnings that not only govern the perception to evaluate overall sustainability but even shape any prospective mitigation strategies against undesirable externalities. In order to attain a sustainable future, it is crucial to comprehend the flaws in our contemporary cultural and philosophical basis in order to devise better initiatives by both public and private institutions.

7.1.1. Co-relating the Results and Discussions with the Literature Review

Moore (2011) and Parenti (2011) have co-related the negative externalities that occur as a result of unfettered industrial activities onto social structures and natural systems for which the defined demarcation appears to be illusionary in nature. However, a market economy approach towards novel innovations concerning renewable energy aims for lowering the socio-economic and ecological externalities (Fresner et al., 2010). Likewise, technologies pertaining to counter the hazardous impacts of emissions, such as carbon capture and utilization which transforms toxic carbon based emissions into economically useful products namely renewable fuels and plastics (Nasr & Thurston, 2006; Styring, 2011). Concurrently, as discussed during the case studies, the appropriate collaboration and intervention of Government is indeed desirable for materializing endeavours and initiatives, which are catered to attaining a higher degree of overall Sustainability.

The pair-wise comparisons between the various optional and negotiable criteria in the MCHM in terms of product design and economic frameworks based on the degree of Government intervention, is rarely discussed in existing product development literature. As contemporary literature on decision modelling and product development towards overall Sustainability focuses more on the performance of the Enterprise that undertakes product development.

Meanwhile, extensive research in economics and management has pointed out the role of economic policy and Government intervention in enabling the competitiveness of certain Industries/Companies (Denning, 2012). However, the focus on the product development and design, which is the key contributing factor to competitiveness, has mostly been kept at a minimum.

In fact, Hede et al. (2011) discussed the role of incorporating social sustainability paradigms such as employment growth and corporate responsibility within product design. Concurrently, Fishman (2012) illustrated the example of General Electric in which the company was able to retain the skilled labour and even hire

additional skilled personnel by increasing its product value via innovation in product design.

The role of MCHM in design optimization as discussed in Chapter 6 and the importance of computational design and engineering tools as outlined in Chapter 4 exemplify the role of technical infrastructure to capture new knowledge, utilize existing knowledge curve and reduce the project timeline without undermining the desired outcomes.

7.1.2. Co-relating Case Studies with Product Development Methods and Approaches to resolving Conflicts

From the case studies in co-relation with the literature review of decision modelling in Chapter 3 and Product Development Processes in Chapter 4, a few pragmatic real life lessons are enumerated as follows:

i. Enterprises engaged in product development should always keep of track of market dynamics and evolutionary patterns of technologies for staying ahead of their competition. This recommendation is attributed to the Law of Accelerating Returns in which diverse sciences and technologies interact with each other and result in disruptive outcomes (Modelski et al., 2008), even though the task appears to be intimidating. Nevertheless, Enterprises can always make suitable trade-offs between their desired market sectors and sizes to define their region of competitiveness and accordingly renew their product lines. Moreover, Alexandre et al. (2003) have pointed out that the degree of maturity of the underlying technology/science of the physical/chemical entities of a product are essential to determine the functionality and the future market oriented success. Meanwhile, the thesis does concur with the previously published literature and existing product development practices to launch successful products. However, as stated previously the thesis lays a strong emphasis on sustainability, resolving contradictions out of a multitude of synergistic/conflicting specifications and economic structures of geographical nations where the products are under development or being marketed.

ii. The product development processes for Systems comprising of sub-systems and components cannot be equated with approaches used for polymer composites, biological products or even drug molecules in which molecular level forces and phenomena play a critical role or even are the actively performing entities towards accomplishing the desired degree of medical care envisioned by the product development teams.

In simple words, the engineering required for fabricating a pacemaker is entirely different from building a biodegradable polymer composite with minerals/cells as discussed in Case 4, even though a few similarities can be accounted between each other.

iii. Each project undergoing development should be accompanied with relevant documentation that mainly outlines project planning, development iterations and milestones.

iv. The project partners must regularly communicate with each other for adhering towards the project deadlines for which meetings between key personnel is crucial for defining the suitability of the outcomes with respect to the desired results.

v. The project partners should invest resources (Section 3.3 in Chapter 3) for establishing a preliminary knowledge curve for reducing the time required to speedup the learning process during the execution of the project. For example, project partners must train their project engineers/managers in technical/non-technical areas which although are essential for the project but for which the participants do not have substantial prior knowledge. Similarly, the various crucial variables of the resources (Section 3.3 in Chapter 3) that are capable of derailing the project should be carefully scrutinized.

Furthermore, it is imperative to establish a process to transfer the training and knowledge between various project participants (managers/engineers) for the smooth flow of the activities. It is essential to note that knowledge transfer need not require advanced computational or IT based systems. On the contrary, defining a suitable product development framework, which delivers insight into potential impediments and enables the project teams to build suitable strategies to

attain their desired goals, can also transfer knowledge. For example, the TRIZ Laws of Technical Evolution, which illustrates the pathway of evolution for new technologies, can enable the project teams to define new options for redefining their technologies or even improving existing ones (Fresner et al., 2010; Russo et al., 2011).

vi. Both Case 3 and 6 reveal that solely the presence of domain knowledge pertinent to the medical device or logistical advantage in terms of access to patients and medical doctors does not guarantee success in a certain product development within a short span of time. However, the Enterprise could increase the probability of success by building suitable collaborations with efficient logistical planning in accordance with the prototyping and preliminary evaluation for human factors/ergonomics activities.

As discussed in Chapter 3 and 4, about the potential emergence of a wide range of conflicts and synergies, when specifications co-relating with criteria pertaining to overall sustainability are considered simultaneously during product development.

TRIZ, Design by Analogy and Case based Reasoning are mentioned as suitable approaches (Fitzgerald et al, 2010; Zhao et al., 2010). However, translating the conflicts precisely into the technical and non-technical specifications with reference to the product design can itself result in an overwhelming endeavor. For example, if a product design has a component whose structure needs to be modified to attain a higher degree of reliability in order to consider the component for multiple life cycles (in terms of Remanufacturing). Meanwhile, the change in design should require a few extra employees with decent wages either in design, production or maintenance to increase social sustainability, nevertheless without outweighing any potential profits (Fishman, 2012).

In certain scenarios, a few small changes in product design can create more market value for the product in the market and outweigh the costs of adding a few extra employees without underutilizing them. On the other hand, in certain scenarios substantial product changes may be required to employ more personnel and may

also demand advanced machinery/material that may prove to be less cost effective if economies of scale are not materialized.

This implies that because there are multiple conflicts and solutions interwoven into each other. Consequently, the most critical conflicts need to be prioritized, in order to be solved by a more advanced version of TRIZ, such as OTSM. Meanwhile, Enterprises should concurrently devise a risk mitigation plan based on technical and business strategies/processes to address conflicts/synergies that cannot be reconciled with the most critical ones. For the stated circumstances, the utilization of MCHM would be considered most appropriate (Khomenko & Ashtiany, 2007).

With reference to the previously stated example, if more employees cannot be appointed in the design engineering phase. Then the Enterprise can choose to appoint employees in the lean production/product development processes to reduce costs and increase productivity that is anticipated to reduce emissions/wastage of resources.

The ultimate objective is to balance the sustainability related goals by an Enterprise, as stated in Chapter 2 (Sutcliffe et al., 2009).

7.1.3. Articulating the whole perspective of the Thesis

i. One repetitive pattern has been observed in the conclusion of every case study in Chapter 6. Wherein any disruptive or significantly advanced innovation has always occurred as a result of a certain degree of support from publicly funded institutions. Usually, some of the most impactful innovations of our modern society do seem to have their roots in public funded universities followed by transfer to either private sector or launching start-ups (Gregorio & Scott, 2003).

In certain interesting cases, it is observed that scholars from academia or private sector owing to their experience in healthcare and research initiate either in-house development of medical devices or form a suitable consortium between various stakeholders to provide specific solutions at very low costs to patients across all economic classes (Chatterjee et al., 2008). Thus, contributing more towards social sustainability.

ii. Moreover, the rapid rate of technology development coupled with globalization has resulted in substantial advancements of these innovations to provide diversity in terms of application areas at very low costs (Modelski et al., 2008). Some of the well-known examples are printed electronics in consumer products to implantable prosthesis and tissue engineering scaffolds. If observed carefully, medical devices are a culmination of engineering and sciences from all disciplines towards healthcare applications.

iii. The electronics and electrical engineering innovations, which form a critical part of medical device, are usually procured by medical device companies (large to small-medium enterprises) from their respective Original Equipment Manufacturers (OEMs). Hence they do not have any control over the suppliers to provide more ecologically sustainable components.

Therefore, the role of policy makers to implement policies for incentivizing development and commercialization of more socially responsible and eco-friendly materials would play a critical role. Concurrently, industry players and public institutions in collaboration with non-profits can materialize initiatives to devise and implement new methodologies for transforming materials waste. The material waste can be categorized mainly into electrical, electronic, plastic/other non-metals, semiconductors and metals so as to be less dependent on socially detrimental mining activity (Eichstaedt, 2011). Some of the most impressive initiatives are GeSI (Global e-Sustainability Initiative) and StEP(Solving the E-waste Problem), respectively (United Nations, 2009).

This implies that a company all by itself can only attain sustainability to the extent of its ability to demand materials from suppliers provided they procure in quantities that provide the suppliers with economies of scale. In addition, the company should be able to leverage a robust learning curve to launch more sustainable products/services and invest in large-scale social responsibility programs. However, not all corporations possess such prowess in technology and political economy and hence the formation of a initiative does mitigate the risks of undesired competition stemming from perverse incentives and the cost intensive

nature of engaging in sustainability at comprehensive scale. Moreover, a company can engage in mutually beneficial and healthy public private partnerships for enhancing is contribution to social sustainability (Jamali, 2012).

iv. The contemporary medical devices range from metal and non-metal prosthesis (external and sometimes internal), instruments, advanced implantable devices and scaffolds in regenerative medicine. The lines between pharmaceuticals, biological and medical devices are slowly blurring due to the rapid growth rate of innovation across diverse disciplines and science and technology. This is the core reason for the thesis to discuss a wide variety of cases from these aforementioned areas in Chapter 6.

v. Moreover, during the case studies it is learnt that solely based on the desired function of the device would govern the nature of the materials and components in accordance with regulatory compliance requirements. As a result, one cannot forcibly incorporate a higher degree of sustainability as the Pareto Optimal Frontier based on the resources outlined in Section 3.3 of Chapter 3 and a company's capabilities to deliver a product within the window of opportunity would pose a major impediment (Zhao et al., 2010). This is also one of the reasons for a few companies to desire a decision model that is comprehensive, objective and faster in terms of its application for gauging a project before pursuing it.

Therefore, the three research propositions mentioned in Section 5.3.1 of Chapter 5 in terms of ability to incorporate sustainability in design phase, the importance of a company's learning curve to attain sustainability and role of socio-economic policies to actualize sustainability has been studied across companies of diverse areas and sizes.

vi. As pointed out by Huesemann and Huesemann (2011), the advancements in technologies should not be considered as an "absolute ideal solution" for solving the challenges pertaining to socio-economic disparities, climate change and ecological degradation. They have explained in simple words that for developing an advanced technology to counter the threat of climate change would entail processes and materials whose development in it itself may exert undesired

ecological and socio-economic externalities. For example, carbon credits and clean development mechanisms have been criticized by social activists and intellectuals for the very same reason, as they support the view purported by these authors (Buen, 2013).

vii. As pointed out by Huesemann and Huesemann (2011), the advancements in technologies should not be considered as an "absolute ideal solution" for solving the challenges pertaining to socio-economic disparities, climate change and ecological degradation. They have explained in simple words that for developing a advanced technology for countering the threat of climate change would entail processes and materials whose development in itself may exert undesired ecological and socio-economic externalities. For instance, carbon credits and clean development mechanisms have been criticized by social activists and intellectuals for the very same reason, as they support the view purported by Huesemann & Huesemann (2011) (Buen, 2013; <http://www.carbontradewatch.org>).

vii. The pair wise comparison approach discussed in Chapter 5 of the criteria in Tier 2 and Tier 3 was identified to be a suitable method to capture the insightful thinking approach of the experts in terms of decision making for complicated situations with respect to socio-economics and business growth objectives. The inclusion of short notes provided with the scoring tables provides flexibility to the users of the MCHM approach to incorporate the recommendations disseminated by the experts within their product development processes. Similarly, the case study approach entailing interviews and active participation with the companies coupled with in-depth analyses of their problems and circumstances provides a pragmatic viewpoint on the scenarios (favouring and impeding factors) that occur in an interdisciplinary industry.

viii. The proposed Multi Criteria Hierarchical Model (MCHM) which is an extensive revision of the Analytical Hierarchical Process decision modelling approach, demands substantial due diligence throughout the product development process. As exemplified in the preceding sections with reference to Design Optimization, certain criteria are a combination of technical as well as non-

technical (or managerial) parameters, such as 'market competitiveness' that cannot be easily characterized by computational methodologies and artificial intelligence. Consequently, this requires regular intervention by the Team(s). This is anticipated to further slow down the design optimization process and depending on the magnitude of optimization required by the project could even render the whole endeavour ineffective.

Meanwhile, the MCHM outlined in Figure 3.2 and its other associated models namely 3.3 to 3.6 bears certain similarities with the Analytical Network Process (ANP), especially for elucidating interrelations between various criteria (Saaty, 2006). In addition to the similarities, the MCHM does not stress on additional rules and restrictions of the outlined interrelations, as described in the Analytical Network Process (Saaty, 2006). Recent research investigations have observed strong co-relations between the Product Development Processes and Complex Adaptive Systems, which are usually encountered in natural systems. These complex adaptive systems, similar to an ANP are a network of interconnected systems that influence each other and continuously interact with each other by a series of multiple feedback loops (McCarthy et al., 2006).

ix. In the case of product development coordination of activities and continuous exchange of information are the critical paradigms for accomplishing an Enterprise's desired goals (Chiva-Gomez, 2004). It is important to note that all the aforementioned domains of sustainability are closely interconnected with the dynamics of our natural ecosystems, which are holistic and emergent in nature, such as the Complex Adaptive System, as opposed to the reductionism, which is encountered within the conventional Analytical Hierarchical Process approach of Decision Modeling (Hermele, 2009; Parenti, 2011).

Furthermore, unlike the ANP, the concept of Hierarchy is included within the MCHM in order to execute prioritization between the criteria in circumstances of irreconcilable conflicts so as to accomplish overall sustainability. The hierarchy of prioritization is based on varying degrees of overall sustainability, ranging from minimum tolerable (Tier 1) to advanced levels as described in Tier 2 and 3. The

thesis intends to point out that a product that is composed of multiple systems and sub-systems is a network as well as a hierarchy of its constituents. This facet has been one of the core reasons for the proposed MCHM to be outlined as a Hierarchical Model in Figure 3.2 and as a interconnected network in Figure 3.6.

x. Similarly, the Strengths, Opportunities, Weaknesses and Threats are simultaneously addressed in Figure 4 (b) and Figure 6 to optimize the overall product development process (Pun et al., 2010; Saaty, 2006).

The elucidated interrelations between the criteria described in Figure 3.6 enables the Teams to chart out a progress evaluation plan, conduct readiness assessment and provide guidelines for establishing a pro-active risk management framework for addressing overall stakeholder welfare (Dey, 2002; Pun et al., 2010).

Similarly, Figure 3.4, 3.5 and 3.6 could aid the teams to plan out an effective Sustainability Roadmap, which resonates with the renowned Balance Score Card framework. Notwithstanding, the advantage of customization of the MCHM (illustrated in Figure 3.2) for each medical device, the development teams would have to manually perform the arduous task of feeding the scores and values in accordance with the complexity of the device. Unless, the teams could devise Knowledge based Engineering applications for automating routine Design Engineering tasks (Corallo et al., 2009).

xi. Detailed studies have demonstrated that exhaustive Design Optimization iterations coupled with the systems thinking analysis for evaluating ecological and stakeholder impacts requires high end computational systems with substantial resources (especially non-renewable) to be expended throughout their life cycle. As a result, ironically exerting an enormous environmental impact that is undesirable (Fiksel, 2006; Parliamentary Office of Science and Technology, 2008).

Although, the experts who were asked to provide their feedback for the multifaceted framework outlined in Chapter 4 via the questionnaire were not satisfied due to the rigidity of the questionnaire structure. However, they were impressed by the inclusion of interviews, which add flexibility to the case study by obtaining more insight on the subjectivity of the multifaceted model. As stated

before, the expertise provided by the experts was sufficient enough to avoid any actual implementation.

The goal of the multifaceted framework is to evaluate the effectiveness of the MCHM and its ability to go beyond conventional decision modelling into design optimization at a comprehensive scale. Ultimately, it was concluded that the MCHM is most effective as a conventional decision-modelling tool for selecting suitable projects and even solving conflicts within product design. However, the framework can inspire suitable counterparts in design optimization tools for selecting and rejecting design candidates or directing the design of the computational models.

Furthermore, the specifications that define the Pareto Optimal Frontier for any given device can be considered as an initiation point for Process improvements (e.g.: reducing time and cost savings) and Innovation (e.g.: new material research). For an advanced medical device, the characterization of Pareto Optimal Frontier could prove exhaustive in nature, and accordingly, an efficient collaborative team supported by an equally effective Organizational framework in conjunction with a robust knowledge transfer mechanism could alleviate the impediment(s).

The aim of the thesis is to holistically comprehend the role of decision modelling to attain sustainability with minimal socio-economic and environmental externalities and concurrently providing a simplistic approach to choosing the best alternative in terms of project or product design by virtue of the hierarchical structure.

7.2. Future Research

The 'pragmatic' multifaceted approach towards product development with reference towards Decision modelling and Design Optimization was proposed and discussed to evaluate the effectiveness of the MCHM in decision modelling as well as design optimization. Additionally, the Multifaceted Framework is, in fact, only a few steps away from implementation provided the magnitude of design modelling and optimization, resources (Section 3.3 of Chapter 3) and their

idiosyncrasies pertaining towards the integration of various tools have been appropriately addressed.

The subsequent step in this investigation would entail a research-based case study in an enterprise engaged in a design intensive R&D activity that is either remotely or closely related to Medical Devices. At the moment, the proposed Multifaceted Framework and the MCHM needs to be recalibrated for medical devices in the domain of Biological and Regenerative Medicine containing a solid architecture (e.g.: scaffolding structures) in conjugation with cells and bimolecular systems.

In addition, as discussed in section 7.1.2 about the emergence of multiple interconnected conflicts/synergies that have to be effectively addressed without jeopardizing bare minimum overall sustainability (Khomenko & Ashtiany, 2007). It is recommended that further research be conducted to address these intertwined conflicts/synergies via the proposed MCHM and Multifaceted Framework (with minimal or substantial modifications). The justification is based on the conclusions from the case studies that materialising tangible/visible change in product design in accordance with welfare of stakeholders results in a more genuine form of Sustainability.

Special Note

The Cultural and Philosophical Paradigms of Industrial Growth and Overall Sustainability

The objective of a nation or an enterprise to either attain a minimal degree of a higher degree of overall Sustainability would require substantial commitment in both feasibility assessments of opportunities to incorporate sustainability and defining initiatives and measures to mitigate undesired outcomes. However, the paradigms and even philosophical underpinnings, which would define the structure of feasibility assessments and the mitigation strategies cannot be entirely excluded by either a nation or an enterprise, committed to overall sustainability.

As mentioned in Fritjof Capra's (2010) book titled "The Tao of Physics: An Exploration of the Parallels between Modern Physics and Eastern Mysticism" in which he explains the importance of comprehending the phenomena in sub-atomic physics, natural ecological systems and civilizations from a holistic perspective as opposed to a reductionist approach.

Likewise, he does mention that since the 17th century, the predominant method of scientific experimentations and observation is rooted within Newtonian and Cartesian paradigms that are closer to reductionism rather than a more holistic approach towards evaluating sub-atomic physics and complex phenomena that occur in sociology, ecology and economics. The Newtonian and Cartesian paradigms are known to perceive every phenomena and entity in existence to be decipherable, predictable and controllable in nature that as Fritjof Capra (2010) points out is quite different from complex phenomena and sub-atomic physics.

However, a reductionism centric approach is not entirely erroneous but in fact limited only up to a certain extent. For instance, the design, testing and validation of a medical device comprising of various sub-systems in which each sub-system is developed separately in a modular fashion with a lower degree of dependency on other sub-systems only to be integrated into a single system. Meanwhile,

developing a bone tissue engineering implant that entails cells, bone minerals and other biochemical cannot be developed in a modular approach. As each of the mentioned entities are strongly interconnected/interdependent to each other wherein the 'whole' is indeed more than just a sum of all the entities connected together.

Moreover, Fritjof Capra (2010) also stated that since the 17th century the method of scientific experimentations and observation that is based Newtonian and Cartesian paradigms has also manifested into economic theories and policies of our industrialized society. Furthermore, Fritjof Capra (2010) critiques that such theories and policies founded upon Newtonian and Cartesian paradigms invariably possess a strong focus on 'control or dominance' of natural ecosystems and societies for sustaining our human civilization. Consequently, the emanating social and environmental externalities lead to undesired outcomes that negatively impact economic growth (Eichstaedt, 2011).

Similarly, the triple bottom line approach towards sustainability has been appropriately criticized to be reductionist in nature as it implicitly considers the economic dimension with higher priority compared to environmental and social domains are externalities which have to be minimized (Magee & Scerri, 2012). Whereas, in reality the social sustainability and ecological stability governs the success at the frontier of economic growth (Stiglitz, 2007). Furthermore, any attempt to undermine the crucial role of natural ecosystems in sustaining our human civilization by the implementing initiatives based on the ethical paradigm of 'man attempting to control nature and engineer the climate' is anticipated to result in catastrophic outcomes for which policy makers across the globe would be unprepared (Capra, 2010; Costanza et al., 1998; Hermele, 2009; Hamilton, 2013).

The existing form of industrial growth that is also founded upon Newtonian and Cartesian paradigms is undergoing a gradual shift from the linear centric 'cradle to grave' approach to the cyclical and harmonious 'cradle to cradle' approach, which is more holistic in nature and centred around overall sustainable growth. To explain further in simple words, the 'cradle-to-grave' approach of product

development entails the disposal of the product at the end of the life cycle as opposed to 'cradle-to-cradle' in which end-of-life options are adopted and 'closing the loop of materials and energy' (Nasr & Thurston, 2006; Styring & Jansen, 2011).

However, the transformation towards a 'cradle-to-cradle' is not entirely sustainable for continuing a resource intensive economic growth. The shortcomings are not only based on the 2nd law of thermodynamics as stated by Huesemann & Huesemann (2011) in which 100% efficiency associated with 'closing the loop of materials and energy' is almost impossible to accomplish. In addition, the ideology of an expansionism centric perpetual economic growth has been criticized as the 'Myth of Progress' because industrial and technological advancements have not entirely lead to a higher degree of happiness within the human society and better sustainability of the environment in general (Wessels, 2006).

The goal of discussing the philosophical and perceptual underpinnings is not meant to discourage the users of the multifaceted framework and the decision models discussed in the thesis. On the contrary, the aim is to provide a more holistic perspective on the current paradigms, which define overall sustainability and even inspire senior management of medical device companies to engage in partnerships with their industrial contemporaries and public institutions to materialize a more sustainable human society.

References

[A]

Abumeri, G, Knouff, BK, Lamb, D, Hudak, D & Graybill, R 2010, 'Benefits of high performance computing in the design of lightweight army vehicle components', *Proceedings of the 27th Army Science Conference*, Smithville, VA, 29 November-2 December.

Aguwa, CC, Monplaisir, L, Sylajakumari, PA & Muni, RK 2010, 'Integrated Fuzzy-Based Modular Architecture for Medical Device Design and Development', *Journal Of Medical Devices*, vol. 4, no. 3, pp. 031007-17.

Akarte, MM, Ravi, B & Creese, RC 1999, 'Casting Process Selection using AHP and Fuzzy Logic'. Paper presented at the *International Seminar on Manufacturing Technology Beyond 2000*, Bangalore.

Akao, Y 1990, 'Quality function deployment: Integrating customer requirements into product design', *Productivity Press,* Cambridge, *MA*.

Akgün, AE, Lynn, GS & Byrne, J 2003, 'Organizational learning: A socio-cognitive framework', *Human Relations*, vol. 56, no. 7, pp. 839– 868.

Akgün, AE, Lynn, GS & Yılmaz, C 2006, 'Learning process in new product development teams and effects on product success: A socio-cognitive perspective', *Industrial Marketing Management*, vol. 35, no. 2, pp. 210–224.

Albers, A, Burkardt, N, Meboldt, M & Saak, M 2005, 'Spalten problem solving methodology in the product development', *Proceedings of the International conference on engineering design*, Melbourne, Australia, 15-18 August.

Alexandre, MT, Furrer, O & Sudharshan, D 2003, 'A hierarchical framework of new products development: an example from biotechnology', *European Journal of Innovation Management*, vol. 6, no. 1, pp.48 – 63.

Almonor, JB 1998, 'Design of an Efficient and Timely Product Development Process for Medical Devices', Masters Thesis, Department of Industrial and Manufacturing Engineering, New Jersey Institute of Technology, Newark, New Jersey.

Alonso, JA & Lamata, MT 2006, 'Consistency in the Analytic Hierarchy Process: A New Approach', *International Journal of Uncertainty, Fuzziness and Knowledge-Based Systems*, vol. 14, no. 4, pp. 445-59.

Almeida, CMVB, Gianetti, BF, Ribeiro, CM 2005, Avaliação do ciclo de vida (ACV): uma ferramenta importante da ecologia industrial. Hottopos, viewed on 16 June 2013, <http://www.hottopos.com/regeq12/art4.htm>

Ambec, S & Lanoie, P 2008, 'Does it pay to be green? A systematic overview', *The Academy of Management Perspectives,* vol. 22, no. 4, pp.45-62.

Andersson, J, Pohl, J, and Eppinger, SD 1998, 'A design process modeling approach incorporating nonlinear elements', *Proceedings of 1998 ASME Design Engineering Technical Conferences*, Atlanta, Georgia, September.

Andrews, RR, *Strategies for Developing and Commercializing Next Generation Medical Devices,* Foster-Miller Inc., viewed on 16 June 2013, <http://thekenshogroup.com/docs/StrategiesforDevelopingandCommercializing.pdf>

Anityasari, M & Kaebernick, H 2008, 'A concept of reliability evaluation for reuse and remanufacturing', *International Journal Of Sustainable Manufacturing*, vol. 1, no. 1/2, pp.3–17.

Annes, J 2005, *Manufatura ambientalmente consciente, Edunisc*, Santa Cruz do Sul, Brazil.

Arntzen-Bechina AA & Leguy CAD 2007, 'An Insight into Knowledge Flow in Biomedical Engineering Science', *The Electronic Journal of Knowledge Management,* vol. 5., no. 2, pp 153–60.

Ashworth, C & Goodland, M 1990, *SSADM – a practical approach*, McGraw-Hill, Maidenhead, UK.

[B]

Baltes, H, Brand, O , Fedder, GK, Hierold, C, Korvink, J & Tabata, O 2008, *Enabling Technology for MEMS and Nanodevices,* Wiley-VCH Verlag GmbH & Co. KGaA, Weinheim, Baden-Württemberg, Germany.

Barker, S & King, A 2007, 'Organizing Reuse: Managing the Process of Design For Remanufacture (DFR)', *POMS 18th Annual Conference*, Production and Operations Management, Paper No. 007-0769, Dallas, Texas, U.S.A, 4-7 May.

Barragan, S, Cappellino, C, Dempsey, N & Rothenberg, S 2003, 'A framework for sourcing product development services', *Supply Chain Management: An International Journal,* vol. 8, no. 3, pp. 271-80.

Benoit, V & Rousseaux, P 2003, 'Aid for aggregating the impacts in life cycle assessment', *International Journal of Life Cycle Assessment*, vol. 8, no. 2, pp. 74-82.

Bermell-Garcia, P & Fan, IS 2008, 'Practitioner requirements for integrated Knowledge Based Engineering in PLM', *International Journal Product Life Cycle Management,* vol. 3 no.1, pp. 3-20.

Bhargava, A, Jamison, DT, Lau, L & Murray, CJL 2001, 'Modeling the effects of health on economic growth', *Journal of Health Economics,* vol. 20, no. 3, pp. 423-40.

Borja, V, Harding,JA & Toh, KTK 2000, 'Product re-engineering process using an enterprise modeling architecture', International Journal of Agile Systems and Management, vol. 213, pp. 214-224.

Bovea, MD, Gallardo, A 2006, 'The influence of impact assessment methods on materials selection for eco-design', *Materials & Design*, vol. 27, no. 3, pp. 209-215.

Boustani, A, Sahni, S, Graves, SC & Gutowski, TG 2010, 'Appliance Remanufacturing and Life Cycle Energy and Economic Savings' in *Proceedings of the IEEE International Symposium on Sustainable Systems and Technology (ISSST)*, IEEE, Arlington, Virginia, pp. 1 – 6.

Bouchard, C, Abi-zeid, I, Beauchamp, N, Lamontagne, L, Desrosiers, J 2010, 'Multicriteria decision analysis for the selection of a small drinking water system', *Journal of Water Supply: Research and Technology-AQUA*, vol. 59, no. 4, pp. 230–42.

Bouyssou, DT, Marchant, M, Pirlot, P, Perny, A, Tsoukias & Ph. Vincke 2000, *Evaluation and Decision Model. A Critical Perspective*, Kluwer Academic Publishers, Dordrecht, Netherlands.

Bras, B & McIntosh, MW 1999, 'Product, process and organizational design for remanufacture – an overview of research', *Robotics and Computer Integrated Manufacturing*, vol. 15, no. 3, pp 167-78.

Brink, C, van Ierland EC, Hordijk L, Kroeze C 2005, 'Cost-effective emission abatement in agriculture in the presence of interrelations: cases for the Netherlands and Europe', *Ecological Economics*, vol. 53, no. 1, pp. 59–74.

Brodwin, D 2012, 'New genomics breakthrough shows need for government funded research', US News, 10 September, viewed on 15 June 2013 <http://www.usnews.com/opinion/blogs/economic-intelligence/2012/09/10/new-genomics-breakthrough-shows-need-for-government-funded-research>

Buen, J 2013, *CDM Criticisms: Don't Throw the Baby out with the Bathwater,* Fridtjof Nansen Institute Climate Policy Perspectives, no. 8, viewed on 16 June 2013, <http://www.fni.no/doc&pdf/FNI-Climate-Policy-Perspectives-8.pdf>

Buyukozkan, GC & Feyzioglu, O 2004, 'A fuzzy-logic-based decision-making approach for new product development, *International Journal of Production Economics*, vol. 90, no. 1, pp.27-45.

[C]

Cakir, MC & Cavdar, K 2006, 'Development of a knowledge-based expert system for solving metal cutting problems', *Journal of materials and design*, vol. 27, no. 10, pp. 1027-34.

Callan SJ & Thomas JM 1996, *Environmental economics and management: theory, policy and applications*, Irwin, Chicago.

Capra F 2010, *The Tao of Physics: An Exploration of the Parallels between Modern Physics and Eastern Mysticism*, 5th edn, Shambhala Publishers, Boston, Massachusetts.

Cappelli, F, Delogu, M & Pierini, M 2006, 'Integration of LCA and EcoDesign guideline in a virtual cad framework', *Proceedings of Life Cycle Engineering*, Leuven, Belgium, 31 May-2 June, pp. 185-88.

Carlos, E, Silva, N & Paulino, GH 2005, 'Topology Optimization Design Of Functionally Graded Structures', *6th World Congresses of Structural and Multidisciplinary Optimization,* Rio de Janeiro, Brazil, 30 May - 03 June.

Cascini, G, Cugini, U, Frillici, FS & Rotini, F 2009, 'Computer-Aided Conceptual Design Through TRIZ-based Manipulation of Topological Optimizations', *Proceedings of the 19th CIRP Design Conference-Competitive Design*, Cranefield University, 30-31 March, pp. 263-270.

Catalano, CE, Falcidieno, B, Giannini, F & Monti, M 2002, 'A Survey of Computer-Aided Modeling Tools for Aesthetic Design', *Journal of Computing and Information Science and Engineering*, vol. 2, no. 1, pp. 11-20.

Chandrasekaran, B, Stone, RB & Mcadam, S DA 2004, 'Developing design templates for product platform focused design', Journal of Engineering Design, vol. 15, no. 3, pp. 208-28.

Chang, H-T & Chen, JL 2004, 'The conflict-problem-solving CAD software integrating TRIZ into eco-innovation', **Advance Engineering Software**, ***vol.*** 35, no. 8-9, pp.553-66.

Chapman, CB & Pinfold, M 1999, 'Design engineering: a need to rethink the solution using knowledge based engineering', **Knowledge-Based Systems**, vol. 12, no. 5-6, pp.257-67.

Charter, M 1998, 'Sustainable Value', *Journal Of Sustainable Product Design*, no.6, pp.57-59.

Chatterji, AK, Fabrizio, KR, Mitchell, W & Schulman, KA 2008, 'Physician-Industry Cooperation In The Medical Device Industry', *Health Affairs*, vol. 27, no. 6, pp. 1532-43

Chiang, TA, Trappey, AJC & Chen, WC 2008, ' Benchmark new product development processes using DEA-based Modularized approach', *Issues in Information Systems*, vol. 9, no. 2, pp. 153-162.

Chiodo 2005, 'Design for Disassembly Guidelines', *Active Disassembly Research Inc.*, United States, viewed on 16 June 2013, <http://www.activedisassembly.com/guidelines/ADR_050202_DFD-guidelines.pdf>.

Chiva-Gomez, R 2004, 'Repercussions of complex adaptive systems on product design management, *Technovation,* vol. 24, no. 9, pp. 707–11.

Cho, K-T & Kim, S-M 2003, 'Selecting medical devices and materials for development in Korea: the analytic hierarchy process approach', *International Journal of Health Planning and Management*, vol. 18, no. 2, pp.161–74.

Choi, SH & Cheung, HH 2008, 'A versatile virtual prototyping system for rapid product development', *Computers in Industry*, vol. 59, no. 5, pp. 477–488.

Clark, KB & Fujimoto, T 1991, *Product Development Performance: Strategy, Organization and Management in the World Auto Industry*, Harvard Business School Press, Boston.

Cohen, M & Howard, J 2006, 'Success and its price: the institutionalization and political relevance of industrial ecology', *Journal of Industrial Ecology,* vol. 10, no. 1-2, pp. 79–88.

Corallo, A, Laubacher, R, Margherita, A & Turrisi, G 2009, 'Enhancing product development through knowledge-based engineering (KBE): A case study in the aerospace industry', *Journal of Manufacturing and Technology Management*, Vol. 20 No. 8 , pp. 1070 – 1083.

Costanza, R, d'Arge, R, de Groot, R, Farberk, S, Grasso, M, Hannon, B, Limburg, K, Naeem, S, O'Neill, RV, Paruelo, J, Raskin, RG, Sutton, P & van den Belt, M 1998, 'The value of the world's ecosystem services and natural capital', *Ecological Economics*, vol. 25, no. 1, pp. 3-15.

Cowan, R 2001, 'Expert systems: aspects of and limitations to the codifiability of knowledge', *Research Policy*, vol. 30, no. 9, pp. 1355–72.

Cui, JR & Zhang, LF 2008, 'Metallurgical recovery of metals from electronic waste: a review', *Journal of Hazardous Material*, vol. 158, no. 2-3, pp.228–56.

Culshaw, B & Kersey, A 2008, 'Fiber-Optic Sensing: A Historical Perspective', *Journal of lightwave technology*, vol. 26, no. 9, pp. 1064-78.

[D]

D'Alessandro, S & Fanelli, D 2009, *The Role of Income Distribution in the Diffusion of Corporate Social Responsibility*, MPRA Paper 18659, University Library of Munich, Germany, viewed on 15 June 2013, <http://mpra.ub.uni-muenchen.de/18659/1/The_Role_of_Income_Distribution_in_the_Diffusion_of_Corporate_Social_Responsibility.pdf>

Daly, HE & Cobb, JB 1989, *For the Common Good*, Beacon Press, Boston.

Damelio, R 1995, The Basics of Benchmarking, 1 edn, Productivity Press, New York.

Dankwort, CW, Weidlich, R, Guenther, B & Blaurock, JE 2004, 'CAD Education Engineers' CAx education—it's not only CAD', *Computer-Aided Design*, vol. 36, no. 14, pp. 1439-50.

Davis, CR 2002, 'Calculated Risk: A Framework for Evaluating Product Development', *MIT Sloan Management Review*, vol.43, no.4, pp.71-77.

Denning, S 2012, 'What Killed Michael Porter's Monitor Group? The One Force That Really Matters', *Forbes*, 20 November 2012, viewed on 16 June 2013, <http://www.forbes.com/sites/stevedenning/2012/11/20/what-killed-michael-porters-monitor-group-the-one-force-that-really-matters/>

De Marco T 1979, *Structured analysis and system specification*, Prentice Hall, Englewood Cliffs.

Deng, Y-M, Britton, GA, Lam, YC, Tor, SB & Ma, YS 2002, 'Feature-based CAD-CAE integration model for injection-moulded product design', **International Journal of Production Research**, vol. 40, no.15, pp. 3737-50.

Denton, M & Ford, S 2009, 'Tapping into Digital Design Tools: Finite-element analysis enables accurate device predictions that improve design, durability, and, ultimately, patient survival', *Medical Device and Diagnostic Industry*, January 1, viewed on 16 June 2013, < www.mddionline.com/article/tapping-digital-design-tools >

DeSimone, LD & Popoff, F 1997, *Eco-efficiency: the business link to sustainable development,* The MIT Press, Massachusetts Institute of Technology, USA.

Dey, PK 2002, 'Project Risk Management: A Combined Analytic Hierarchy Process and Decision Tree Approach', *Cost Engineering,* vol. 44, no. 3, pp. 13-26.

Ding, Y & Strong, D 2010, 'A Three-Step Procedure (3SP) for the Best Use of Skilled Labour', *International Journal of Business Research and Management (IJBRM)*, vol. 1, no. 2, pp. 87-104.

Dobbs, J & Cormican, K 2007, 'A design for environment product analysis', Paper presented at the *4th International on Product Life Cycle Management Conference*, July, Kilometro Rosso, Italy.

Dodrill, D 2010, *Sustainability and Medical Device Packaging*, European Medical Device Technology, May 2, viewed on 16 June 2013, <http://www.emdt.co.uk/article/sustainability-and-medical-device-packaging>.

Dougherty, D 1992, 'Interpretive Barriers to Successful Product Innovation in Large Firms', *Organization Science*, vol. 3, no. 2, pp. 179–202.

Dwivedia, SN & Sharan, A 2003, 'Development of knowledge based engineering module for diagnosis of defects in casting and interpretation of defects by non destructive testing', J*ournal of Materials Processing Technology*, vol.141, no. 2, pp.155–62.

Dyer, J 2000, *Collaborative Advantage: Winning Through Extended Enterprise Supplier Networks*, Oxford University Press, UK.

[E]

Edwards, ET (Intellijject, LLC) 2008, 'The Importance of Utilizing Human Factors Engineering in Developing Biomedical Innovation', *12th Annual Meeting National Collegiate Inventors and Innovators Alliance*, Hadley, Massachusetts, 20th to 22nd March, pp. 03-12.

Eichstaedt, P 2011, *Consuming the Congo: War and Conflict Minerals in the World's Deadliest Place,* Chicago Review Press, Chicago.

Eldrandaly, K 2207, 'An Intelligent MCDM Approach for Selecting the Suitable Expert System Building Tool', *The International Arab Journal Of Information Technology*, vol. 4, no. 4, October 4, pp.365-72

ElMaraghy, W 2009, 'Knowledge Management in collaborative engineering', *International Journal Collaborative Engineering*, vol. 1, nos. 1/2, pp. 114-124.

Esposito, F 2011, 'Sustainability issues looming for medical-device designers', *PlasticNews.com*, 26 April, viewed on 15 June 2013, <http://www.wvma.com/20110426187/Latest-News/sustainability-issues-looming-for-medical-device-designers.html>

Eshlaghy, AT, Mottaghi, H & Shafieyoun, R 2011, 'Effective factors on sustainability of manufacturing processes, overcoming shrinkage in improved processes', *African Journal of Business Management*, vol. 5, no. 7, pp. 2700-7.

Espregueira-Mendes, J, Pereira, H, Sevivas, N, Passos, C, Vasconcelos, JC, Monteiro, A, Oliveira, JM & Reis, RL 2012,'Assessment of rotatory laxity in anterior cruciate ligament-deficient knees using magnetic resonance imaging with Porto-knee testing device', *Knee Surgery, Sports Traumatology, Arthroscopy: official journal of the ESSKA.*, vol. 20, no. 4, pp. 671-8.

[F]

Faniel, P 2011, *RE-INVENTING MEDICAL DEVICES Numbers May Drive the Business,*
but it's Your People Who Drive the Numbers. 5 Major Simultaneous Changes in the Medical
Devices Industry. How Will You and Your Company Deal with Them?, Management Centre
Europe, Executive Issue No. 37, Brussels, Belgium.

Fenlon, AJ & Walton, PRB 2000, 'An integrated visualization and design toolkit for flexible prosthetic heart valves', In *Proceedings of the conference on Visualization,* IEEE Computer Society Press, Los Alamitos, CA, USA, pp. 453-6.

Finger, S & Dixon, JR 1989, 'A review of research in mechanical engineering design, part I: Descriptive, prescriptive and computer–based models of design processes', *Research Engineering Design*, Vol. 1, No. 1, pp. 51-68.

Finger, S & Dixon, JR 1989, 'A review of research in mechanical engineering design, part II: Representations, Analysis, and Design for the life cycle," *Research Engineering Design*, Vol. 1, No. 2, pp. 121-137.

Filho, AG, Pigosso, DCA, Ometto, AR & Rozenfeld, H 2009, 'Remanufacturing on a Framework for Integrated Technology and Product-System Lifecycle Management (ITPSLM)', Proceedings of the 1st CIRP Industrial Product-Service Systems (IPS2) Conference, Cranefield University, 1-2 April 2009, pp. 273-279.

Fiksel, J 2006, 'Sustainability and resilience: towards a systems approach', *Sustainability: Science, Practice, & Policy***,** vol. 2, no. 2, pp. 14-21.

Fishman, A, Gandal, N & Shy, O 1993, 'Planned Obsolescence as an engine of technological progress', *The Journal of Industrial Economics*, Vol. 41, No. 4, pp. 361-370.

Fishman, C 2012, 'The Insourcing Boom', *The Atlantic*, 28th November 2012, viewed on 15 June 2013, <http://www.theatlantic.com/magazine/archive/2012/12/the-insourcing-boom/309166/>

Fitzgerald, DP, Herrmann, JW & Schmidt, LC 2010, 'A Conceptual Design Tool for Resolving Conflicts Between Product Functionality and Environmental Impact', *Journal of Mechanical Design,* vol. 132, no. 9, pp. 091006-1 to 091006-11.

Fjelstad, J 2010, *Flexible Printed Electronics: Past, Present and Future,* 26 April, viewed on 15 June 2013, **<**http://industrial-printing.net/content/flexible-printed-electronics-past-present-and-future?page=0%2C0**>**

Forman, EH 1990, 'Random indices for Incomplete Pair wise Comparison Matrices', *European Journal of Operational Research,* vol. 48, no. 1, pp. 153-55.

Fortin, C & Huet, G 2007, 'Manufacturing Process Management: iterative synchronisation of engineering data with manufacturing realities', *International Journal of Product Development 2007,* Vol. 4, No.3/4 , pp. 280 – 295.

Fowlkes, WY & Clyde, MC 1995, *Engineering Methods for Robust Product Design: Using Taguchi Methods in Technology and Product Development* , 1 edn, Prentice Hall, New Jersey.

Fresner, J, Jantschgi, J, Birkel, S, Bärnthaler, J & Krenn, C 2010, 'The theory of inventive problem solving (TRIZ) as option generation tool within cleaner production projects', *Journal of Cleaner Production,* vol. 18, no. 2, pp. 128–36.

[G]

Gaha, R, Benamara, A & Yannou, B 2011, 'Influence of geometrical characteristics on eco-designed products' in *Proceedings of the IMProVe International conference on Innovative Methods in Product Design*, Venice, Italy, 15-17 June, pp. 242-47.

Gallo, M, Guizzi, G & Naviglio, G 2010, 'About optimal remanufacturing policies and secondary markets supplying', *In* **Proceedings of the 11th WSEAS international conference on mathematics and computers in business and economics and 11th WSEAS international conference on Biology and chemistry**, World Scientific and Engineering Academy and Society (WSEAS), Stevens Point, Wisconsin, USA, pp. 373-8.

Garnsworthy, J & Bell, P 2004, 'What can the medical device industry teach us about safety', *Total Vehicle Technology*, Brighton, UK, April, pp. 26-27.

Ghazalli, Z & Atsuo, M 2009, 'The Development of the Computer Aided Remanufacturing System (CARES) Part I: Software Development (Phase I) and a Simulation Study'. Paper Presented at the *Fifth International Workshop on Computational Intelligence & Applications*, IEEE SMC Hiroshima Chapter, Hiroshima University, Japan 10-12 November.

Gitlin, J 1995, 'Why Older People Accept or Reject Assistive Technology', *Generations, Journal of the American Society on Aging,* Vol. 29, no. 1, pp. 4146.

Goedkoop, MJ, van Halen, CJG, te Riele, HRM & Rommens, PJM 1999, 'Product Service systems Ecological and Economic Basics'.

Goedkoop, M, Spriensma, R 2000, 'The ecoindicator-99: a damage oriented method for life cycle impact assessment: methodology report', Pré Consultants BV, Amersfoort, The Netherlands.

Gonçalves, C, Machado, C and Cavenaghi, V 2009, 'Use of life cycle assessment in sustainable manufacturing: review of literature, analysis and trends', *20th Annual Conference of Production and Operations Management Society*, Orlando, Florida, May 1 to 4, United States of America.

Goodland R 2002, Sustainability: Human, Social, Economic and Environmental, Encyclopedia of Global Environmental Change, John Wiley & Sons / World Bank, New York.

Greening, L & Bernow, S 2004, 'Design of coordinated energy and environmental policies: use of multicriteria decision making', *Energy Policy*, vol. 32, no. 6, pp. 721-35.

Gregorio & Scott, S 2003, 'Why do some universities generate more start-ups than others?', *Research Policy*, vol. 32, no. 2, pp. 209–227.

Griffin, A & Hauser, JR 1996, 'Integrating R&D and Marketing: A review and analysis of the literature', *Journal of Product Innovation Management*, Vol. 13, No. 3, pp. 191-215.

Griffin, A 1997, 'The Effect of Project and Process Characteristics on Product Development Cycle Time', *Journal of Marketing Research*, Vol. 34, no. 1, pp. 24–35.

[H]

Halog, A 2004, 'A Life Cycle Approach for Strategic Selection of Sustainable Product Improvement Alternatives Under Data Uncertainty', *The Journal of Sustainable Product Design*, Vol. 4, no. 1-4, pp. 3-19.

Hambali A, Sapuan SM, Ismail N & Nukman, Y 2009, 'Application of analytical hierarchy process in the design concept selection of automotive composite bumper beam during the conceptual design stage', *Scientific Research and Essays*, vol. 4, no.4, pp. 198-211.

Hamilton, C 2013, *Earthmasters: The Dawn of the Age of Climate Engineering*, Yale University Press, Connecticut.

Hammond R, Amezquita, T & Bras, B 1998, 'Issues in Automotive Parts Remanufacturing Industry: Discussion of Results from Surveys Performed among Remanufacturers', *Journal of Engineering Design and Automation*, Vol. 4, No. 1, pp. 27-46.

Handler, D & Grossman, R 2009, *The Role of Income Distribution and Broadband Penetration in Developing Countries*, Technical Report, Cisco Systems Inc., viewed on 15 June 2013, <http://www.cisco.com/web/about/ac79/docs/pov/Income_Distribution_POV_1123_1207FINAL.pdf>

Hanson, JJ & Hitchcock, RW 2009, 'Towards Sustainable Design for Single-use Medical Devices', *Proceedings of the 31st Annual International Conference of the IEEE EMBS Minneapolis*, IEEE, pp. 5602-05.

Hart, S 2005, *Capitalism at the Crossroads: The Unlimited Business Opportunities in Solving the World's Most Difficult Problems*, Wharton School Publishing, University of Pennsylvania, Philadelphia, USA.

Hart, CG 2010 , 'Multidisciplinary design optimization of complex engineering systems for cost assessment under uncertainty', Doctoral Thesis, The University of Michigan

Hartley, JF 1994, '*Case studies in Organizational research*' in C Cassel & S Gillian (eds), *Qualitative Methods in Organizational Research: A Practical Guide*, Sage Publications, Thousand Oaks, California.

Hassler, C, Boretius, T & Stieglitz, T 2011, 'Polymers for Neural Implants Review', *Journal of Polymer Science Part B: Polymer Physics*, vol. 49, no. 1, pp. 18–33.

Hauschild, M, Jeswiet, J & Alting, L 2005, 'From Life Cycle Assessment to Sustainable
Production: Status and Perspectives', *CIRP Annals – Manufacturing Technology*, vol.54,
no.2, pp. 1-21.

Hayes, J 2010, *Fiber Optics Technician's Handbook*, Delmar Publishers, Albany, New York.

Hermele, K 2009**, '**The Use and Misuse of Reductionist Measures of the Nature-Economy Interface', *Proceedings of the Fifth biannual conference Science and Policy for a Sustainable Future*, US Society for Ecological Economics, Washington, DC, 31 May – 3 June.

Hemphill, L, McGreal, S & Berry, J 2002, 'An aggregating weighting system for evaluating sustainable urban regeneration', *Journal of Property Research*, vol. 19, no. 4, pp. 553-75.

Hilbert, M 2012, 'Toward a synthesis of cognitive biases: How noisy information processing can bias human decision making', *Psychological Bulletin*, vol. 138, no. 2, pp. 211–37.

Hede, S, Ferreira, PV, Lopes, MN & Rocha, LA 2011, 'Development Of Sustainable Medical Devices'. Paper presented at the *Semana da Escola de Engenharia (One Week Conference at the School of Engineering)*, University of Minho, Azurem, Portugal, 24-27 October.

Hermann, BG, Kroeze, C & Jawjit, W 2007, 'Assessing environmental performance by combining life cycle assessment, multi-criteria analysis and environmental performance indicators', *Journal of Cleaner Production*, vol. 15, no. 18, pp. 1787-96.

Herrmann, C, Bergmann, L, Thiede, S & Halubek, P 2007, 'Total Life Cycle Management - An Integrated Approach Towards Sustainability', *Paper Presented at the 3rd International Conference on Life Cycle Management*, University of Zurich at Irchel, Switzerland, 27-29 August.

Hijikata, Y 2012, *Physics and Technology of Silicon Carbide Devices,* InTech, Croatia.

Hill, T & Westbrook, R 1997, 'SWOT Analysis: It's Time for a Product Recall', *Long Range Planning*, Vol. 30, no. 1, pp. 46–52.

Hölttä-Otto, K & Weck, O 2007, 'Degree of Modularity in Engineering Systems and Products with Technical and Business Constraints', *Concurrent Engineering*, vol. 15, no.2, pp. 113-26.

Huesemann MH, Huesemann JA 2011, *Technofix: Why Technology Won't Save Us or the Environment*, New Society Publishers, British Columbia, Canada.

Hu, G, Wang, Y & Bidanda, B 2006, 'Product Lifecycle Management Challenges in Trans-National Environments', Paper presented at the *Industrial Engineering Research Conference*, Orlando, Florida, USA, 20-24 May.

Hummel, JM, Rossum, WV, Gijsbertus, JV & Rakhorst, G 2002, 'Product design planning with the analytic hierarchy process in inter–organizational networks', *R&D Management,* vol. 32, no. 5, pp. 451–58.

Hobbs, B & Meier, P 2003, *Energy decisions and the environment: A guide to the use of multicriteria methods,* 2nd edn, Kluwer Academic Publishers, Netherlands.

Hon, C, Hou, J & Tang, L 2005, 'The application of Delphi method for setting up performance evaluation structure and criteria weights on warehousing of third party logistics', *Proceedings of the 35th International Conference on Computers and Industrial Engineering,* Istanbul, Turkey.

Hsu, T-R 2005**, '**Micro Assembly- A technology on the frontier of new industrial automation', *keynote speech delivered at the 8th International Conference on Automation Technology*, Taiwan, 5 May.

Hwang, YH & Park, J-G 2006, 'Approaches and Requirements to Develop and Improve the Standard Processes for a Research and Development Organization', *Systems Engineering,* Electronics and Telecommunications Research Institute , vol. 9, no. 1, pp. 35-44.

[I]

Ijomah, W, Bennett, JP, Pearce, J 1999, 'Remanufacturing: Evidence of Environmentally Conscious Business Practice in the UK', *Proceedings of the IEEE International Symposium on Electrics and the Environment*, Danvers, USA, 11-13 May, pp. 192-196.

Isaksson, O, Keski–seppälä, S & Eppinger, SD 2000, 'Evaluation of design process alternatives using signal flow graphs', *Journal of Engineering Design*, vol. 11, no. 3, pp. 211–24, viewed on 16 June 2013 <http://web.mit.edu/eppinger/www/pdf/Isaksson_JED2002.pdf>

[J]

Jagdev, HS & Browne, J 1998, 'The extended enterprise - a context for manufacturing'', *Production Planning & Control*, Vol. 9 No. 3, pp. 216-29.

Jamali D 2004, 'Success and failure mechanisms of public private partnerships (PPPs) in developing countries: Insights from the Lebanese context', *The International Journal of Public Sector Management*, vol. 17, no. 5, pp. 414-30

Jansen, R 1992, *Multi-objective decision support for environmental management,* Kluwer Academic Publishers, Dordrecht, Germany.

Jasch, C 2000, 'Environmental performance evaluation and indicators. Journal of Cleaner Production 2000, vol. 8, pp. 79-88.

Javadi, AA & Bello-Dambatta, A 2008, 'Analytic Hierarchy Process for the Sustainability Appraisal of Contaminated Land', *Proceedings of the Intelligent Computing and Engineering – ICE*, pp. 360-9.

Jensen, FV 1997, *Introduction to Bayesian Networks*, Springer, New York, 1st edition.

Jerrad, RN, Barnes, N & Reid, A 2008, 'Design, Risk and New Product Development in Five Small Creative Companies', *International Journal of Design*,Vol.2, No.1,pp.21-30.

Jeswiet, J 2003, 'A Definition for Life Cycle Engineering', *36th International seminar on Manufacturing Systems*, June 3, Saarbrucken, Germany. Plenary Speech; pp 17 – 20.

Jia, D, Qin, W & Zuo, Z 2010, 'Application of Fuzzy Analytic Hierarchy Process on Design Evaluation of Diesel Engine Structure Aimed to Improve Volume Power', *Proceedings of the International Conference on Intelligent Systems and Knowledge Engineering (ISKE)*, Hangzhou, China, 15th- to 16thNovember, pp. 504-7.

Jones, DJ & Masters, MT 2008, 'Medical Device Development Process', Medical Device Solutions Battelle Memorial Institute. Published and used by INCOSE with permission.

[K]

Kablan, M 2004, 'Decision support for energy conservation promotion: an analytic hierarchy process approach', *Energy Policy*, vol. 32, no. 10, pp. 1151–8.

Kadamus, C 2008, *Sustainable design for medical devices,* Medical Device and Diagnostic Industry, 1 September, viewed on 15 June 2013 <http://www.mddionline.com/article/sustainability-medical-device-design>

Kaebernick,H, Kara, S & Sun, M 2003, 'Sustainable product development and manufacturing by considering environmental requirements', *Robotics and Computer Integrated Manufacturing,* Vol. 19, No. 6, pp. 461-468.

Kaljun, J & Dolsak, B 2011, 'Artificial intelligence in aesthetic and ergonomic product design process', Proceedings of the *34th International Convention MIPRO,* Opatija, Croatia, pp. 959 – 964, 23-27 May.

Khomenko, N & Ashtiany, M 2007, 'Classical TRIZ and OTSM as a scientific theoretical background for non-typical problem solving instruments', *Proceedings of the conference ETRIA TRIZ-Future 2007*, Frankfurt, Germany, 6-8 November.

Kindström, D & Kowalkowski, C 2009, 'Development of industrial service offerings: a process framework', Journal of Service Management, vol. 20, no. 2, pp. 156-72.

King, AM & Burgess, SC 2005, 'The Development of a Remanufacturing Platform Design: a strategic response to the Directive on Waste Electrical and Electronic Equipment', *Proceedings of the Institution of Mechanical Engineers, Part B: Journal of Engineering Manufacture*, vol. 219, no. 8, pp. 623-31.

King, AM, Burgess, SC, Ijomah, W & McMahon, CA 2006, 'Reducing waste: Repair, recondition, remanufacture or recycle?', **Sustainable Development**, vol. 14, no. 4, pp. 257-67.

Kodiyalam, S, Yang, RJ, Gu, L and Tho, C 2002, 'Large Scale Multidisciplinary Optimization of Vehicle System in a Scalable, High Performance Computing Environment', *Structural and Multidisciplinary Optimization*, vol. 26, no. 3-4, pp. 256-63.

Kodiyalam, S, Yang RJ, Gu L & Tho C 2004, 'Large Scale Multidisciplinary Optimization of Vehicle System in a Scalable, High Performance Computing Environment', *Structural and Multidisciplinary Optimization*, vol. 26, no. 3/4, pp. 256-63

Kortman JGM, Lindeijer, EW, Sas, H & Sprengers, M 1994, 'Towards a single indicator for emissions an exercise in aggregating environmental effects', Den Haag, Netherlands; 1994.

Krishnan, V & Ulrich, KT 2001, 'Product Development Decisions: A Review of the Literature', *Management Science*, vol. 47, no. 1, pp. 1-21.

Krugman, P 2012, *End This Depression Now!,* W. W. Norton & Company, New York.

Kulon, J, Broomhead, P & Mynors, DJ 2006, 'Applying knowledge-based engineering to traditional manufacturing design', **International Journal of Advanced Manufacturing Technology**, vol. 30, no. 9-10, pp. 945-51.

Kumar, SA & Suresh, N 2007, *Production and Operations Management (With Skill Development, Caselets and Cases),* 2nd edn, New Age International Publishers Limited, New Delhi, India.

Krishnan, V & Ulrich, KT 2001, 'Product Development Decisions: A Review of the Literature', *Management Science*, vol. 47, no. 1, pp.1-21.

[L]

Labuschagne, C. and Brent, AC 2005, 'Sustainable Project Life Cycle Management: The need to integrate life cycles in the manufacturing sector', International Journal of Project Management, vol. 23, no. 2, pp. 159-68.

Lai, V, Wong, B & Cheung, W 2002, 'Group decision making in multiple criteria environment: A case using AHP in software selection', *European Journal of Operational Research*, vol. 137, no. 1, pp 134-44.

Lee, CKM, Lau, HCW & Yu, KM 2005, 'An object-based knowledge integration system for product development: a case study', **Journal of Manufacturing Technology Management**, vol. 16, no.2, pp.156-77.

Lee, SH 2005, 'CAD–CAE integration approach using feature-based multi-resolution and multi-abstraction modeling techniques', *Computer-Aided Design,* vol. 37, no. 9, pp. 941–55.

Lee, S, Yoon, Y & Kim, J 2007, 'A study on making a long-term improvement in the national energy efficiency and GHG control plans by the AHP approach', *Energy Policy*, vol. 35, no. 5, pp. 2862-8.

Liang, Z, Yang, K, Yuan, S, Zhang, H & Zhang, Z 2006, 'Decision support for choice optimal power generation projects: Fuzzy comprehensive evaluation model based on the electricity market', *Energy Policy*, vol. 34, no. 17, pp. 3359-64.

Liberatore, MJ & Nydick, RL 2008, 'The analytic hierarchy process in medical and health care decision making: A literature review', *European Journal of Operational Research*, vol. 189, no. 1, pp. 194–207.

Linnér, B-O and Selin, H 2003, 'The Thirty Year Quest for Sustainability: The Legacy of the 1972 UN Conference on the Human Environment', Annual Convention of International Studies Association, Portland, Oregon, 25 February – 1 March, USA.

Long, PH 2008, 'Medical Devices in Orthopedic Applications', *Toxicologic Pathology,* vol. 36, no. 1, pp. 85-91.

Lund, R 1985, 'Remanufacturing: The experience of the United States and implications for developing countries', *UNDP Project Management Report No 2. World Bank Technical Paper*, no. 31, pp. 24-34.

[M]

Magee, L & Scerri, A 2012, 'From Issues to Indicators: A Response to Grosskurth and Rotmans', *Local Environment*, vol. 17, no. 8, pp. 915-33.

Magne, P 2010, 'Virtual prototyping of adhesively restored, endodontically treated molars', *Journal Prosthetic Dentistry*, vol. 103, no. 6, pp. 343-51.

Malhotra, MK, Grover, V & Desilvio, M 1996, 'Reengineering the new product development process: A framework for innovation and flexibility in high technology firms', *Omega*, vol. 24, no. 4, pp. 425-41.

Mallick , DN & Schroeder, RG 2005, 'An Integrated Framework for Measuring Product Development Performance in High Technology Industries', *Production and Operations Management*, vol. 14, no. 2, pp. 142–58.

Malmi, T & Ikaheimo, S 2003, 'Value Based Management practices—some evidence from the field', *Management Accounting Research*, vol. 14, no. 3, pp. 235-54.

Marques, CSA & Aguiar, EM 2004, 'Reverse Logistics: An Important Tool for the Solid Waste Management', *Proceedings of the Global Conference on Sustainable Product Development and Life Cycle Engineering*, Berlin, Germany, 29 September – 1 October.

Marra, M, Ho, W & Edwards, JS 2011, 'Managing supply chain knowledge in the new product development process: A social network analysis approach', *Proceedings of the IEEE International Conference on Industrial Engineering and Engineering Management (IEEM)*, 6-9 December, pp. 1607-11.

Matlis DR 2007, 'Design for Manufacturability: Building Quality by Design A White Paper for the Medical Device Industry', June, viewed on 16 June 2013, <www.ptc.com/WCMS/files/141875/en/Design_for_Manufacturability_Building_Quality_by_Design.pdf>

Matlis, DR 2009, 'Managing the Total Product Life Cycle', *Medical Product Outsourcing*, July/August, viewed on 16 June 2013, <www.mpo-mag.com/articles/2009/07/managing-the-total-product-life-cycle >

McCarthy, IP, Tsinopoulos, C, Allen, P and Rose-Anderssen, C 2006, 'New Product Development as a Complex Adaptive System of Decisions', *Journal of Product Innovation and Management*, vol. 23, no. 5, pp. 437–56.

McConnaughey, J 2013, 'Gulf Of Mexico Dolphin Deaths Point To Continued Effects Of BP Oil Spill, Group Alleges', The Huffington Post, 2 April 2013, viewed

on 16 June 2013,<www.huffingtonpost.com/2013/04/02/gulf-of-mexico-dolphin-deaths-bp_n_3001408.html>

Meredith, JR, Raturi, A , Amoako-Gyampah, K & Kaplan, B 1989, 'Alternative research paradigms in operations', *Journal of Operations Management*, vol. 8, no. 4, pp. 297-326.

Miller, C 2007, 'Bringing a new medical device to market: The challenges of picking a winner', *Minnesota Physician*, vol. 21, no. 8, pp.1-2.

Modelski, G, Devezas, T & Thompson, W 2008, *Globalization as an Evolutionary Process: Modeling Global Change,* Routledge, London.

Mont, O 2000, 'Product-Service Systems', *The International Institute of Industrial Environmental Economics*, Stockholm, Sweden.

Moore, JW 2011, 'Transcending the Metabolic Rift: Towards a Theory of Crises in the Capitalist World-Ecology', *Journal of Peasant Studies*, vol. 38, no. 1, pp. 1-46.

[N]

Nag, S & Banerjee, R 'Fundamentals of Medical Implant Materials', University of North Texas in Narayan, R (editor) 2012, Materials for Medical Devices, *ASM Handbook*, vol. 23, pp. 6-17, viewed on 16 June 2013, <www.asminternational.org/content/ASM/StoreFiles/05285G_Sample.pdf>

Nair, K, Muraleedharan, CV & Bhuvaneshwar, GS 2003, 'Developments in mechanical heart valve prosthesis', *Sadhana*, vol. 208, no. 3-4, pp. 575-87.

Nandwana, D, Bhupendra, NK, Bhargava, T, Nandwana, K & Jawale, G 2010, 'Design, Finite Element Analysis and Optimization of HRC Trays used in Heat Treatment Process', Paper presented at the *World Congress on Engineering* II, 30 June-2 July.

Nasr, N & Thurston, M 2006, 'Remanufacturing: A Key Enabler to Sustainable Product Systems' in *the Proceedings of 13th CIRP International Conference on Life Cycle Engineering,* pp. 15-18.

Nigim, K, Munier, N & Green, J 2004, 'Pre-feasibility MCDM tools to aid communities in prioritizing local viable renewable energy sources', *Renewable Energy*, vol. 29, no. 11, pp. 1775–91.

Nukala, S & Gupta, SM 2005, 'Multi-Criteria Analysis of Potential Recovery Facilities in a Reverse Supply Chain', *Proceedings of the SPIE International Conference on Environmentally Conscious Manufacturing V*, pp. 155-162.

[O]

Olsthoorn, X, Tyteca, D, Wehrmeyer, W, Wagner, M 2001, 'Environmental indicators
for business: a review of the literature and standardization methods', *Journal of Cleaner Production*, vol. 9, no. 5, pp. 453–63.

Ohlendorf, M., 2006, Dissertation TU Braunschweig, Simulationsgestützte Planung und Bewertung von Demontagesysteme, Vulkan Verlag, Essen.

[P]

Pacelli, L 2004, *The Project Management Advisor: 18 Major Project Screw-ups, and How to Cut Them Off at the Pass,* Prentice Hall, NJ

Viewed on 8th March 2013 <http://office.microsoft.com/en-us/project-help/know-when-to-pull-the-plug-on-a-doomed-project-HA010066435.aspx>

Packard, V 1963, *The Waste Makers*, Longmans, Harlow, UK, pp. 68-77.

Pagell, M, Wu, Z & Murthy, N 2005, 'Understanding End-of-life Product Management using an Eco-centric Perspective of Supply Chain Management', *Business Aspects of Closed Loop Supply Chains Workshop*, Nashville.

Parametric Technology Corporation (PTC) 2008, *Managing the Total Product Life Cycle: The Changing Face of Medical Device Product Development*, viewed on 7 June 2013, <http://www.single-sourcing.com/products/value/3988_PLM_QMS_WP_EN.pdf>.

Parendo, PK 2011, 'Excellence Framework for New Product Development', Proceedings Minnesota Quality Conference held on 14th March, viewed 14 June 2013
<www.perryssolutions.com/publications/Excellence%20Framework%20for%20NPD%20-%20Perrys%20Solutions.pdf>

Parliamentary Office of Science and Technology (POST) 2008, *ICT and CO2 emissions*, viewed on 15 June 2013, <www.parliament.uk/documents/post/postpn319.pdf>

Parlikad, AKN, McFarlane, DC & Kulkarni, AG 2005, '***Improving product recovery decisions through enhanced information*', Proceedings in** *12th CIRP Life Cycle Engineering Seminar*, Grenoble, France.

Parenti, C 2011, *Tropic of Chaos: Climate Change and the New Geography of Violence,* Nation Books, New York.

Pun, KF, Chin, KS, Yiu, MYR 2010, 'An AHP approach to assess new product development performance: an exploratory study', *International Journal of Management Science and Engineering Management*, vol. 5, no. 3, pp. 210-18.

Patil, RR 2010, 'Five steps to creating reliable medical devices', *EE Times*, 7 September, viewed on 15 June 2013 <http://www.embedded.com/design/prototyping-and-development/4207444/Five-steps-to-creating-reliable-medical-devices->

Patton, MQ 1990, *Qualitative Evaluation and Research Methods,* 2nd edn, Sage Publications, Newbury Park, CA.

Petrie, J, Stewart, M, Basson, L, Notten, P & Alexander, B 2006, 'Structured Approaches to Decision Making for Cleaner Products and Processes', Center for

Risk, Environment and Systems Technology and Analysis, Department of Chemical Engineering, University of Sydney.

Pineda-Henson R, Culaba AB & Mendoza GA 2002, 'Evaluating environmental performance of pulp and paper manufacturing using the analytic hierarchy process and life-cycle assessment', *Journal of Industrial Ecology*, Vol. 6, no.1, pp. 15-28.

Pineda-Henson, R & Culaba, AB 2004, 'A diagnostic model for green productivity assessment of manufacturing processes', *International Journal of Life Cycle Assessment*, Vol. 9, no.6, pp. 379-86.

Price, AR, Keane, AJ & Holden, CME 2010, 'On the Coordination of Multidisciplinary Design Optimization Using Expert Systems', *Proceedings of 4th International Conference on Learning and Intelligent Optimization,* pp. 212-5.

Pubule, J, Grabis, J & Blumberga, D 2011, *Industrial processes and emission of pollutants*,
Riga Technical University, Latvia, Plasma for environmental Protection (PlasTEP), Partly funded by European Union, viewed on 15 June 2013, <http://www.plastep.eu/fileadmin/dateien/Events/2011/110725_Summer_School/Industrial_Emissions_Pubule_27.07.2011..pdf>

Purser, RE, Park, C and Montuori, A 1995, 'Limits to Anthropocentrism: Toward An Ecocentric Organization Paradigm', *Academy of Management Review*, vol. 20, no. 4, pp. 1053-1089.

Putri, NT & Yusof, SM 2009, 'Critical Success Factors for Implementing Quality Engineering Tools and Techniques in Malaysian's and Indonesian's Automotive Industries: An Exploratory Study', *Proceedings of the International Multi Conference of Engineers and Computer Scientists*, Vol. II, Lecture Notes in Engineering and Computer Science, 1-2, International Association Engineers-Iaeng, Hong Kong.

Pennsylvania Department of Environmental Protection 2009, *Recycling Works Here's how,* viewed on 16 June 2013,

<www.dep.state.pa.us/dep/deputate/airwaste/wm/recycle/Recywrks/recywrks1.htm>.

Project Management Book of Knowledge 2010, Project Management Institute, Pennsylvania, United States.

Pujari, D 2006, 'Eco-innovation and new product development: understanding the influences on market performance', *Technovation*, vol.26, no.1, pp.76-85.

[Q]

Qi, J, Yan, G, Zou, H, Liu, B & Lei, Y 2004, 'The manufacturing process management system based on resource optimal allocation', *Proceedings of The 8th International Conference on Computer Supported Cooperative Work in Design*, vol.1, Xiamen, China, 26-28 May, pp. 267–71.

[R]

Rainey, DL 2005, *Product innovation: Leading change through integrated product development*, Cambridge University Press, Cambridge, UK

Ramjerdi, F 2008, 'Decision Making tools and Sustainability', *Proceedings of the COST 356 seminar*, European Cooperation in the field of Scientific and Technical Research, Oslo, Norway, 20th February.

Rebelo de Mira, R & Kroeze, C 2206, 'Greenhouse gas emissions from willow based electricity: a scenario analysis for Portugal and The Netherlands', *Energy Policy*, Vol. 34, August no. 12, pp.1367-77.

Reddy, PK, Singh, K, Sagar, S, Gupta, S & Ravi, B 2007, 'Domain Knowledge Modelling for DFM of Castings', *Proceedings of the International Conference on Total Engineering, Analysis and Manufacturing Technologies*, Bangalore, Oct 4th -6th.

Reliance Medical Consortium, Successful Medical Device Development: Critical Factors
Reliance Medical Consortium, viewed on 16 June 2013, <www.clinquest.com/Collateral/Documents/English-US/med_device_critical_success_factors.pdf>.

Ren, J, Wang, J & Jenkinson, I 2007, 'A Bayesian network approach for offshore risk analysis through linguistic variables', *China Ocean Engineering*, Vol. 21, no. 3, 371–388.

Rogers, M 2001, *Engineering Project Appraisal: The Evaluation of Alternative Development Schemes,* Blackwell Publishing Professional, UK.

Robertson, S & Robertson, J 2006, *Mastering the Requirements Process*, ACM Press Books, New York.

Robledo, A, Daniel P. Schrage, DP & Ashok, SV 2011 'A Systems Engineering Modeling and Simulation Approach for Rotorcraft Drive System Optimization', *Proceedings of the American Helicopter Society 67th Annual Forum*, Virginia Beach, VA, May 3-5.

Roslender, R & Hart, SJ 2003, 'In search of strategic management accounting: theoretical and field study perspectives', *Management Accounting Research*, vol. 14, no. 3, pp. 255-279.

The Royal Commission on Environmental Pollution 1988, *12th report: Best Practicable Environmental Option*, UK.

Russo, D, Regazzoni, D & Montecchi, T 2011, 'Eco-design with TRIZ laws of evolution', *Procedia Engineering* 2011, vol. 9, pp. 311-22.

[S]

Saaty, T 1980, *The analytic hierarchy process,* McGraw Hill, New York.

Saaty, TL 1990, 'How to make a decision: the analytic hierarchy process', *European Journal of Operational Research*, vol. 48, no. 1, pp. 9-26.

Saaty, TL 2006, 'Rank from comparisons and from ratings in the analytic hierarchy/ network processes', *European Journal of Operational Research*, vol. 168, no. 2, pp. 557-70.

Saaty, T 2008, 'Decision making with the analytic hierarchy process', *International Journal of Services Sciences*, vol. 1, no. 1, pp.83-98.

Saaty, TL 2009, 'Applications of Analytic Network Process in Entertainment', *Iranian Journal of Operations Research*, vol. 1, no. 2, 2009, pp.41-55.

Saunders, M, Lewis, P & Thornhill, A 2007, *Research methods for business students.* 4th edn, Prentice Hall, London.

Scharnhorst, W, Althaus, H-J, Hilty, L and Jolliet, O 2006, 'Environmental assessment of End-of-Life treatment options for an GSM 900 antenna rack', *International Journal Of Life Cycle Assessment*, vol. 11, no.6, pp. 426-436.

Schmidt, S, Horch, K & Normann, R 1993, 'Biocompatibility of silicon-based electrode arrays implanted in feline cortical tissue', *Journal of Biomedical Materials Research*, vol. 27, no. 11, pp. 1393-9.

Schweiger, R 2006, 'Some aspects of upfront CAE and CAD/CAE Integration', *1st Technology Workshop AUTOSIM*, NAFEMS is the International Association for the Engineering Modelling, Analysis and Simulation Community, 17-18 January, Barcelona, viewed on 16 June 2013, <http://www.autosim.org/meetings/barcelona06/Page5/>.

Schut, EJ & van Tooren, MJL 2007, 'A Knowledge Based Engineering approach to automation of conceptual design option selection', *Proceedings of the 45th American Institute of Aeronautics and Astronautics Aerospace Sciences Meeting and Exhibit*, AIAA-2007-0968, Reno, Nevada.

Seppälä, J & Hämäläinen, RP 2001, 'On the meaning of the distance-to-target weighting method and normalisation in life cycle assessment', *International Journal of Life Cycle Assessment*, vol. 6, no. 4, pp. 211-8.

Shastri, VP, Rahman, N, Martin, I & Langer, R 1998, 'Application of Conductive Polymers in Bone Regeneration', *MRS Proceedings*, vol. 550, no. 215, pp. 550-215.

Shimada , K 2011, 'Current Issues and Trends in Meshing and Geometric Processing for Computational Engineering Analyses', *Journal of Computing and Information Science in Engineering,* vol. 11, no. 2, pp. 021008-1 to 13.

Siler, W & Buckley, JJ 2004, *Fuzzy Expert Systems and Fuzzy Reasoning,* Wiley Interscience, New Jersey.

Singh, S 2006, 'Optimization of a Knowledge Based Design System: Using AHP & Pattern Recognition (Case Study – Transformer Bushing)', Master's Thesis, Thapar Institute of Engineering and Technology, Patiala, India.

Shrivastava, P 1994, 'Ecocentric Leadership in the 21st Century', *Leadership Quarterly*, vol. 5, no. 3-4, pp. 223-226.

Shrivastava, P 1995, 'Ecocentric Management for A Risk Society', *Academy of Management Review*, vol. 20, no. 1, pp. 118-137

Sloan, TW 2007, 'Safety-cost trade-offs in medical device reuse: a Markov decision process model', *Health Care Management Sciences*, vol. 10, no. 1, pp. 81–93.

Sobelman, N 2008,*Beyond Compliance: Medical Device Product Development Balancing Product Development Effectiveness with Regulatory Compliance*, Kalypso Research Inc.

Stadler, W 1979, 'A survey of multicriteria optimization or the vector maximum Problem Part I: 1776-1960', *Journal of Optimization Theory and Applications*, Vol. 29, no. 1, pp. 1–52.

Stahel, WR 1982, *The Product-Life Factor in An Enquiry into the Nature of sustainable societies: The Role of the Private Sector*, (edited by Grinton Orr, S.), Houston Area Research Center.

Stahel, W R 1994, *The Utilization-focused Service Economy: Resource Efficiency and Product Life Extension, in The Greening of Industrial Ecosystems*, National Academy Press, Washington, pp. 178-190.

Stiglitz, J 2007, *Making Globalization Work*, W. W. Norton and Company, New York.

Styring P, Jansen D 2011, *Carbon Capture and Utilizations in the green economy: Using CO2 to manufacture fuel, chemicals and materials*, Report no. 501 2011, The Centre for Low Carbon Futures, UK; University of Sheffield, UK; Energy Research Centre, Netherlands, viewed on 15 June 2013, <http://www.lowcarbonfutures.org/news/post/62-carbon-capture-and-utilisation-in-the-green-economy-policy-brief-released>

Subrahmanian, E, Rachuri, S, Bouras, A, Fenves, SJ, Foufou, S & Sriram, RD 2006, 'The Role of Standards in Product Lifecycle Management Support', Technical Report from National Institute of Standards and Technology, no. NISTIR 7289.

Suh, NP 2001, 'Axiomatic design: Advances and applications', *Oxford University Press*.

Sundin, E 2004, 'Product and Process Design for Successful Remanufacturing', Phd Thesis, Linkoping Studies in Science and Technology, Linkoping Institute of Technology.

Suomala, P 2003, 'The Life Cycle Dimension of New Product Development Performance Measurement', *Proceedings of 6th Manufacturing Accounting Research Conference*, Twente, 26th -28th May.

Sutcliffe, L, Maier, A, Moultrie, J & Clarkson, J 2009, 'Development of a framework for assessing sustainability in New Product Development', *Proceedings of the 17th International Conference on Engineering Design (ICED'09),* vol. 7, Stanford, CA, 24-27 August, , pp. 289-300.

Systems Engineering Handbook version 3.2.2 2011, International Council on Systems Engineering, San Diego, California.

Szychta, A 2002, 'The scope of application of management accounting methods in Polish enterprises', *Management Accounting Research*, vol. 13, no. 4, pp. 401-18.

Szykman, S, Fenves, SJ, Keirouz, W, Shooter, SB 2001,'A Foundation for Interoperability in Next-generation Product Development Systems', *Computer-Aided Design,* vol. 33, no. 7, pp. 545-59

[T]

Tatikonda, MV & Montoya-Weiss, M 2001, 'Integrating Operations and Marketing Perspectives of Product Innovation: The Influence of Organizational Process Factors and Capabilities on Development Performance', *Management Science*, Vol. 47, January 1, pp. 151-172.

Tikare, V, Heinstein, M & Kempka, S 2005, 'The Role of Customized Computational Tools in Product Development',Sandia National Laboratories, Albuquerque, New Mexico.

Trappey, AJC, Hsu, F-C, Trappey, CV & Lin, C-I 2006, 'Development of a patent document classification and search platform using a back-propagation network', *Expert Systems with Applications,* vol. 31, no. 4, pp. 755–65.

Trotta, MG 2010, 'Product Lifecycle Management: Sustainability and knowledge management as keys in a complex system of product development', *Journal for Industrial Engineering and Management*, vol. 3, no. 2, pp. 309-322.

Tyteca, D, Carlens, J, Berkhout, F, Hertin, J, Wehrmeyer, W & Wagner, M 2002, 'Corporate environmental performance evaluation: evidence from the MEPI project', *Business Strategy and the Environment*, vol. 11, no. 1, pp. 1-13.

Tzeng, GH, Tsaur, SH, Laiw, YD & Opricovic, S 2002, 'Multicriteria analysis of environmental quality in Taipei: public preferences and improvement strategies', *Journal of Environmental Management*, vol. 65, no. 2, pp. 109– 20.

Tzeng, G-H, Chiu,Y-C, Chen, B, Shyu, JZ 2006, 'An evaluation model of new product launch strategy**,** *Technovation*, vol.26, no. 11, pp.1244–52.

[U]

Ulrich, KT & Eppinger, SD 2004, *Product Design and Development*, 3rd edn, McGraw-Hill, New York.

United Nations University 2009, *E-waste: Annual Gold, Silver "Deposits" in New High-Tech Goods Worth $21 Billion+; Less Than 15% Recovered*, 6th July, viewed on 15 June 2013, <http://unu.edu/news/releases/step-news-release-6-july-2012-e-waste-precious-metals-recovery.html>

United Nations Documents 1987, *Our Common Future, Chapter 3: The Role of the International Economy,* United Nations, New York, US, viewed June 4th 2013**,** **<**http://www.un-documents.net/ocf-03.htm**>**

[V]

Van der Aalst, WMP, ter Hofstede, AHM, Weske, M 2003, 'Business Process Management: A Survey, Business Process Management, *Proceedings of the First International Conference*, Springer Verlag.

Van Erck, RPG 2003, 'A monetary evaluation of the sustainability of GTL fuel production in South Africa'. Master's thesis, Faculty of Technology Management, Technical University Eindhoven, the Netherlands.

Venkatamuni, T, Ramakrishna Rao, A 2010, 'Evaluating customer preferences in lean product design-an AHP Approach', *International Journal of Engineering Science and Technology* , Vol. 2, no. 7, pp. 3255-66.

Venkatachalam, AR, Mellichamp, JM & Miller, DM 1993, 'A knowledge-based approach to design for manufacturability', *Journal of Intelligent Manufacturing,* Vol. 4, no. 5, pp. 355–366.

Vickers, JJ & Boyle, CA 2008, 'Approach for Sustainable Product Development Using Scenario Network Mapping and Eco-design', *Proceedings of the 3rd International Conference on Sustainability Engineering and Science*, New Zealand Society for Sustainability Engineering and Science, Auckland, NZ, 9th - 12th December.

Vidal, J 2012, 'Rio+20: Earth summit dawns with stormier clouds than in 1992', *The Guardian UK*, 19 June, viewed on 15 June 2013,

<www.guardian.co.uk/environment/2012/jun/19/rio-20-earth-summit-1992-2012>

Vogel, SA 2001, 'Satisfying QSR Requirements with Collaborative Production Management Systems', *Medical Device & Diagnostic Industry,* 1 July.

Vogel, SA 2001, 'Satisfying QSR Requirements with Collaborative Production Management Systems: A technology based on the Internet and intranets can automate the tasks required for regulatory compliance', Medical Device and Diagnostic Industry, 1 July, viewed on 7 June 2013, <http://www.mddionline.com/mddi-index-ad.html?gotourl=http://www.mddionline.com/article/satisfying-qsr-requirements-collaborative-production-management-systems>

Vogel, D 2005, 'Good Products from Good Processes', *Medical Device & Diagnostic Industry,* 1 April, viewed on 16 June 2013, <www.mddionline.com/article/good-products-good-processes>

Vogel, D 2006, 'How to Avoid the Biggest Mistakes in Medical Device Development', *Mass High Tech*, February 20, viewed on 16 June 2013, <www.inea.com/PDF/how_to_avoid_the_biggest_mistakes_in_medical_device_development.pdf>

[W]

Wang, J, Yao, C, Zhang, Z2010, 'A fuzzy-AHP comprehensive evaluation method for optimization design of machine tool', *Proceedings of the International Conference of Mechanic Automation and Control Engineering (MACE)*, Wuhan, China, 26th-28th June, pp. 2652–6.

Wapshott, N 2011, *Keynes Hayek: The Clash that Defined Modern Economics,* W. W. Norton and Company, New York.

Welle, B & Haymaker, J 2011, 'A Knowledge-Based Approach to Problem Formulation for Product Model-Based Multidisciplinary Design Optimization in

AEC ', *Proceedings of 2011 AAAI Spring Symposium Series,* Stanford, CA, pp. 106-112.

Weiss, Z and Karwasz, A 2005, 'Recycling oriented disassembly design', *Proceedings of 12th CIRP Seminar on Life Cycle Engineering*, Grenoble, France, 3 – 5 April.

Wejnert, B 2002, 'Integrating Models of Diffusion of Innovations: A Conceptual Framework', *Annual Review of Sociology (Annual Reviews)*, vol. 28, pp. 297–306.

Wenzel, H & Alting, L 2004,'Architecture of Life Cycle', keynote at *Global Conference on Sustainable Product Development and Life Cycle Engineering*, Sept. 29th – Oct. 1st, 2004, PTZ, Berlin.

Werner Dankwort, C, Weidlich, R, Guenther, B & Blaurock, JE 2004, 'CAD Education Engineers' CAx education—it's not only CAD', *Computer-Aided Design,* Vol. 36, December no. 14, pp. 1439-1450.

Wessels, T 2006, *The Myth of Progress: Toward a Sustainable Future,* 1st edn, University of Vermont Press, Vermont.

Westbrook, R 1994, 'Action research: a new paradigm for research in production and operations management', *International Journal of Operations & Production Management*, vol. 15, no. 12, pp. 6-20.

Wheelwright, SC & Clark, KB 1992, **Revolutionizing Product Development: Quantum Leaps in Speed, Efficiency, and Quality**, The Free Press, New York.

Wiegers, KE, Secrets of Successful Project Management [Accessed on 2nd September 2012] http://www.processimpact.com/articles/proj_mgmt_tips.html

Wilkie, J & Young, A 2009, 'Why Health Matters for Economic Performance', *Economic Round-up*, No. 1, pp. 57-72.

Winpenny, JT 1991, 'Values for the environment: A guide to economic appraisal', in C Heady, 1992, Public Administration and Development, Vol. 12, December no. 5, pp. 512.

Wu, C, Lin, C & Chen, H 2007, 'Optimal selection of location for Taiwanese hospitals to ensure a competitive advantage by using the analytic hierarchy process and sensitivity analysis', *Building and Environment*, vol. 42, no. 3, pp 1431–44.

Wu, C-R, Chang, C-W & Liao, C-C 2009, 'Group Decision Making Apply to Select Collaborative Technology of Software Contractor', *Proceedings of International Conference on Business and Information*, Vol. 6, Kuala Lumpur, Malaysia, July 6-8, ISSN 1729-9322.

World Commission on Environment and Development 1987, *Our Common Future*, Oxford University Press, UK.

Wyatt, DF, Wynn, DC & Clarkson, PJ 2009, 'Comparing Representations for Product Architecture Design through Life-Cycle Evaluation Methods', *2nd Nordic Conference on Product Lifecycle Management*, GÖTEBORG, January 28-29.

Wysoki, RK, Beck, R and Crane, DB 2000, '*Effective Project Management*', Wiley Computer Publishing, New York.

[X]

Xerox 2003, *Environment, Health & Safety Progress Report*, viewed on 15 June 2013, <http://www.xerox.com/downloads/usa/en/e/ehs_pr_2003.pdf>

Xiong, H & Sun, S 2006, 'Design and realization of case-based reasoning product conceptual design system', *Proceedings of 7th International Conference on Computer-Aided Industrial Design and Conceptual Design*, Hang Zhou, CHINA, 17-19 November.

Xu, C & Morrison, P 2005, 'Sustainable Product Development And Business Performance: A Product Life Cycle Approach', *ANZMAC 2005 Conference: Entrepreneurship, Innovation and New Product Development*, Australia, pp.143-151.

[Y]

Yahya, RS 2003, 'Genetic algorithm (GA) and particle swarm optimization (PSO) in engineering electromagnetics', *Proceedings of the 17th International Conference on Applied Electromagnetics and Communications*, 1-3 October.

Yamamoto K, Matsuda M, Hirano A, Takizawa N, Iwashima S, Yakushiji T, Fukuda M, Miyasaka T, Sakai K 2009, 'Computational evaluation of dialysis fluid flow in dialyzers with variously designed jackets', *Artificial Organs,* vol. 33, no. 6, pp. 481-6.

Yin, RK 2003, *Applications of case study research Applied Social Research Methods Series,* vol. 34, SAGE Publications, Thousand Oaks, California.

Yang, QZ, Sun, JP & Zhu, CF 2006, 'Medical device innovation methods and case studies', *SIMTech technical reports*, Vol. 7, No. 4, October-December, pp. 232-238.

Yang, Q Z, Chua, BH & Song, B 2009, 'A Matrix Evaluation Model for Sustainability Assessment of Manufacturing Technologies', World Academy of Science, Engineering and Technology, August 32, pp. 493-8.

Yin, RK 1994, *Case study research: Design and methods Applied Social Research Methods Series,* vol. 5, SAGE Publications, Thousand Oaks, California.

[Z]

Zhao, Y, Pandey, V, Harrison Kim, H, Thurston, D 2010, 'Varying Lifecycle Lengths Within a Product Take-Back Portfolio', *Journal of Mechanical Design*, Vol. 132, September no. 9, pp. 091012[1]-[10].

Zhong-Wu, L, Guang-Ming, Z, Hua, Z, Bin, Y & Sheng, J 2007, 'The integrated eco-environment assessment of the red soil hilly region based on GIS—A case study in Changsha City, China', *Ecological modelling*, vol. 202, no. 3-4, pp. 540-6.

Zlotin, B, Zusman, A & Philatov, V 1999, *Tools for classical TRIZ*, Altshuller, G, Ideation International Inc., Michigan.

Zobel, T, Almroth, C, Bresky, J & Burman, J-O 2002, 'Identification and assessment of environmental aspects in an EMS context: an approach to a new reproducible method based on LCA methodology', *Journal of Cleaner Production* , vol. 10, no. 4, pp. pp. 381-96.

Zopounidis, C & Doumpos, M 2002, 'Multicriteria classification and sorting methods: a literature review', *European Journal of Operational Research*, vol. 138, no. 2, pp. 229-46.

Websites referred in the Dissertation which have been viewed and confirmed up to 15th June 2013

[A]

The Advanced Renal Education Program 2013, <www.advancedrenaleducation.com>

Altair HyperWorks 2013, Michigan, United States, <www.altairhyperworks.com>

[B]

BASF SE, Eco-efficiency Analysis, Ludwigshafen, Germany, <http://www.basf.com/group/corporate/en/sustainability/eco-efficiency-analysis/index>.

Boothroyd Dewhurst, Inc 2013, Rhode Island, United States <www.dfma.com>

[C]

Cambridge Consultants 2010, Cambridge, UK, <www.cambridgeconsultants.com/news/pr/release/49/en>.

Conformité Européenne 2013, CE marking, Brussels, Belgium, <http://ec.europa.eu/enterprise/policies/single-market-goods/cemarking/index_en.htm >)

[D]

3DS, Dassaut Systems 2003, Overview SolidWorks http://www.3ds.com/products/solidworks/overview/

[E]

Ekos International, <www.ekosi.com>

[F]

Food and Drug Administration 2012, *CFR - Code of Federal Regulations Title 21, PART 820 of the Food and Drug Administration*, Maryland, United States <www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=820> .

CFR - Code of Federal Regulations 2012, Title 21 21CFR820.70, 1 April, viewed on 15 June 2013, <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=820.70>.

Food and Drug Administration 2013, Maryland, United States, <www.fda.gov/MedicalDevices/default.htm>.

Food Drug Administration, Center for Devices and Radiological Health, 2002, General Principles of Software Validation: Final Guidance for Industry and FDA Staff, Rockville, MD, viewed on 16 June 2013, <www.fda.gov/cdrh/comp/guidant/938.html>.

Food and Drug Administration 2002, 'General Principles of Software Validation: Final Guidance for Industry and FDA Staff', January 11, <http://www.fda.gov/downloads/MedicalDevices/.../ucm085371.pdf>

Food and Drug Administration 2000, 'Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management', July 8, <http://www.fda.gov/downloads/MedicalDevices/.../ucm094461.pdf>

Fraunhofer Institute for Manufacturing Technology and Advanced Materials, *INKtelligent printing*®, Bremen, Germany, <http://www.ifam.fraunhofer.de/content/dam/ifam/de/documents/IFAM-Bremen/2801/fachinfo/spektrum/en/Produktblatt-2801-EN-Funktionsstrukturen-INKtelligent-printing.pdf>.

Functional Mock-Up Interface 2013, Linköping, Sweden, <www.fmi-standard.org>.

[I]

Institute of Product Development, Technische Universität München, Munich, Germany, <www.dsmweb.org>

International Medical Device Regulators Forum 2011, Brussels, Belgium , <www.imdrf.org>.

International Organization for Standardization, Environment. Health protection. Safety, Geneva, Switzerland, <www.iso.org/iso/home/store/catalogue_ics/catalogue_ics_browse.htm?ICS1=13>.

International Organization for Standardization, Geneva, Switzerland, <www.iso.org/iso/home/store/catalogue_ics.htm>

IQMS Inc. 2013, Paso Robles, California, <www.iqms.com>

[M]

Massachusetts Institute of Technology, 2013, Boston, Massachusetts, <http://web.mit.edu/newsoffice/2013/mit-eni-renew-energy-partnership-0213.html>

Medical Device and Diagnostic Industry 2013, <www.mddionline.com>

Methodology and Tools oriented towards Knowledge based Applications, available at: http://web1.eng.coventry.ac.uk/moka/

MML Working Group 2002, *MOKA User Guide (MOKA Modeling Language Core Definition)*.

[O]

Object Management Group, Massachusetts, United States <*www.omg.org*>

[P]

Perry's Solutions 2013, Minnesota, United States, <www.perryssolutions.com/index.php>.

Pre Consultants BV, The Netherlands, <www.pre-sustainability.com>

[Q]

Quality Function Deployment Institute 2013, Michigan, United States, <www.qfdi.org>

[S]

SAVE International, Dayton, Ohio, <*www.value-eng.org*>.

SIEMENS, Plano, Texas, <http://www.plm.automation.siemens.com/en_us/>.

Spine-Health 2013, < http://www.spine-health.com/glossary/institutional-review-board>.

[U]

United Nations Documents, Our Common Future, *Chapter 3: The Role of the International Economy: From A/42/427, Our Common Future: Report of the World Commission on Environment and Development*, New York, United States, **<**http://www.un-documents.net/ocf-03.htm**>**.

UNEP 2002, Life Cycle Initiative, viewed on 15th June 2013 http://www.uneptie.org/pc/sustain/lcinitiative/home.htm

[W]

Wilde Analysis 2013, Cheshire, UK, <wildeanalysis.co.uk>.