CRANFIELD UNIVERSITY

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DOCTOR OF PHILOSOPHY (PhD) THESIS

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Supervisors: Professor Ashutosh Tiwari and Doctor Jeffrey Alcock

Academic Year 2008 to 2012

This thesis is submitted in partial fulfilment of the requirements for the degree of Doctor of Philosophy

In Loving Memory of My Inspirational Father

Kundan Singh Sagoo

(1949 – 1993)

“We can't solve problems by using the same kind of thinking
we used when we created them”

Albert Einstein

Abstract

Design rationale is a methodology aimed at capturing and representing design decisions according to a designated structure. Additionally, these design decisions and their underlying arguments can be made available for examination at a later date. The literature review identified that there is currently a lack of information describing the use of design rationale methods and computational support tools with the medical device domain. Furthermore, the review of literature has also recognised that there are no existing guidelines available for medical device manufacturers and regulatory authorities to follow in order to capture and represent the design decisions in the case of medical devices.

Medical devices are instruments which are used for diagnosis, screening, monitoring, or the treating of patients suffering from disease, injury, or disability. Medical devices are products that require rigorous regulation before they can be placed onto the market. If problems are encountered with a device once it has been placed onto the market, the device is recalled by the relevant regulatory authority. Device recalls can often result in the device manufacturers having to evaluate the design decisions that were made during the product development stages in order to address the reported problems and implement a solution. As a result, medical device manufacturers can incur unexpected rework and/or redesign costs, and in even more severe circumstances, incur high litigation costs.

This research; reviews the state-of-the-art in design rationale and identifies its key capabilities, analyses design rationale's feasibility for use with the medical device domain, identifies the regulatory approval processes for medical devices and compares them, analyses the possibilities of utilising design rationale with the regulatory approval of medical devices, and develops a set of guidelines. The guidelines detail the necessary steps that are required to capture and represent the design decisions for medical devices. The utility of this contribution has been verified through the process of validation with experts and researchers.

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To the highest consciousness of all, I offer my love and light to you for making everything possible. Thank you!

List of Publications

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Sagoo, J. (2008). Developing Microelectromechanical Systems (MEMS). MRes Thesis, Cranfield University, U.K.

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Sagoo, J., Tiwari, A. and Alcock, J. Guidelines for Utilising Design Rationale with the Regulatory Approval of Medical Devices.

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List of Abbreviations

µIDs – Micro-Integrated Devices

510(k) – Premarket Notification

BSi – British Standards Institute

CA – Competent Authority

CAD – Computer Aided Design

CAE – Claims, Arguments, and Evidence

CASE – Computer-Aided Software Engineering

CDRH – Center for Devices and Radiological Health

CSCW – Computer-Supported Co-operative Work

CE – Conformité Européenne

DBMS – Database Management System

DR – Design Rationale

DRC – Design Rationale Capture

DRL – Decision Representation Language

EC – European Commission

EU – European Union

EU REP – European Union Representative

FDA – U.S. Food and Drug Administration

FO – Feature Orientated

FR – Functional Representation

GHTF – Global Harmonisation Task Force

GMP – Good Manufacturing Practices

GSN – Goal Structuring Notation

HCI – Human-Computer Interface

HDE – Humanitarian Device Exemption

IBIS – Issue-Based Information System

IDEF – Integration Definition for Function Modelling

IDE – Investigational Device Exemption

ISO – International Standards Organisation

KBS – Knowledge-Based Systems

MDD – Medical Device Directive

MDR – Medical Device Reporting Regulations

MHRA – Medicines and Healthcare products Regulatory Agency

MRI – Magnetic Resonance Imaging

NB – Notified Body

NLP – Natural Language Processing

ns/nm – Non-Sterile and/or Non-Measuring

PCA – Patient-Controlled Analgesia

PHI – Procedural Hierarchy of Issues

PLM – Product Lifecycle Management

PMA – Premarket Approval Application

PMS – Post Market Surveillance

PO – Process Orientated

PSS – Product-Service System

QMS – Quality Management System

QOC – Questions, Options, and Criteria

QSR – Quality System Regulations

s/mf – Sterile and/or Measuring-Function

SWOT – Strengths, Weaknesses, Opportunities, and Threats

TPLC – Total Product Life Cycle

U.K. – United Kingdom

UML – Unified Modelling Language

U.S. – United States

WHO – World Health Organisation

WWW – World Wide Web

CHAPTER 1

INTRODUCTION

1. Introduction

This chapter firstly provides the reader with a background to the research investigation and presents the research focus. The aim and objectives of the research are presented followed by a summary of the approach utilised for the research investigation. Following this, the novelty of the research and contribution to knowledge are outlined and the structure of the thesis is presented.

1.1 Background to the Research Investigation

Design rationale records designers' knowledge of what issues should be addressed, how specific solutions are generated, as well as judgements as to why a particular solution should (or might not) work (Wang *et al.*, 2012). Essentially, design rationale is a methodology directed towards problem solving and decision making in a design context which relies on understanding human cognitive processes and understanding the variety of design domains (Li *et al*., 2002).

The research is interested in investigating the novel application of design rationale with the regulatory approval of medical devices. Having analysed the many definitions of design rationale that are available in the wider literature (Chapter 2), the author of this thesis considers the following definition appropriate for this research investigation: design rationale is a methodology aimed at capturing and representing design decisions according to a designated structure.

Medical devices are instruments which are used for diagnosis, screening, monitoring, or the treating of patients suffering from disease, injury, or disability. The number and variety of medical devices is vast and incorporates most healthcare products other than medicines, this includes everything from lancets to implantable pacemakers and magnetic resonance imaging (MRI) scanners. Uniquely, medical devices are products that require rigorous regulation before they can be sold in the United States (U.S.) or countries that are member states of the European Union (EU). It is understood that manufacturers of medical devices are held to a higher standard than manufacturers of

many other products due to the potential severity of the consequences of introducing inferior or unsafe products to the market-place (McAllister and Jeswiet, 2003).

Medical devices must be designed and manufactured according to the regulations and standards which are defined by the relevant regulatory authorities in the country in which the device is to be sold. In the U.S., medical devices are regulated by the Center for Devices and Radiological Health (CDRH) of the U.S. Food and Drug Administration (FDA). In the EU, the regulatory approval of medical devices relies on the use of notified bodies (NBs), which are independent commercial organizations that implement regulatory control over medical devices. It is understood that NBs have the ability to issue the CE mark, the official marking required for certain medical devices (Kaplan *et al.*, 2004). Both the U.S. and EU regulatory approval systems classify medical devices pursuant to their inherent risks and accordingly assign different regulatory control mechanisms to each designated class of device (Chai, 2000).

Currently, there is no available evidence in the published literature that reports on the application of design rationale methods and computational support tools with the medical device domain.

The advantages of design rationale, in addition to the significant developments of methods and tools observed in recent years and the inherited knowledge from the philosophy of argumentation, make it an ideal candidate for capturing and representing the design decisions undertaken during the development of medical devices. These design decisions could be used in conjunction with the existing regulatory approval processes for medical devices in the U.S. and EU. As a result, this could potentially provide important benefits to both medical device manufacturers and regulatory authorities.

Utilising design rationale with medical devices is challenging as it is currently uncertain as to what steps the device manufacturers and regulatory authorities should follow in order to apply and effectively utilise methods and tools in order to capture and represent the design decisions of medical devices.

This research is therefore necessary to provide enhanced knowledge and understanding of the incorporative and methodical process required to implement a solution whereby the design decisions of medical devices can be captured and represented according to a designated structure.

1.2 Research Focus

The literature review (Chapter 2) indicates that there has been recent advancement in the area of design rationale research including the utilisation of capture tools in different industrial locales such as; aerospace engineering design, civil engineering, artificial intelligence, knowledge management, human-computer interaction, and software development. At the beginning of the research, however, it was discovered that there were, among others, four significant gaps in knowledge. There was no literature available which addressed:

1. The utilisation of methods and tools to capture and represent the design decisions of medical devices,
2. The feasibility of design rationale for use with the regulatory approval of medical devices,
3. How design rationale methods and tools could be utilised with the regulatory approval of medical devices and the benefits it could provide, and
4. The steps required for medical device manufacturers and regulatory authorities in order to capture and represent the design decisions of medical devices.

1.3 Primary Research Question, Aim and Objectives

1.3.1 Primary Research Question

In view of the need for the research and the gaps in knowledge that have been identified in Chapter 2, the following primary research question was established to guide the research presented in this thesis:

Can Design Rationale be used with the regulatory approval of medical devices?

1.3.2 Research Aim

The aim of this research is to develop a set of guidelines which detail the steps required to capture and represent the design decisions in the case of a medical device.

1.3.3 Research Objectives

In order to address the primary research question and the research aim, the following six research objectives were defined:

1) To understand the state-of-the-art in design rationale research and medical device design.
2) To compare the state-of-the-art in design rationale research with the current state-of-the-art in medical device design.
3) To identify the individual activities that constitute the U.S. and EU regulatory approval processes for medical devices.
4) To analyse the possibilities of utilising design rationale methods and tools with the U.S and EU regulatory approval process activities.
5) To develop a set of descriptive guidelines.
6) To validate the guidelines.

1.4 Summary of the Research Approach

Identification, collection, and analysis of data were conducted at a variety of stages of the research. The overall methodology for the research, described in Chapter 3, was guided by the primary research question and the ensuing research objectives. Since the focus of the research was to investigate the application of design rationale and its utilisation with the regulatory approval of medical devices, a flexible research approach was applied to the overall methodology which is comprised of individual methods detailed in Chapters 2 and 4 through to 9. Furthermore, due to the research being largely inductive in its approach, the research did not aim to prove or disprove any existing theories or generate hypotheses.

1.5 Contribution to Knowledge

The research intends to generate new knowledge through an investigative analysis of how design rationale can be utilised with the regulatory approval of medical devices and the benefits it can provide. By executing a flexible research design, new knowledge is able to be identified directly from the data. There are several novel aspects of this research which will demonstrate a contribution to knowledge by:

- Generating new knowledge within the area of design rationale research
- Generating new knowledge within the area of medical device regulatory approval
- Identifying the individual steps required to facilitate the utilisation of design rationale when regulating the approval of medical devices for the U.S. and EU markets
- Conducting a study which focuses on the practical implications of utilising design rationale with the regulatory approval of medical devices

As a result, the research provides a contribution to knowledge by presenting novel methods, findings, and conceptual models through the process of answering the primary research question.

1.6 Thesis Structure

In order to provide the reader with a coherent approach in understanding the process followed by the research, which has been meticulously designed and followed according to the methodology implemented for each individual chapter as described in Chapter 3, this thesis has been structured by following an investigational process from the preliminary research investigation to the conclusions. This process begins with an introduction to the background of the research and identification of the gaps in existing knowledge that need to be addressed. Following this, the state-of-the-art practices in the related research domains are identified. This is followed by the development, application and validation of a solution that addresses the identified research gaps. Finally, this thesis discusses the findings from the research, presents conclusions and recommendations for future research, and highlights the contribution to knowledge.

This section presents the structure of the thesis according to its content. It outlines the main activities and outcomes of each of the chapters. The interconnections between the chapters and the research objectives are described. The structure of this thesis is divided into nine chapters as follows.

Chapter 1 – Introduction – presents the research background which includes the focus, aim and objectives. This chapter introduces the reader to the research investigation presented in this thesis and explains the rationale underlying the need for the investigation. In this chapter, a summary of the research approach is provided, contribution to knowledge is highlighted and the thesis structure is outlined. This chapter presents the interconnections between each of the chapters in this thesis.

Chapter 2 – Literature Review – reviews literature on the state-of-the-art research in the areas of design rationale and medical device design. Literature relevant to this research investigation is reviewed and gaps in existing knowledge are identified. This chapter explores the context of the research and identifies the gaps in knowledge that the research is targeting. This chapter presents the fulfilment of the first objective of the research and provides the necessary foundation for the research activities presented in the following chapters.

Chapter 3 – Research Design – defines the methodological approach that has been designed, developed and applied to fulfil the research objectives. This chapter presents the methods used to perform the research and provides the rationale for their selection and utilisation. This chapter explains the methodology used in conducting this research including the process followed to achieve the final outcome of the research – the guidelines which are presented in Chapter 7.

Chapter 4 – Comparing the State-of-the-Art in Design Rationale with Medical Device Design – presents a comparison of the state-of-the-art in design rationale capabilities with the existing best practices that are available in the literature regarding medical device design. In this chapter, the current best practices in the medical device domain are compared with design rationale. The fulfilment of the second research objective is

presented in this chapter. This chapter defines the basis for a systematic research investigation.

Chapter 5 – Regulatory Approval of Medical Devices – presents a detailed analysis of the U.S. and EU regulatory approval processes for medical devices. This chapter identifies the existing processes for medical device approval in the U.S. and EU. This chapter reveals the different process activities that are currently required for placing medical devices in the U.S. and EU markets. In this chapter, the accomplishment of the third research objective is presented. Regulatory approval process activities identified in this chapter are used in the following chapter.

Chapter 6 – Utilising Design Rationale with the Regulatory Approval of Medical Devices – analyses the possibilities of utilising design rationale with the different activities that constitute both the U.S. and EU regulatory approval processes for medical devices as identified in the previous chapter. This chapter identifies the regulatory approval process activities where design rationale could be utilised and highlights the benefits it could provide. The activities identified in this chapter are used in the following chapter to form the basis for developing the guidelines. This chapter addresses the fulfilment of the fourth research objective.

Chapter 7 – Guidelines for Utilising Design Rationale with the Regulatory Approval of Medical Devices – presents the guidelines that have been developed to address the identified gaps in existing knowledge. This chapter reports on the development and utilisation of the guidelines. The guidelines present a step-by-step approach for medical device manufacturers and regulatory authorities to follow in order to; capture and represent design decisions, review design decisions, and diagnose a problem and design a solution. This chapter addresses the fifth research objective.

Chapter 8 – Validation – addresses the validity of the guidelines which are presented in Chapter 7. This chapter assesses how the guidelines have fulfilled the aim of this research investigation. Validation of the guidelines indicates that the developed guidelines provide guidance for medical device manufacturers and regulatory

authorities on the steps required to capture, represent and review the design decisions in the case of a medical device. This chapter presents the fulfilment of the final research objective.

Chapter 9 – Discussion and Conclusions – provides a detailed discussion on the research findings as presented in the previous chapters. This chapter firstly explains how the findings from the research have answered the primary research question and then provides the authors perspective on the findings and the research process. This chapter analyses the key research findings, summarises the contribution to knowledge and presents recommendations for future work and further advancement based on the outcomes of the research.

Figure 1-1 illustrates the thesis structure.

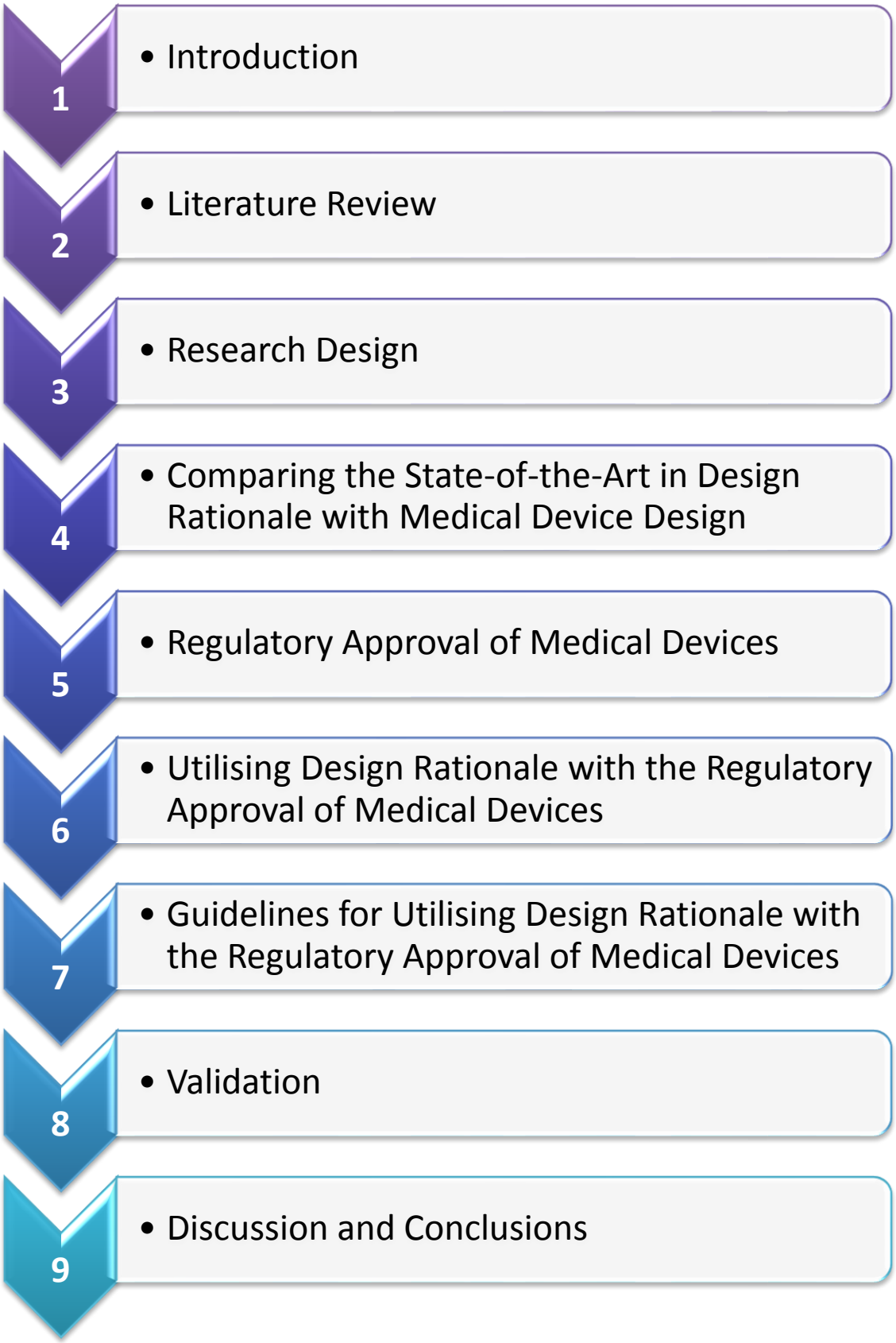

Figure 1-1: Thesis structure

CHAPTER 2

LITERATURE REVIEW

2 Literature Review

This chapter provides grounding for the research by examining the state-of-the-art and relevant literature related to the design rationale research and medical device domains. Gaps in existing knowledge are identified and addressed as they form the basis for this research investigation.

The review of literature presented in this chapter has taken the form of an examination of published literature that is explicitly associated with the design rationale research and medical device areas. Analysis and synthesis of the literature was performed primarily in this chapter and during the research activities. Therefore, literature applicable to this research investigation will also be presented in Chapters 4, 5, 6, 7 and 8 in conjunction with the findings from the research and discussion presented in Chapter 9. The review of the literature provides an essential grounding of the research in current and relevant knowledge. Gaps in existing knowledge and understanding are identified in this chapter and the first objective of the research is addressed.

This chapter is presented in the following stages. Firstly, the methodology followed by this literature review is presented and described. This is followed by an examination of the key findings generated through the analysis of the literature. Following this, the findings from the literature reviewed are discussed. Finally, the research questions guiding this review are addressed and the identified gaps in knowledge are summarised and investigated further to provide the basis from which the research can develop.

2.1 Review Methodology

This section describes the stages that were methodologically followed for reviewing the current and relevant literature related to this research investigation. The methodology consists of four stages as follows. The scope and research questions guiding this review are initially defined. Secondly, the search strategy developed and implemented for identifying the relevant literature is detailed. This is followed by the approach developed for analysing the literature related to this review. Following this, the

methodology followed for answering the research questions is presented. These stages are described in the following subsections of this chapter.

2.1.1 Review Scope and Research Questions

In determining the scope of this literature review, the focus has been on published articles that are related to design rationale methods within a wider multidisciplinary context which includes literature related to medical device design. For example, the papers that have been considered relevant to this review are associated with design rationale methods and computational support tools including their applications, and existing best practices for medical device design.

Some examples of publications that are within the scope of this review are those such as Moran and Carroll (1996) in which a collection of work describing the concepts of design rationale has been presented, and Bracewell *et al.* (2009) who have published articles on the utilisation of a prototype design rationale support tool in the aerospace industry.

Outside the scope of this review are publications that focus on the technical architectures of computational support tools and contributions on topics that are related to design psychology. It has been noted that there are many similarities and connections between the design rationale and design psychology research communities. However, this review is concerned with structured methods and tools that enable the capture and communication of deliberated design decisions.

Research questions have been posed to guide this literature review. It is intended that the following three questions will assist in ensuring a thorough and comprehensive review of literature: (1) what is what is meant by design rationale and how is it commonly defined; (2) what are the state-of-the-art in design rationale methods of representation and capture tools; and (3) what are the current capabilities of design rationale?

2.1.2 Literature Search Strategy

Initially, the search strategy involved identifying the relevant data sources, keywords, and publication timeframe. However, some seminal papers outside of the timeframe (1990 - 2012) that were considered relevant were also cited in the review. Databases were used as part of the search strategy to identify a range of publications appropriate to the review. These were; SCOPUS, Science Direct, Cambridge Journals, Elsevier, Emerald, Design Society online repository, and also including the traditional library cataloguing systems. Internet searches were also used to identify publications and their corresponding databases. The keywords identified were associated with deliberating design decisions (design rationale, design history, design intent, design knowledge capture, knowledge management, design thinking, design process, decision-making, and design rationale capture tools). During the acquisition of appropriate and new articles, these keywords were refined.

A large number of publications in the specified time period were discovered using the keyword search in the different databases. To remove any duplications of the published work and to ensure relevance to the review, the lists were edited and refined, and the titles and keywords of the articles were checked. Initially, a vast range of articles, reports, and books were identified using the search terms. Of the identified papers, the abstracts and introduction chapters were then read and if they were considered relevant, the paper was fully examined. From this selection process, the full papers relevant to this study have been established to be directly associated with this research investigation. During the literature search and acquisition, a number of objectives were defined with the purpose of addressing the three research questions. These included; to ascertain what researchers had focussed on within the design rationale research area, to identify what methods had been utilised and in what applications, and essentially how this informed the current investigation.

2.1.3 Analysis of the Literature

The literature reviewed covered a wide range of different topics. Therefore, the analysis itself involved clustering the papers into the main themes and contributions. These were

defined based on the papers that were reviewed in detail and grouped according to the ten key themes and the analysis of their coverage by the various authors. The key themes based on the total number of papers reviewed (101) in detail are presented (Table 2-1) including the number of papers covering each key theme and the percentage of the total papers.

Table 2-1: Key themes and contributions of design rationale literature

Design rationale literature – key themes based on total number of papers reviewed in detail	No. of papers covering theme	Percentage of total papers
1. Capture and documentation techniques	16	16%
2. Capture tools and development approaches	17	17%
3. Empirical evaluations and case studies	10	10%
4. Factors that undermine the widespread adoption of design rationale systems	5	5%
5. General concept and definition	12	12%
6. Representations	14	14%
7. Retrieval Strategies	6	6%
8. Reuse	7	7%
9. Reviews and surveys	7	7%
10. Utility and usability	7	7%

A large number of authors have covered representations for capturing deliberated design decisions (Lee and Lai, 1991; Moran and Carroll, 1996; Nomaguchi *et al*., 2004), capture tools and their development approaches (Karacapilidis and Papadias, 2001; Bracewell and Wallace, 2003; Burge and Brown, 2008), empirical evaluations and case studies (Burge, 2006; Falessi *et al*., 2006), and capture and documentation techniques including the reasoning of designers (Horner and Atwood, 2006; Aurisicchio *et al*., 2007; Bracewell *et al*., 2009).

It is interesting to note that authors have addressed the factors undermining the widespread adoption of design rationale systems for practical industrial application (Regli *et al*., 2000; Horner and Atwood, 2006; Burge, 2008). More recently, authors have been addressing the different strategies for effective retrieval and reuse of deliberated design decisions (Kim *et al*., 2005; Kim *et al*., 2007; Wang *et al*., 2009).

There are a variety of review and survey papers that have been published addressing the different aspects associated with design rationale research (Regli *et al*., 2000; Li *et al*., 2002; Eng *et al*., 2009), and the general concept of design rationale providing definitions (Lee, 1997; Dutoit *et al*., 2006; Burge and Bracewell, 2008).

2.1.4 Answering Research Questions

Analysis of the published articles has formed the basis of the findings in this chapter in order to address the three research questions posed. Methods employed for analysing the literature to answer each of the three research questions are presented in the following subsections.

2.1.4.1 Defining Design Rationale

Literature was analysed with the purpose of understanding how the design rationale research community have defined what design rationale is. From the selected articles that were analysed, the definitions for design rationale that were provided by the authors were noted along with the article reference. Once all of the articles had been analysed, the popular definitions for design rationale were listed. These are provided in section 2.2.1.1 of this chapter.

2.1.4.2 Identifying the State-of-the-Art in Design Rationale Representations and Capture Tools

Literature was analysed with the intentions of, firstly, identifying the most common methods that have been extensively used to represent design rationale, and secondly, discovering the design rationale representation frameworks that have been developed since the year 2000. The argument structures and methods for selecting and organising information as defined by the common frameworks are noted and a brief description of their background is provided. Methods for representing design rationale and capture tools based on these methods that have been developed since the year 2000 are presented and a brief description of their structures is given. These are provided respectively in sections 2.2.2 and 2.2.3 of this chapter.

2.1.4.3 Categorising the Current Capabilities of Design Rationale

The term ‘capability’ is described to be “*the power or ability to do something*” (Oxford Dictionaries, 2010) whereby the ‘something’ can be performing an action for example. Literature was analysed with the goal of being able to categorise the current capabilities of design rationale (the ability of design rationale to perform specific actions). This analysis took the form of a two-stage process.

In the first stage, descriptions of the actions that design rationale methods and tools are able to perform were taken from the literature. Each action was noted. The outcome (end result of the action) was noted in the form of what can be accomplished by design rationale. The verb describing the design rationale action was extracted from the statement of the action. This information was then used to derive an initial capability list composed of the following attributes: action, description in the literature, outcome, and verb.

In the second stage, ‘higher-level’ design rationale capabilities were compiled by a process of grouping ‘similar’ capabilities together. The methodology for this grouping of initial capabilities used a two-stage process. Firstly, the similarity of the verbs that were extracted from the actions was assessed. Similarity was assessed using the ‘synonym’ function of the Microsoft Word 2007 software (U.K. edition). Each category was then named after the appropriate verb. For example, the first capability category contained the verbs “answer” and “solve” which Microsoft Word stated “solve” as being a synonym of “answer.” Therefore, “answer” was selected as the capability name. For the capability named “communicate,” the following verbs were found to be synonyms of communicate: express, design, transmit, and note.

Secondly, the capability sub-categories were derived. These capability sub-categories were defined by the subsequent noun in the defined action. For example, in the action; ‘to capture design knowledge’, ‘answer was identified as a higher-level capability category (verb), and ‘design questions’ was defined as a capability sub-category of capture (nouns). The list of initial capabilities was then sorted and grouped by capability

and capability sub-categories to give the final list of the capabilities for design rationale. These are provided in section 2.2.4 of this chapter. The full list of capabilities which include the descriptions can be found in: Appendix A: List of Compiled Design Rationale Capabilities. A full listing of the capability names comprising of the verbs and synonyms is provided in Table 2-2. The synonyms column (Table 2-2) shows the verb or verbs that are synonymous to the action (verb) in the verb column. The arrow (>) symbol in the synonyms column indicates that the following verb after this symbol is synonymous to the previous verb. The tilde character (~) indicates that the verb is selected as the capability name. These capabilities were named, using the verb and synonym as the basis, and assigned a category identification letter (designated A to M).

Table 2-2: List of the categorisation for the verbs and synonyms

Verbs	Synonyms	Category name
Answer	~	Answer
Solve	Answer	Answer
Capture	~	Capture
Express	Communicate	Communicate
Describe	Express > Communicate	Communicate
Transmit	Convey > Communicate	Communicate
Note	Communication > Communicate	Communicate
Design	~	Design
Determine	~	Determine
Document	~	Document
List	Record > Documentation > Document	Document
Record	Documentation > Document	Document
Explain	~	Explain
Justify	~	Justify
Provide	~	Provide
Represent	~	Represent
Illustrate	Demonstrate > Reveal > Expose > Representation > Represent	Represent
Expose	Representation > Represent	Represent
Structure	~	Structure
Support	~	Support
Assist	Support	Support
Teach	~	Teach

The following section of this chapter presents the key literature findings that were generated from the literature analysis.

2.2 Results: Key Literature Findings

The results are presented in the order of the research questions of this chapter. First of all, an overview of design rationale is provided which includes its associated definitions, the need for capturing a designs rationale, benefits provided by design rationale, and the challenges faced by the design rationale research community. Secondly, the state-of-the-art in design rationale representation frameworks and design rationale capture tools are presented and reviewed. Following this, the capabilities that design rationale currently has to offer are presented. Finally, an overview of medical device design is provided.

2.2.1 An Overview of Design Rationale

2.2.1.1 Definitions of Design Rationale

The term ‘design rationale’ (DR) has been referred to in many different ways by the design rationale community representing a variety of meanings. There has been some interest by the DR research community in describing what constitutes DR, with authors presenting varied descriptions.

Six different ways in which DR has been referred to as (Moran and Carroll, 1996) are summarised as follows: (1) an expression of the relationships between a designed artefact, its purpose, the designer’s conceptualisation, and the contextual constraints on realising the purpose; (2) the logical reasons given to justify a designed artefact; (3) a notation for the logical reasons for a designed artefact; (4) a method of designing an artefact whereby the reasons for it are made explicit; (5) documentation of the reasons for the design of an artefact, the stages or steps of the design process, and the history of the design and its context; and (6) an explanation of why the designed artefact is the way it is. It was identified (Lee and Lai, 1991) that the term ‘design-rationale’ was being used in the following three different ways: a historical record of the reasons for

the choice of an artefact (Yakemovic and Conklin, 1990), a set of psychological claims embodied by an artefact (Carroll and Rosson, 1990), and a description of the design space (MacLean *et al*., 1989).

Table 2-3 lists the popular definitions for DR available in the literature.

Table 2-3: List of popular definitions for design rationale

Authors (date)	Definitions of design rationale
Wang *et al*. (2012)	"DR is an effective way of capturing the missing part of an integrated representation of design knowledge, and can be viewed as a valuable intellectual asset of an enterprise"
Kannengiesser and Gero (2011)	"DR can be understood either as a passive and fixed description of the history of designing, or as a dynamic act that constructs the assumptions underpinning the design decisions as they are needed in a current situation"
Mix *et al*. (2010)	"DR is the combination of specifications, motivations and actions for the purpose of creating designs"
Nkwocha *et al*. (2010)	"DR bridges the information gap between the need a system fulfils and its final design"
Wang *et al*. (2009)	"DR can offer designers useful information about how previous designs evolved and in what context such evolution happened"
Haynes *et al*. (2008)	"DR can answer questions about why a given design takes the form that it does"
Burge and Bracewell (2008)	"DR provides a history of the design process as well as capturing the intent behind the decisions made"
Atwood and Horner (2007)	"DR is a potential solution to help designers identify issues that they may have otherwise left unconsidered"
Dutoit *et al*. (2006)	"DR is the reasoning that goes into determining the design of the artefact"
Tang *et al*. (2006)	"DR is a method of capturing the knowledge and reasoning that justify the resulting design"
Kim *et al*. (2005)	"DR is the result of complex reasoning and decisions"
Li *et al*. (2002)	"DR is a methodology for problem solving and decision making in a design context"
Lee (1997)	"DR can include not only the reasons behind a design decision but also the justification for it, the other

	alternatives considered, the trade-offs evaluated, and the argumentation that led to the decision"
Shum (1996)	"DR is a representation of the reasoning behind the design of an artefact"
McKerlie and MacLean (1994)	"DR is an approach to design which emphasises working with explicit representations not only of possible design solutions, but also of the reasons and processes behind them"

It has been explained (Haynes *et al*., 2008) that the purpose of DR was intended to capture the reasons why designers make the design decisions that they do, how they moved through a design space to identify questions and the answers to solutions to those questions, and the criteria they used to determine that a particular solution will work, or will work better than other possible alternatives. It has also been expressed (Burge and Brown, 2008) that rationale differs from other types of documentation because it documents more than the results of each decision; it documents what the decisions were, what alternatives were considered and rejected, and what arguments were used in making the alternative selections.

It has been highlighted that DR is essentially a methodology directed towards problem solving and decision making in a design context which relies on understanding human cognitive processes and understanding the variety of design domains (Li *et al*., 2002). In this context, it is described that a design rationale capture (DRC) tool intends to let designers think and discuss design within a certain knowledge representation framework (Regli *et al*., 2000).

The definitions for DR have presented various analogous descriptions of what constitutes a DR but they do not explain what a DR does not include. The descriptions showed a general consensus of what DR is based on similar interpretations by researchers. As pointed out by Li *et al*. (2002) some of the definitions are generic and could be accepted by everyone nevertheless some of the definitions were defined with a specific purpose and based on the current understanding of research in the DR domain. This view is echoed by Atwood and Horner (2007) who also state that DR may mean

different things to the different researchers and practitioners within the DR research community.

It has been argued (Medeiros and Schwabe, 2008) that there is no agreement in the literature regarding the definition of design, although different definitions were available (Simon, 1981; Schön, 1983; Goel and Pirolli, 1989; Hubka and Eder, 1996; Winograd, 1996). In the context of design, it is understood by researchers within the wider design community that there is no single, universally accepted concise definition of design although several classifications have been proposed (Atwood *et al*., 2002). It is also understood that design is concerned with the construction of artefacts and artefacts are systems produced by people to help them meet their goals (Simon, 1981). This therefore raises some important questions as to what DR actually is and whom it is intended for other than the designer who captures and uses it.

2.2.1.2 The Need for Capturing a Design's Rationale

It is understood that large amounts of knowledge and experience are seldom captured and are stored in the minds of individuals (Wallace *et al*., 2005). It was identified by Wallace *et al*. (2005) that when individuals leave an organisation or a particular part of it, they take their knowledge with them, and in such instances this knowledge is lost forever. More importantly, addressing the issues of how to capture, store and retrieve design knowledge independently of human sources has been identified as a requirement for industrial organisations (Wallace *et al*., 2005).

It has been explained by Burge (2008) that there is an increasing acknowledgement of the importance of knowledge to organisations and rationale has the potential to make a key contribution to capturing and retaining that knowledge. This is further iterated by Medeiros and Schwabe (2008) who consider DR to have a potential value for supporting design reuse, because it prevents the experience and the knowledge invested in a design from being lost. Hooey and Foyle (2007) have stated that the need for a DRC tool is prevalent in a wide array of NASA's design projects including Constellation, small satellites, air traffic control automation, and robotics. They have

argued that if DR could have been captured in an efficient and effective manner during the Apollo Era in the 1960's, NASA would be able to take advantage of this design knowledge and applied the lessons learned to existing projects.

Aurisicchio *et al*. (2007; 2008) have recognised that aerospace engineering design relies heavily on the use of past experience, and engineering designers are frequently required to revisit previous design solutions and understand the rationale for their generation. Additionally, Bracewell *et al*. (2009) have explained that engineering designers cannot retain all the information they require in order to solve complex design problems in their heads, therefore retrieval of information is externally sourced from colleagues, documents, models, engineering drawings and databases. In particular, it is considered that the expert knowledge of an experienced designer is invaluable and DR can help to capture this knowledge (Burge and Kiper, 2008). The re-use of previous design knowledge is considered to be a potentially important way to improve the design efficiency (Brissaud *et al*., 2003).

Burge and Brown (2008) have acknowledged that there are many ways that rationale can be used in the development and maintenance of software. They have explained that rationale can serve as documentation by capturing knowledge of the original developers for use by new people joining the team, since the software maintainers are not often the developers. As software evolves over time, the original reasons or rationale behind the design and implementation decisions may be lost.

Burge *et al*. (2008) have described that the general goal of rationale research was to use records of rationale to improve the processes of creating various physical artefacts, also including software and governmental policies. They have explained that in order to support the aforementioned goal, rationale research has sought to develop methods and software that enable: the elicitation of useful rationale from its authors; the recording of useful rationale; the structuring and indexing of rationale to aid its retrieval; retrieval of rationale when it is useful; delivery of that rationale to those for whom it is useful; and use of the rationale by those people.

A survey on architecture DR conducted by Tang *et al*. (2006) revealed that 85% of architects that they had surveyed agreed that the use of DR was important in justifying design decisions, and 80% of the respondents are said to have failed to understand the reasons of a design decision without the support of DR. Additionally, it was discovered that 74% of the respondents had a tendency to forget their own design decisions. According to the Tang *et al*. (2006), the results from the survey had clearly indicated the need in capturing the DR for system maintenance.

2.2.1.3 Benefits of Utilising Design Rationale

Many claims have been made by DR researchers regarding the benefits provided by using DRC tools to capture and represent rationale, and about the consequences of not documenting DR. One such claim is that, DR helps to expose the underlying propositions and mechanics of a given theoretical position by exposing the otherwise invisible reasoning that unifies a theoretical construct with a constructed object (Haynes *et al*., 2008). Additionally, one of the potentially most promising roles for DR representations and tools according to Haynes *et al*. (2008), is to act as a repository for design knowledge and cases, and one of the strengths of DR is that it makes explicit how design criteria are applied to influence a given design decision.

Researchers have argued that by capturing DR, knowledge that is usually implicit is made explicit, additionally, this knowledge becomes available for re-examination at a later date, for example, if and when the requirements change (Dutoit and Paech, 2000). Moran and Carroll (1996) have suggested that DR would seem to be a helpful aid for teaching students or inexperienced designers; because it provides an explanation for why particular design components or features were chosen.

Lee and Lai (1991) have declared that an explicit representation of design rationales can bring many benefits; however, this depended largely on the computational language used for representing design rationales. MacLean *et al*. (1991) listed two major benefits from DR representation which were aiding in reasoning and aiding in communication. These were further elaborated in terms of enabling the designers to envisage the

available design alternatives in a more structured way including arguments for and against.

Jarczyk *et al*. (1992) have provided an example of the potential benefit of recording DR for large software systems. They have explained that a significant amount of time and money could be saved on future releases of software providing the rationale was recorded for the initial version. This was considered to be where DRC tools seemed to promise to be the most useful, and even the modest success of such tools could provide substantial benefits.

Lee (1997) classified common services into the following four major groups according to the user group who was considered to benefit from the services provided by a DR system: (1) better design (designers); (2) better maintenance (system maintainers); (3) learning (new trainee, students, learning programs); and (4) documentation (to be used by future designers and maintainers). It was also considered that well-structured design rationales could help designers follow the issues and alternatives being explored including their evaluations, which in turn clarified the overall structure of the reasoning process and supported decision making.

It has been argued by Burge *et al*. (2008) that rationale matters because it useful for creating artefacts in general and particularly software engineering. There are two ways defined by Burge *et al*. (2008) in which rationale documentation methods can be useful for artefact creation. The first way is by providing a record of the reasoning associated with decision-making, and the second is by actively shaping the process of reasoning about decisions. Two further ways are also described in which a record of the decision-making process can be useful to serve as a memory aid for those who have participated in the decision-making, and the other is to inform those who did not participate in the decision-making process but are affected by the decisions. In addition to the value of simply recording DR, rationale can be useful by aiding decision-making.

2.2.1.4 Challenges Currently Faced by the Design Rationale Research Community

As well as the suggested benefits of capturing DR and using DRC tools, researchers have also commented on the challenges currently facing researchers in the DR community. One of the challenges described for DR research was to discover the most helpful and accessible representations for design reasoning (Shum and Hammond, 1994). Lee and Lai (1991) explained how each DR representation must consider the costs and benefits involved in trade-offs among the following three general dimensions: expressiveness, human usability, and computational tractability.

Jarczyk *et al*. (1992) have highlighted an important issue for the application of DRC tools and identified a difficult problem which was how to integrate the DRC tool into the overall design process and into the designer's natural working environment without disrupting the design process. Bracewell *et al*. (2009) identified that a hindrance to the adoption of rationale capture tools in industry was the need of previous DR tools for a dedicated Database Management System (DBMS) to store the rationale. According to Bracewell *et al*. (2009), this did not fit well with the designers' regular working practices and IT support systems.

Fischer *et al*. (1996) have pointed out that documenting the decisions could hinder the design process if it is viewed as a separate process and that there were fundamental obstacles to the effective documentation and use of DR that needed to be considered. It was also claimed by Fischer *et al*. (1996) that DR served design if it helped designers: (a) to improve their work; (b) to cooperate with other people holding stakes in the design; and (c) to understand existing artefacts (learn from past designs). Additionally, the change of working practice to capture DR could result in low designer participation since the benefits of DR were not always demonstrated immediately (Myers *et al*., 1999).

Regli *et al*. (2000) have argued that a DRC tool was not effective as an individual system. They elucidated that together with other design support systems, such as Computer-Aided Design (CAD) or Computer-Aided Software Engineering (CASE)

tools, a DRC tool could contribute to the design process by providing designers with a knowledge representation framework, including the tools to capture DR, design reasoning and communication during the design process.

Horner and Atwood (2006) have explained that the inherent problem of identifying the impact of rationale across different design problems added a net cost to the utilisation of rationale, which in turn, decreased the overall utility in the design process. They have also stated that one problem with DRC tools was that there was no absolute measure of effectiveness. This posed a difficulty for the designers to understand which rationale would be the most useful. Burge and Brown (2000) have also commented on problems with DR by firstly stating; capturing, or recording DR was a particularly difficult problem. Secondly, the recording of all decisions made, including those rejected could be a time consuming and expensive process.

A study conducted by Conklin and Yakemovic (1991) found that there was a nearly a universal intuitive notion that DR would be beneficial in the long term, however, the immediate cost of capturing DR discouraged the practice. There was also a strong consensus that rationale was very valuable, but there was an equally strong concern that the costs of its capture may be too high, and in order to justify the costs, it's essential to establish ways in which the rationale could be useful (Burge and Bracewell, 2008).

One of the major stumbling blocks in rationale research has been the fear that rationale may not be worth the costs of its capture (Burge *et al*., 2008). Several key issues that impeded the application of argumentation-based DR methods were highlighted by Tang *et al*. (2007). Firstly, it was considered to be a cognitive burden in capturing complete explanations and secondly, there was a lack of traceability when changes to the design occurred.

Burge (2008) has listed the numerous proposed uses for rationale and the barriers to its capture and use. The proposed uses included: providing additional documentation; assisting new personnel in learning about the design; and supporting software maintenance. The barriers identified to DR capture and uses included: the effort

involved in capturing it; potential liability issues if decisions can be tracked; and the potential for disrupting design.

Burge and Brown (2008) have argued that while capture and representation are important for DR, the real value of a DRC tool is how well the rationale can be put to use. They continue to state that capturing DR was not useful if it was never looked at again, and if rationale was to be useful to the designers, the designers generally tended to assist with the capture and recording of DR particularly if they could put it to immediate use. The use of DR depended on its representation format and content, and rationale was only useful if software developers actually used it (Burge and Brown, 2008).

A summary of the challenges currently facing the DR community are summarised in Table 2-4. Comments made by the authors are noted and the date is referenced.

Table 2-4: Summary of the challenges for design rationale

Authors (date)	Challenges
Aurisicchio and Bracewell (2009)	Recognised that a key challenge in engineering design research was that of enabling designers to capture, in a digital way, design information of the type that was generally documented in personal design journals.
Burge (2008)	Identified two major obstacles that need addressing: (1) need to understand the requirements and problems of the practitioners DR is intending to support; and (2) need to provide evidence of the value of DR solutions through formal empirical evaluations of existing and new DR approaches.
Billa *et al*. (2007)	Commented on issues that may prevent a DR model from being used in healthcare settings as being due to legal value of the patient record. The physician may be held accountable for their action (diagnosis and specified treatment).
Atwood and Horner (2007)	Identified essential barriers and problems that inhibit the success of DR systems. These were: cognitive barriers, capture barriers, retrieval barriers, usage barriers, and organisational barriers.

Dutoit *et al*. (2006)	Discussed the intrusiveness of the effort required for DR capture which required designers to write up their rationale in a given framework. This required a great deal of additional work to the normal design process. Other challenges included political and legal factors.
Horner and Atwood (2006)	Classified DR challenges into four categories: cognitive limitations; capture limitations; retrieval limitations; and usage limitations.
Regli *et al*. (2000)	Presented challenges for representations and capture. The challenge for representations was to find the best method to assist designers in decision-making and to possess three qualities: ease of input, effective view and activeness. Challenges for capture included devising a method to capture process knowledge with minimal overhead and with least interference of design activities.

This section has provided an overview of DR which includes its associated definitions, its need, the benefits of utilising design rationale and the challenges currently faced by researchers. The following subsection presents the state-of-the-art in DR representation frameworks.

2.2.2 Design Rationale Representation Frameworks

A DR representation framework is described to explicitly document the reasoning and argumentation occurring in a design (MacLean *et al*., 1991). It is understood that the representation determines the methods used to capture and retrieve the rationale, but more importantly, a good representation schema is described to be vital in enabling effective design rationale capture, retrieval and reuse (Regli *et al*., 2000). Dutoit and Paech (2000) have described that DR can be represented in several different ways which include: natural language justifications, as rules in knowledge-based systems (KBS), or as arguments that were structured in rhetorical steps.

The importance of selecting an appropriate representation framework has been emphasised by numerous authors (Lee and Lai, 1991; Shum, 1991; Moran and Carroll, 1996; Lee, 1997; Regli *et al*., 2000; Li *et al*., 2002; Dutoit *et al*., 2006; Medeiros and

Schwabe, 2008; Wang *et al*., 2012). According to Lee and Lai (1991), the choice of representation is considered to be especially important when a human is the user of the representation. DR is also considered to be an important part of the integrated knowledge representation as it is able to describe the complex reasoning used (Wang *et al*., 2012). A DR representation should be able to explain the design reasons and also to describe the artefact (Liang *et al*., 2009).

Lee (1997) has explained how it was impossible to represent an entire DR explicitly however, whatever was represented must be accessible, and it must have some form of structure. The choice of representation is considered to be especially important when a human is the user of the representation (Lee and Lai, 1991).

Fundamentally, DR must have a method for capture, representation, and construction in order for it to be used (Moran and Carroll, 1996). Most approaches to representing DR include the notion of criteria that are used in design decisions as a basis for evaluating, comparing, and selecting alternative solutions (Kannengiesser and Gero, 2011). The most common argument structures and methods for selecting and organising information, and that have been extensively used to represent DR are; Issue-Based Information System (Kunz and Rittel, 1970), Procedural Hierarchy of Issues (McCall, 1991), Questions, Options, and Criteria (MacLean *et al*., 1991), and Decision Representation Language (Lee and Lai, 1991). An overview of these and other representation approaches that have been developed since the year 2000 is provided in the following sub-sections.

2.2.2.1 Issue-Based Information System

The issue-based information system method (IBIS) uses an issue-based approach and was originally applied to large-scale projects in planning and policy making for the United Nations, the Commission of European Communities and the former West German Government (Dutoit *et al*., 2006). Since IBIS was proposed and applied in the 1970s and 1980s (Kunz and Rittel, 1970), it has become the dominated method in the DR community and it has been studied, improved and applied in many areas such as;

architecture and planning, environmental design and planning, engineering design, computer system design, group meetings, and individual brain storming (Li *et al.*, 2002).

IBIS consists of three node types (Issue, Positions, and Arguments) and eight link types (supports, objects-to, replaces, responds-to, generalizes, specializes, questions, and suggested-by). Issues can have numerous counter positions which are prospective responses to the issue raised. A position can have a single or multiple arguments to either support or object-to it. Issues can also generalize or specialize other issues, and can be suggested-by or question other issues, positions, or arguments. Figure 2-1 illustrates the gIBIS (graphical IBIS) notation (Conklin, 1989) which has been adapted from the IBIS method for use in the software engineering domain by extending its vocabulary and adding a graphical representation by displaying each IBIS as a directed graph (Shum, 1991). Relationships among the three elements (issues, position and argument) in gIBIS are displayed (Figure 2-1).

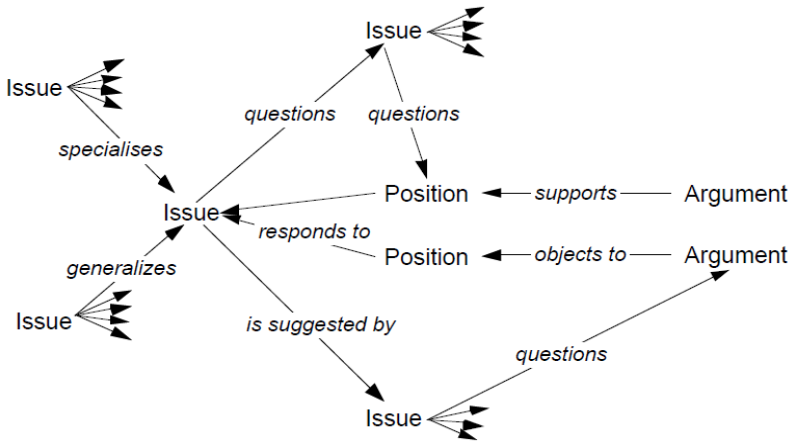

Figure 2-1: Legal argumentation moves in gIBIS (Shum, 1991)

The following eight features of IBIS that are commonly shared by most other argumentative approaches to DR have been identified by Burge *et al*. (2008): (1) Using a fixed conceptual schema of elements and relationships between pairs of them; (2) Dividing rationale into the reasoning about individual decision-making tasks (referred to as issues in IBIS); (3) Representing decision-making tasks as questions to be answered; (4) Proposing decision alternatives for each decision-making task (referred to

as positions in IBIS); (5) Evaluating the proposed decision alternatives by stating and considering pros and cons of these alternatives (referred to as arguments on positions in IBIS); (6) Evaluating the evaluations by stating and considering pros and cons (referred to as arguments on arguments in IBIS); (7) Deciding a decision task by selecting one decision alternative on the basis of its evaluation; and (8) Using several relationships to link the separate decision-making processes (referred to as inter-issue relationships in IBIS).

A study conducted by Bracewell and Wallace (2003) suggested that the practical use of the existing IBIS DRC tools were hampered by various problems. It was described that for every issue, solution or argument captured, the user was required to summarise it meaningfully into no more than five or six words, which was likely to prove an intolerable burden to the designer. It was also identified that the DRC tools had no clear and consistent way of representing the element status, so the user was forced to adopt textual conventions in labels in order to represent the status information. This resulted in the loss of clarity of the design arguments.

In order to address the recognised problems of existing IBIS tools, Bracewell and Wallace (2003) have introduced a graph-based IBIS DRC tool called the Design Rationale editor (DRed) which is understood to allow a much clearer view of the rationale structure and content than has previously been possible. An evaluation of the DRed tool in industry was shown to make the design process faster overall and more rigorous, and the rationale structure was clear to see and understand both by users and others. According to Bracewell and Wallace (2003), the tunnelling links in DRed simplified the preparation and presentation of large rationale structures in a way that no other DR system provided. Another particular advantage of the IBIS-based DRed DRC tool was the natural and intuitive interface which indicated that the system was easy to learn, easy to use and clear as an archival method (Bracewell and Wallace, 2003).

DRed is a graphical software tool for design rationale capture that, despite essentially still being a research prototype, has proved robust and useful enough gradually to achieve use in an international aerospace company and like Compendium (Shum *et al*.,

2006), both of these DRC tools are developments of the IBIS concept (Bracewell *et al*., 2007). Figure 2-2 shows the links available in DRed (Kim *et al*., 2007). It is described by Kim *et al*. (2007) that a DRed path is the list of the links starting from a specific element and finishing at a specific element.

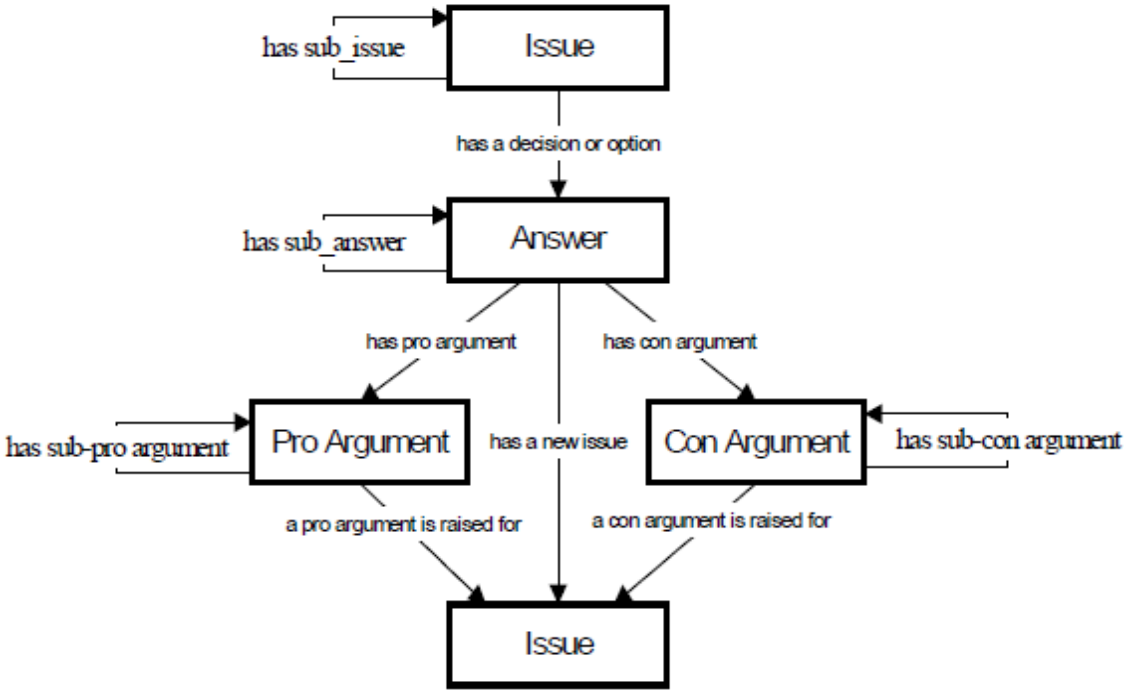

Figure 2-2: An overview of different link types among the DRed elements (Kim *et al*., 2007)

2.2.2.2 Procedural Hierarchy of Issues

The procedural hierarchy of issues (PHI) (McCall, 1991) method extends the original IBIS structure by introducing a quasi-hierarchical issue-serves-issue structure as illustrated in Figure 2-3. PHI is described to be a system of question-answering processes in which the question-answering processes are related to each other by inter-issue dependencies called ‘serve relationships’.

PHI has altered the IBIS structure by simplifying the relations among issues by use of the ‘serve’ relationship. It provides two methods that assess design issues which are known as deliberation and decomposition. The deliberation process is similar to that of IBIS whereby an argumentative approach is used. However, the decomposition process

includes the incorporation of a hierarchical structure and the introduction of a second argumentative process for solving issues.

A central point of the PHI method is the 'Prime Issue' which should be explicitly raised and resolved. The end-point of using this method is that the prime issue is resolved. McCall (1991) has commented on how IBIS focuses on the argumentative processes associated with debate and disagreement. However, it is understood that PHI advances this and generalises the concept of argumentation as basing conclusions on premises (McCall, 1991).

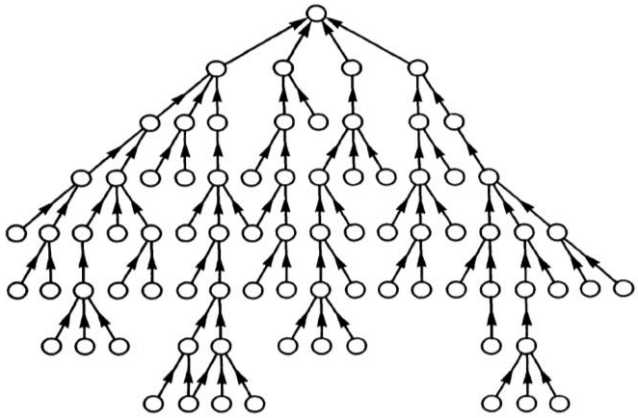

Figure 2-3: A quasi-hierarchical structure of sub-issues in PHI (McCall, 1991)

Regli *et al*. (2000) have explained that a major advantage of PHI is that associated elements (issues, sub-issues, answers, and arguments) can be presented in the format of outlined text using indentations. In PHI, design is represented in a tree like-structure of nested issue-resolution process (Figure 2-3).

In comparison to IBIS, PHI is described to provide dependency relationships between issue resolutions, and it also takes into consideration the pros and cons of alternative answers. The PHI concept has generated the development of a number of issue-based hypermedia systems which include; MIKROPLIS (McCall, 1989), ViewPoints (Fischer *et al*., 1989), AAA (Schuler and Smith, 1990), JANUS (McCall *et al*., 1990a), and PHIDIAS (McCall *et al*., 1990b).

2.2.2.3 Design Space Analysis: Questions, Options, and Criteria

Design Space Analysis is described to be an argumentative-based approach for representing DR. It uses a semi-formal notation called questions, options, and criteria (QOC), to represent the design space surrounding an artefact (MacLean *et al*., 1991). It incorporates six types of elements (Questions, Options, Criteria, Assessments, Arguments, and Decisions) and includes relationships between the elements (inter-question relationships).

MacLean *et al*. (1991) have explained that a design space analysis did not produce a record of the design process but was rather a co-product of design which had to be constructed in conjunction with the artefact. By using the design space analysis, an artefact is placed in the space of different possibilities and explanations are sought as to why certain characteristics of the artefact or artefact were chosen from the identified possibilities. The QOC notation is illustrated in Figure 2-4.

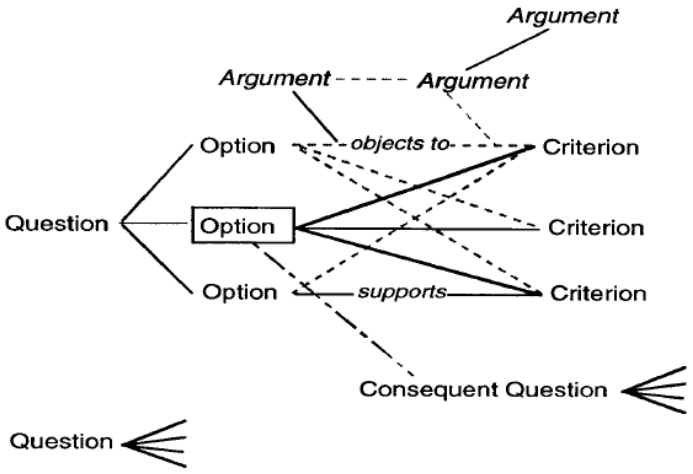

Figure 2-4: QOC notation (Shum and Hammond, 1994)

The systematic development of a space of design options which are structured by questions is emphasised by the QOC representation (Figure 2-4). This is described as being different from IBIS-derived systems, whereby the aim of these are to capture the history of the design deliberation process (Regli *et al*., 2000). The design space is represented in QOC using three components (questions, options, and criteria) as illustrated by the QOC notation in Figure 2-4. The questions are used to discover the

main issues to structure the space of alternatives, whereas the options are used to offer possible answers to the questions. The criteria are then used as a basis for the evaluation and selection from the different options.

One of the advantages highlighted by Regli *et al*. (2000) was that QOC could be used to 'reverse-engineer' a part of a system or artefact whereby the information could be preserved for future use. Another advantage pointed out by Dutoit *et al*. (2006) was that QOC did not allow the designer to ignore questions regarding the features of an artefact. Li *et al*. (2002) have mentioned that the QOC representation brings the design objectives into explicit focus and as a result is able to overcome one the limitations identified in the IBIS structure. However, Dutoit *et al*. (2006) have highlighted that the authors of the QOC approach (MacLean *et al*., 1991) did not create software to support the framework although other researchers have incorporated QOC into some systems.

2.2.2.4 Decision Representation Language

Decision representation language (DRL) was developed for representing and managing the qualitative elements of decision making which includes; the alternatives considered, their existing evaluations, the arguments underlying those evaluations, and the evaluation criteria used (Lee and Lai, 1991). The term 'decision rationale' has been defined by Lee and Lai (1991) as being the representation of the qualitative elements (decision problems, alternatives, goals, claims, and groups). It has been mentioned that many of these qualitative elements and relationships correspond to certain aspects of IBIS and QOC (Dutoit *et al*., 2006).

A 'decision rationale management system' is described to provide an environment for capturing decision rationale and the computational systems which uses it (Lee and Lai, 1991). It has been acknowledged that DRL was proposed as an explicit representation of DR which focussed on the deliberation leading to a decision (Li *et al*., 2002). The object vocabulary in DRL consists of the following five design spaces; argument space, criteria space, alternative space, evaluation space, and the issue space. Figure 2-5 provides an illustration of the DRL graphical notation.

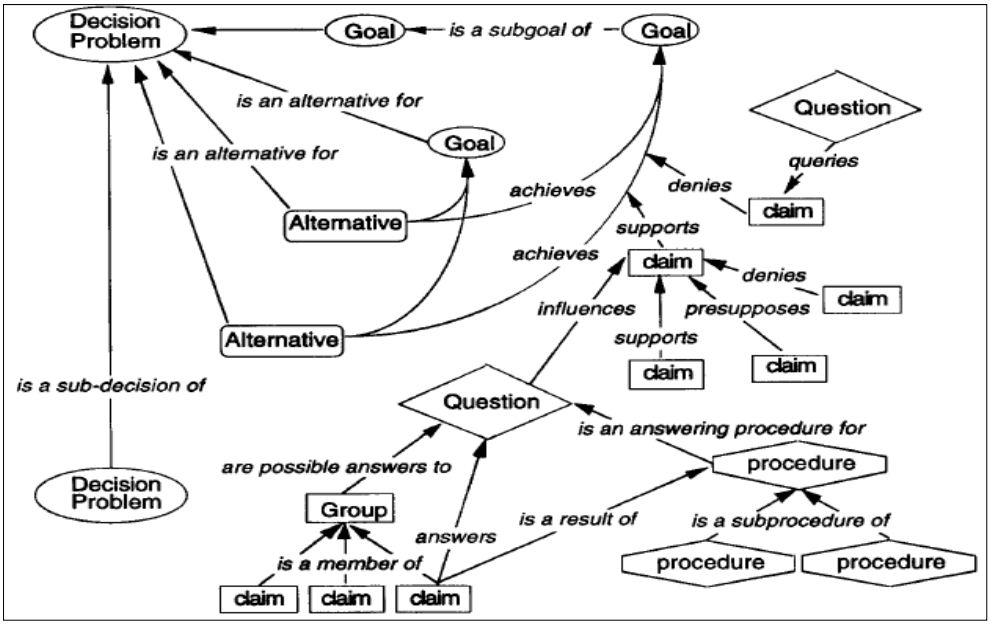

Figure 2-5: DRL notation (Shum, 1991)

The DRL model (Figure 2-5) has been embedded in the SIBYL system (Lee, 1990). SIBYL has been described to be a system that supports decision making by representing and managing qualitative aspects of decision making processes which include the alternatives, goals to be satisfied, and the arguments that evaluate the alternatives of the desired goals (Li *et al*., 2002). In SIBYL, the user does not have interaction with the graphs that display the entire DRL model. However, numerous views operating on subsets of the entities are available to the user (Shum, 1991). It is understood that SIBYL is able to computationally manipulate DR data in order to explore the implications of different aspects of design before finally making a commitment (Li *et al*., 2002).

2.2.2.5 Other Design Rationale Representation Frameworks

Since the year 2000, there has been some considerable development in design rationale representation frameworks. Table 2-5 lists the representation frameworks that have been identified from the available literature. Details such as the names of the authors including the date of publication, name of the representation framework, knowledge representation method and the design domain in which the representation framework has been applied to is provided (Table 2-5).

Table 2-5: List of design rationale representation frameworks

Authors (date)	Representation name / acronym	Knowledge representation	Design domain
Schubanz *et al.* (2012)	EvoPL	Extending QOC	Product line evolution planning – software engineering
Kannengiesser and Gero (2011)	Function-Behaviour-Structure (FBS)	FBS Ontology	Generic
Galvao *et al.* (2010)	Eclipse Modelling Framework (EMF)	N/A	Modelling of architecture variability in software product lines
Liang *et al.* (2009)	DR Representation in Patent Documents	N/A	Patent documentation
Bracewell *et al.* (2009)	Design Rationale editor (DRed)	Extending IBIS	Aerospace engineering design
Burge and Brown (2008)	RATSpeak	Extending DRL	Software development
Medeiros and Schwabe (2008)	Kuaba	Extending IBIS	Generic
Billa *et al.* (2007)	DR based model for the representation of a patient's medical record	Extending IBIS/QOC	Medical patients records
Tang *et al.* (2007)	AREL	Rationale-based architecture model	Software design
Boehm and Kitapci (2006)	WinWin	Extending IBIS/DRL	Software architecture
Lacaze *et al.* (2006)	Traceability, Exploration and Analysis Model (TEAM)	Extending QOC	Safety critical systems
Nomaguchi *et al.* (2004)	Hierarchical model of DR	Extending IBIS	Generic products
Brissaud *et al.* (2003)	Design process rationale capture and support	Conjectures and criteria	Engineering design
Kato *et al.* (2002)	Integrated Design Information Management System (IDIMS)	N/A	Email communication

Table 2-5 shows that IBIS is the most popular choice for representing design knowledge within the DR research community. From the frameworks that are listed (Table 2-5), IBIS has been used more than any other method as the basis to represent design knowledge in a variety of design domains. This is followed by QOC and then DRL as the most popular methods to represent DR.

2.2.3 Design Rationale Capture and Capture Tools

2.2.3.1 Design Rationale Capture

The task of eliciting, recording, and organising design knowledge is called DR capture, or DRC as it is more commonly abbreviated (Gruber, 1990). It has been described that the primary requirement of the DRC process is that it captures design descriptions in a form that supports the communication and reuse of design knowledge (Regli *et al*., 2000).

During the design process, DR is captured by recording the reasoning and by creating a structure (formal or semi-formal) in order for the DR to be used in the decision-making process during the design of an artefact. The DRC process is described to generally consist of two phases which are defined as knowledge recording and DR construction (Regli *et al*., 2000). Knowledge recording requires the capture of vast amounts of raw information during the design process, and DR construction involves the extraction, organisation, and storage of rationale knowledge based on the DR representation framework.

One common way of documenting rationale has been described to use the structure of a designed artefact instead of the structure of an argumentative schema to organize rationale (Burge *et al*., 2008). Lee and Lai (1991) affirmed that this was one of the simplest and least labour-intensive ways to record rationale. When designing physical artefacts, this could be achieved by linking textual rationale to a digital model of the artefact being designed (Burge *et al*., 2008).

It has been pointed out by Regli *et al*. (2000) that the main aim of the DRC process was to capture design descriptions in a form that supported the reuse and communication of deliberated design knowledge. It was further recognised by Regli *et al*. (2000) that DRC methods could be divided into the following two categories: user-intervention based capture (user manually records and documents design information as it is generated during the design process), and automatic rationale capture (DRC tool automatically captures rationale). The user-intervention approach to DR capture often required the use of design documentation (documentation method) regarding the designed artefact. More than often, these were in the form of design reports that were created by individual designers or design teams at the end of a design process. This type of documentation recorded the design decisions that were taken during the artefacts development. However, this did not always include the argument for or against the decisions taken.

To capture DR using the automatic capture method required the presence of a method to capture the communication of designers and design teams. Systems such as Computer-Supported Co-operative Work Tools (CSCW) could be used for communication amongst designers and included a variety of tools such as; telephone, tape recorders, video camera, other shared applications, or email in order to capture oral discussions (Regli *et al*., 2000). Using the automatic capture method, DR could be determined from digital archives. However, there was a limitation using this method because there was no structure to the communication captured this way. This in turn, made retrieving the desired design knowledge difficult to obtain due to the lack of structure.

2.2.3.2 Capture Tools

A key goal of DRC tools is to provide an external design argument representation in order for users, generally designers, to create, direct, and review arguments. DR representation frameworks are the critical interface between the user and the DRC tool. Since the emergence of the first argumentation-based approach taken to capture rationale, there has been a growing interest in developing DRC tools to assist designers from different domains to record and reuse DR. It has been described that a DRC tool needs to record the analysis of various alternatives so that designers could easily make

their decision, and after the design is completed, be able store its rationale for future use (Regli *et al*., 2000). It is further explained by Regli *et al*. (2000) that DRC tools are intended to support communication, reflection, and analysis in design.

The main approaches to developing DRC tools are either process-orientated (PO) or feature-orientated (FO). Regli *et al*. (2000) have explained that the FO approaches were frequently used in areas where a relatively high degree or standardisation occurred, and focussed on the representation of the artefact and the established rules which governed the design process. The PO approach was often used to create historical representations of the design process in dynamic domains where design principles were not well established (Shum and Hammond, 1994; Conklin and Yakemovic, 1991). The PO approach originated from the IBIS argumentation framework by Kunz and Rittel (1970).

The main difference between the FO and PO approach is that the FO approach constructs DR as a logical structure whereas in the PO approach the DR is descriptive. As pointed out by Regli *et al*. (2000), the different approaches (PO and FO) were based on the different stages of the design process whereby the design could be either process-orientated or feature orientated. The DR using the PO approaches were usually represented using graph-based notations which included; the use of nodes and links whereby the nodes indicated issues (questions), positions (options), and arguments. The links were indicated the different relationships among the nodes. This type of representation framework was described to provide a flexible structure and ease in recording the DR.

Figure 2-6 shows the flow of information in most DRC tools (Atwood and Horner, 2007). It is described that designers initially consider alternatives to design issues that they are faced with during the design of an artefact. Following this, they capture and store the rationale for their design decisions using a DRC tool. After this, another designer can browse the DRC tool to review the earlier decisions made and potentially apply these to current or new designs. This is described to take place in an organisational context.

Table 2-6 lists the commercial and prototype DRC tools from the year 2000 to date that have been identified in this review. The DRC tools have been categorised according to; the name of the computational system including the author and year of publication, knowledge representation framework used, knowledge capture method (semi-automatic - 'Semi'; user-intervention – 'UI'; automatic – 'Auto'), knowledge retrieval (query or navigate), and design domain that the tool is being or has been developed for.

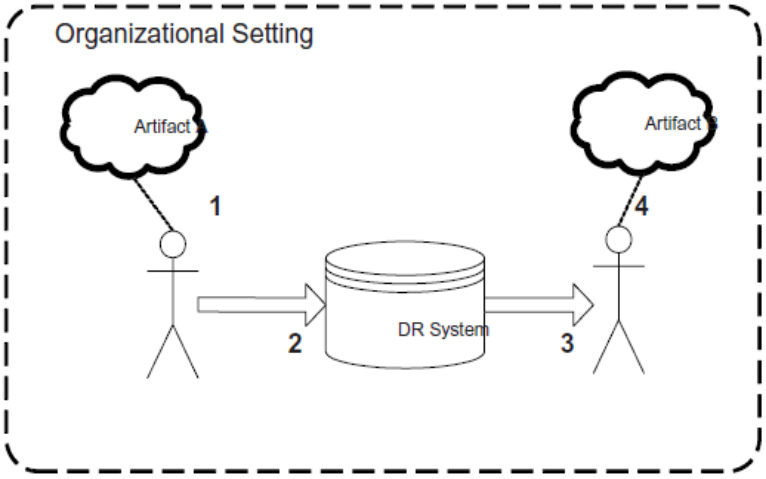

Figure 2-6: Flow of information in most design rationale capture tools (Atwood and Horner, 2007)

Table 2-6: List of prototype and commercial design rationale capture tools

DRC tool acronym / name and authors (date)	Knowledge representation	Knowledge capture	Knowledge retrieval	Design domain	Year
DRC in PLM Systems (Pavkovic *et al.*, 2010)	Extending IBIS	UI	Query	Generic	2010
Kuaba (Medeiros and Schwabe, 2008)	Extending IBIS	Semi	Query	Generic	2008
SEURAT (Burge and Brown, 2008)	RATSpeak/ Extending DRL	UI	Query	Software Development	2008

AREL (Tang *et al*., 2007)	N/A	UI	Query	Software Design	2007
DREAM (Lacaze *et al*., 2006)	TEAM/Extending QOC	UI	Query or Navigate	Safety Critical Systems	2006
WinWin (Boehm and Kitapci, 2006)	Extending IBIS/DRL	UI	N/A	Software Architecture	2006
Sysiphus (Dutoit *et al*., 2005)	Extending QOC	UI	Navigate	Software Engineering Courses	2005
Design Process Rationale (Brissaud *et al*., 2003)	Conjectures and Criteria	UI	N/A	Engineering Design	2003
CodeLink (Zaychik and Regli, 2003)	N/A	Auto	N/A	Software Development	2003
DRed (Bracewell and Wallace, 2003)	Graph-based IBIS	UI	Query or Navigate	Aerospace Engineering	2003
IDIMS (Kato *et al*., 2002)	Integrated Design Information Management System	UI	Navigate	Satellite Development	2002
R-Objects Pepper (Ernst, 2002)	IBIS Meta-Model	UI	Navigate	Generic	2002
HERMES (Karacapilidis and Papadias, 2001)	Extending IBIS	UI	Query	Generic	2001
Compendium (Conklin *et al*., 2001)	IBIS	UI	Navigate	Meeting Facilitation	2001

As can be observed from Table 2-6, there have been many DRC tools that have been developed since the year 2000 and the majority of these either use the IBIS structure or

have extended it. The design domains covered include: meeting facilitation (Conklin *et al*., 2001); satellite development (Kato *et al*., 2002); aerospace engineering (Bracewell and Wallace, 2003); software design and development (Zaychik and Regli, 2003; Dutoit *et al*., 2005; Boehm and Kitapci, 2006; Palyagar and Richards, 2006; Tang *et al*., 2007; Burge and Brown, 2008); engineering design (Brissaud *et al*., 2003); safety critical systems (Lacaze *et al*., 2006); and generic activities (Karacapilidis and Papadias, 2001; Ernst, 2002; Medeiros and Schwabe, 2008).

This section has presented the state-of-the-art in prototype and commercially available DRC tools that have been developed since the year 2000. The following section presents the capabilities that DR currently has to offer.

2.2.4 Design Rationale Capabilities

The compiled list of capabilities for DR is provided in Table 2-7. Listed (Table 2-7) are; the actions that design rationale can perform, reference to indicate where the action was obtained from, outcomes of those actions, the extracted verb from the action, capability name of which the action is assigned to, capability sub-category name based on the noun of the action, and the capability identifier (labelled A to M) to denote the category of which the action is assigned to. The thirteen categories of DR capabilities that were identified from the literature reviewed and listed in Table 2-7 are: (A) Answer, (B) Capture, (C) Communicate, (D) Design, (E) Determine, (F) Document, (G) Explain, (H) Justify, (I) Provide, (J) Represent, (K) Structure, (L) Support, and (M) Teach.

The capability sub-categories are: (Capability | A) design questions and design problems; (Capability | B) design knowledge and designers decisions; (Capability | C) design relationships, design space, information and logical reasoning; (Capability | D) artefact; (Capability | E) reasoning; (Capability | F) design decisions, design history, decision-making processes, design reasoning and logical reasoning; (Capability | G) design and reasoning; (Capability | H) argument; (Capability | I) historical evidence; (Capability | J) design reasoning, rationale and reasoning; (Capability | K) designers decisions; (Capability | L) designers; and (Capability | M) design.

Table 2-7: List of identified design rationale capabilities

Reference	Actions	Verbs	Outcomes	Capability names	Capability sub-category names	Categories
Haynes *et al*. (2008)	To answer design questions.	Answer	Questions concerning a particular design are answered.	Answer	Design Questions	A
Li *et al*. (2002)	To solve design problems.	Solve	Available method for problem solving in a design context.	Answer	Design Problems	A
Tang *et al*. (2006)	To capture design knowledge.	Capture	Design knowledge and reasoning captured.	Capture	Design Knowledge	B
Haynes *et al*. (2008)	To capture designers decisions.	Capture	Designer's decisions and reasoning are captured.	Capture	Designers Decisions	B
Moran and Carroll (1996)	To express the design relationships.	Express	Design relationships are expressed.	Communicate	Design Relationships	C
MacLean *et al*. (1989)	To describe the design space.	Describe	Description of the design space is provided.	Communicate	Design Space	C
Atwood and Horner (2007)	To transmit information.	Transmit	Information transmitted from one designer to another.	Communicate	Information	C
Moran and Carroll (1996)	To note logical reasoning.	Note	Logical reasoning is noted.	Communicate	Logical Reasoning	C
Moran and Carroll (1996)	To design an artefact with explicit reasoning.	Design	Reasoning behind the design is made explicit.	Design	Artefact	D
Dutoit *et al*.	To determine the	Determine	Reasoning underlying a	Determine	Reasoning	E

(2006)	reasoning behind a design.		design is determined.			
Burge and Brown (2008)	To document the design decisions.	Document	Design decisions are documented.	Document	Design Decisions	F
Jarczyk *et al*. (1992)	To list the design decisions and reasoning.	List	Design decisions are explicitly listed.	Document	Design Decisions	F
Yakemovic and Conklin (1990)	To record the design history.	Record	Historical evidence of the reasoning is provided.	Document	Design History	F
Moran and Carroll (1996)	To document the design history.	Document	Historical evidence of the design process is provided	Document	Design History	F
Burge *et al*. (2008)	To document the decision-making processes.	Document	Decision-making processes are documented.	Document	Decision-Making Processes	F
MacLean *et al*. (1991)	To document the design reasoning.	Document	Design reasoning is documented.	Document	Design Reasoning	F
Moran and Carroll (1996)	To record logical reasoning.	Record	Logical reasoning of a designed artefact is recorded.	Document	Logical Reasoning	F
Moran and Carroll (1996)	To explain the reasoning behind the designed artefact.	Explain	Explanation of the designed artefact is provided.	Explain	Design	G
Gruber and Russell (1996)	To explain the reasoning behind the design.	Explain	Explanation of the designed artefact is provided.	Explain	Reasoning	G
Lee (1997)	To justify the argument behind the design decisions made.	Justify	Justification of the design decisions is provided.	Justify	Argument	H

Burge and Bracewell (2008)	To provide historical evidence.	Provide	Historical evidence of the design process is provided.	Provide	Historical Evidence	I
Shum (1996)	To represent the design reasoning.	Represent	Reasoning underlying the designed artefact is represented.	Represent	Design Reasoning	J
Carroll and Rosson (1990)	To illustrate rationale behind the artefact.	Illustrate	Rationale is embodied within the artefact.	Represent	Rationale	J
McKerlie and MacLean (1994)	To represent the reasoning of design solutions.	Represent	Representation of the design solutions.	Represent	Reasoning	J
Haynes *et al*. (2008)	To expose the reasoning underlying an artefact.	Expose	Rationale for a constructed artefact is exposed.	Represent	Reasoning	J
Regli *et al*. (2000)	To structure designers decisions.	Structure	Designer's decisions structured to a given framework.	Structure	Designers Decisions	K
Dutoit *et al*. (2006)	To structure designers decisions.	Structure	Designer's decisions structured to a given schema.	Structure	Designers Decisions	K
Lee (1997)	To assist designers in decision-making.	Assist	Structured decision-making process.	Support	Designers	L
Atwood and Horner (2007)	To support designers.	Support	Reasoning and argumentation communication support system is established.	Support	Designers	L
Moran and Carroll (1996)	To teach others about design.	Teach	Explanation of the designed artefact is provided.	Teach	Design	M

2.2.5 An Overview of Medical Device Design

2.2.5.1 Medical Devices

The term medical device has been defined by the FDA to be; "*an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes*" [1][1].

In comparison, the European Commission (EC) have defined a medical device to mean; "*any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease, diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, investigation, replacement or modification of the anatomy or of a physiological process, control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means*" [2].

2.2.5.2 The Infusion Pump

An example of a medical device is the infusion pump. The FDA has defined an infusion pump to be a medical device that is used in a healthcare facility to pump fluids into a patient in a controlled manner (CDRH: FDA, 2010a). The device may use a piston

[1] Numbers in the square brackets [n] indicate the citing of internet resources. A full list of the resources used can be found in the References: Internet Resources.

pump, a roller pump, or a peristaltic pump and may be powered electrically or mechanically. The device may also operate using a constant force to propel fluid through a narrow tube which determines the flow rate. The device may include means to detect a fault condition, such as air in, or blockage of, the infusion line and to activate an alarm. Figure 2-7 provides an illustrative example of an infusion pump.

Figure 2-7: An example of an infusion pump (image obtained from: http://gzhuaxi.com/)

The FDA has defined the infusion pump system to include the following (CDRH: FDA, 2010a):

- Infusion pump;
- Fluid infusion set for the complete fluid pathway from, and including, the drug reservoir or fluid source container (e.g., bag cassette, vial, syringe), infusion set, extension sets, filter and valves, clamps, up to and including patient connection;
- Components and accessories (e.g., power cord, wireless controller);

- Network (i.e., any device or system physically or wirelessly connected to the infusion pump);
- Patient;
- Environment of use (e.g., clinical setting, temperature, humidity); and
- User (physician or lay user).

There are many different types of infusion pumps, which are used for a variety of purposes and in a variety of environments. The FDA has described [20] that infusion pumps may be capable of delivering fluids in large or small amounts, and may be used to deliver nutrients or medications – such as insulin or other hormones, antibiotics, chemotherapy drugs, and pain relievers. The FDA continues to describe that some infusion pumps are designed mainly for stationary use at a patient's bedside. Others, called ambulatory infusion pumps, are designed to be portable or wearable. The number of commonly used infusion pumps that are designed for specialised purposes have been identified by the FDA as follows [20]:

- Enteral pump - A pump used to deliver liquid nutrients and medications to a patient's digestive tract.
- Patient-controlled analgesia (PCA) pump - A pump used to deliver pain medication, which is equipped with a feature that allows patients to self-administer a controlled amount of medication, as needed.
- Insulin pump - A pump typically used to deliver insulin to patients with diabetes. Insulin pumps are frequently used in the home.

The FDA has also identified that different infusion pumps operate in the following different ways [20]:

- In a syringe pump, fluid is held in the reservoir of a syringe, and a moveable piston controls fluid delivery.
- In an elastomeric pump, fluid is held in a stretchable balloon reservoir, and pressure from the elastic walls of the balloon drives fluid delivery.
- In a peristaltic pump, a set of rollers pinches down on a length of flexible tubing, pushing fluid forward.

- In a multi-channel pump, fluids can be delivered from multiple reservoirs at multiple rates.
- A "smart pump" is equipped with safety features, such as user-alerts that activate when there is a risk of an adverse drug interaction, or when the user sets the pump's parameters outside of specified safety limits.

The FDA has explained how clinicians and patients rely on pumps for safe and accurate administration of fluids and medications [21]. However, the FDA has identified problems that can compromise the safe use of infusion pumps. These problems are presented in the following subsection.

2.2.5.3 Reported Infusion Pump Problems

As with other medical devices, infusion pumps are not without risks. Significant safety issues related to infusion pumps have recently been reported by the FDA (CDRH: FDA, 2010b). The FDA has stated that it has witnessed an increase in the number and severity of infusion pump recalls (CDRH: FDA, 2010a). A recall is when a product is removed from the market or a correction is made to the product because it is either defective or potentially harmful [22]. Analyses of medical device reporting regulations (MDRs) by the FDA have revealed device problems that appear to be the result of faulty design (CDRH: FDA, 2010a).

Between January 2005 and December 2009, the FDA received over 56,000 MDRs associated with the use of infusion pumps, including numerous injuries and deaths. Of these reports, it is stated that approximately 1% were reported as deaths, 34% were reported as serious injuries, and 62% were reported as malfunctions (CDRH: FDA, 2010a). These adverse event reports and device recalls have not been isolated to a specific manufacturer, type of infusion pump, or use environment; rather, they have occurred across the board (CDRH: FDA, 2010b).

The FDA has explained how it has evaluated a broad spectrum of infusion pumps across manufacturers and has concluded that there are numerous, systemic problems with device design, manufacturing, and adverse event reporting (CDRH: FDA, 2010a). Many

of the reported events are related to deficiencies in device design and engineering, which can either create problems themselves or contribute to user error. In come reports, the manufacturer was unable to determine or identify the problem and reported the problem as "unknown." It has been noted by the FDA (CDRH: FDA, 2010a) that subsequent root cause analyses revealed that many of the design problems were foreseeable and, therefore, preventable.

According to the FDA (CDRH: FDA, 2010b), the most common types of reported problems have been associated with software defects, user interface issues, and mechanical or electrical failures. Examples of these types of problems are provided as follows [23]:

- **Software problems:**
    - A software error message is displayed, stating that the pump is inoperable. This occurs in the absence of an identifiable problem.
    - The infusion pump interprets a single keystroke as multiple keystrokes (a problem called a "key bounce"). For example, the user programs an infusion rate of 10 mL/hour (millilitres per hour), but the device registers an infusion rate of 100 mL/hour.
- **Alarm errors:**
    - The infusion pump fails to generate an audible alarm for a critical problem, such as an occlusion (e.g., clamped tubing) or the presence of air in the infusion tubing.
    - The infusion pump generates an occlusion alarm in the absence of an occlusion.
- **Inadequate user interface design (human factors issues):**
    - The design of the infusion pump screen confuses the user, or the infusion pump does not respond as it should (i.e., with a warning or alarm) when inappropriate data is entered.
    - The infusion pump screen doesn't make clear which units of measurement the user is expected to enter. For example, the user may enter weight in pounds when the infusion pump requires it in kilograms.

  - Pump labels or components become damaged under routine use. For example, cleaning the pump, as the user-maintainer believes is acceptable practice, may damage the pump, making it unreliable for clinical use. Users with long fingernails may damage the print on the pump keys, making them unreadable.

- **Broken components:**
  - The infusion pump may have been dropped or damaged during use, which may result in an over-infusion or an under-infusion if the pump continues to be used without being repaired.
  - The plastic casing of an insulin pump, although promoted as waterproof, is prone to cracking, allowing water to enter the case and to cause the pump to malfunction. See Figure 2-8.
  - Slight misalignment of tubing places stress on the pump door, resulting in eventual cracking of pump case. See the following figures: Figure 2-9, Figure 2-10 and Figure 2-11.
- **Battery failures:**
  - A design issue causes over-heating of the battery and leads to premature battery failure. See Figure 2-12.
  - A patient returns from ambulating and forgets to plug in the infusion pump. The infusion pump alarms with a low battery message, but the speaker volume is set too low, and the alarm goes unnoticed. The infusion pump powers off after the battery is depleted.
  - The battery is not replaced during the recommended end of life routine maintenance.
- **Fire, sparks, charring, or shocks:**
  - The user plugs in or unplugs the device from an electrical outlet and receives a shock, and/or sparks are seen.
  - A burning smell or flames are noted on the infusion pump. See Figure 2-13.

Figure 2-8 shows an image of the cracks between the operating buttons that allow water to get inside of the case.

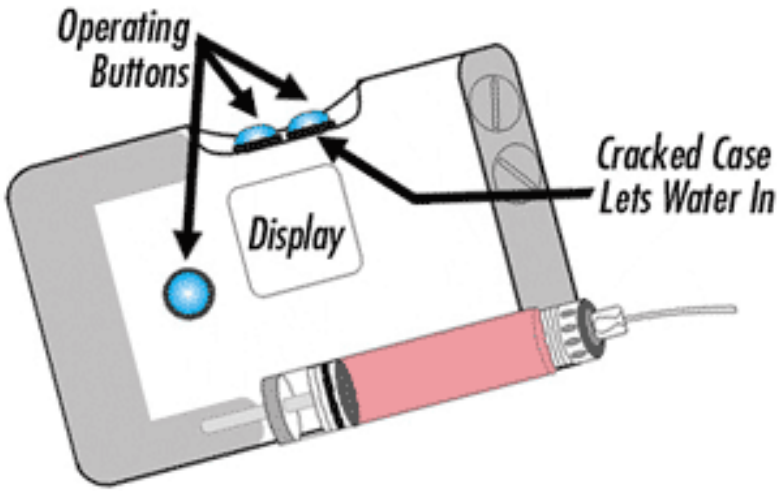

Figure 2-8: Image showing the cracks between the operating buttons which allow water inside [23]

Figure 2-9, Figure 2-10 and Figure 2-11 respectively show images of the; proper positioning of the tubing set, a close up of the tubing set out of alignment (the bump in the door will catch on the lower flange of the tubing set instead of fitting between the lower and upper flanges as intended), and the cracked door hinge resulting from stress caused by the misaligned tubing.

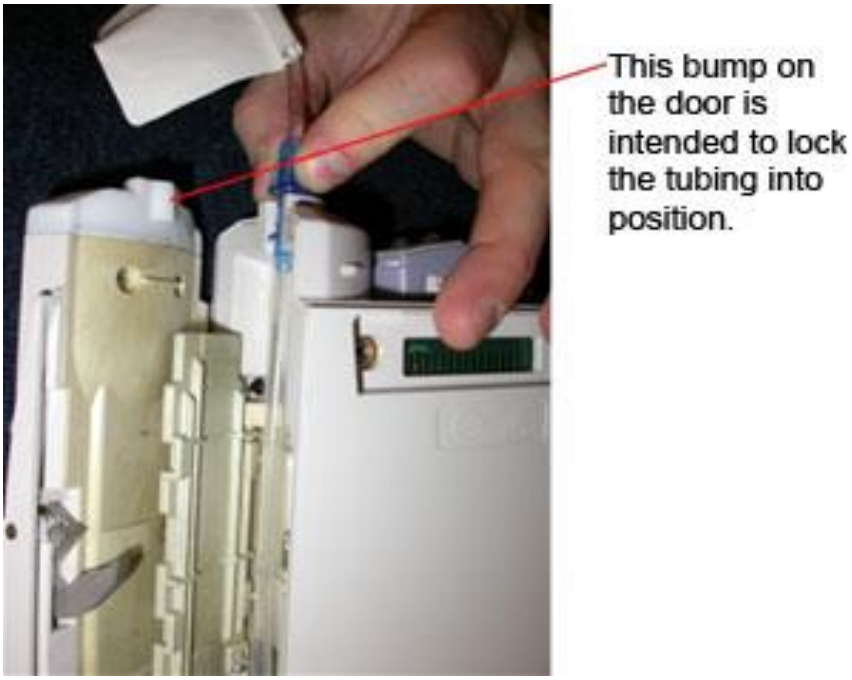

Figure 2-9: Image showing the proper position of the tubing set [23]

Figure 2-10: Close up image of the tubing set out of alignment [23]

Figure 2-11: Image showing a cracked door hinge resulting from stress caused by misaligned tube [23]

Figure 2-12 shows an image of a design issue with the sealed lead-acid battery of the infusion pump. As shown (Figure 2-12), the damage to the battery is caused by over-heating which, in turn, is the result of overcharging.

Figure 2-12: Image showing sealed lead-acid battery damage [23]

Figure 2-13 shows two images linked together, the photomicrograph on the right illustrates the charring and melting of failed connectors after a fire that occurred when pump modules were attached to a running unit [23].

Figure 2-13: Image showing the charring and melting of failed connectors [23]

Based on the design issues which have been identified with the infusion pump, the FDA has announced (CDRH: FDA, 2010b) that it is taking steps to address infusion pump

problems through the Infusion Pump Improvement Initiative [24]. Details on the infusion pump improvement initiative are provided in the following subsection.

2.2.5.4 Infusion Pump Improvement Initiative

The FDA has recently launched the infusion pump improvement initiative (CDRH: FDA, 2010b) to address infusion pump safety problems. The FDA has explained how better infusion pump design and engineering could prevent recurrence of many of the problems that have been observed. It has been stated by the FDA (CDRH: FDA, 2010b) that is has taken actions to respond to the issues that have arisen on a largely case-by-case basis; however, many of the same problems continue to occur.

By launching the infusion pump improvement initiative, the FDA is taking a more proactive and comprehensive approach to prevent safety problems by fostering the development of safer, more effective infusion pumps, and supporting the safer use of these vital medical devices. Through the infusion pump improvement initiative, the FDA has stated [24] that it is taking the following steps to prevent infusion pump problems:

1. Establishing additional requirements for infusion pump manufacturers;
2. Proactively facilitating device improvements; and
3. Increasing user awareness.

In order to provide greater assurance that the design deficiencies are identified and corrected before they lead to safety issues, the FDA has described how manufacturers of infusion pumps are now required to include additional design and engineering information as part of their premarket submissions and conduct additional testing of their devices (CDRH: FDA, 2010b). The FDA has issued a new, total product life cycle (TPLC) draft guidance document for infusion pump manufacturers (CDRH: FDA, 2010a). The guidance document has been developed to assist manufacturers of infusion pumps in preparing premarket notification submissions and to identify device features that manufacturers should address throughout the total product life cycle. By issuing

new guidance to manufacturers, the FDA intends to improve the quality of infusion pumps in order to reduce the number of device recalls and infusion pump MDRs.

It has been explained by the FDA (CDRH: FDA, 2010b) that the draft guidance recommends that manufacturers are to provide detailed design and engineering information to the FDA during premarket review, and that each infusion pump premarket submission should include a comprehensive discussion of steps the manufacturer has taken to mitigate the risks involved at each stage of the device's life cycle. The stages include; design, manufacture, servicing and maintenance, and use. The draft guidance also recommends that manufacturers are to conduct validation testing specific to the setting where the device is intended to be used. This is to account for the real-life environmental or user interface issues. When manufacturers are demonstrating the substantial equivalence of a new infusion pump intended for the U.S. market, the FDA has recommended that manufacturers submit information using a framework known as the assurance case or assurance case report (CDRH: FDA, 2010a). Details on the assurance case report are provided in the following subsection.

2.2.5.5 Assurance Case Practice for Medical Devices

An assurance case is described as a formal method for demonstrating the validity of a claim by providing a convincing argument together with supporting evidence (CDRH: FDA, 2010a). An assurance case structures arguments to help ensure that the top-level claims are credible and supported. The FDA has further described that in an assurance case, many arguments, with their supporting evidence, may be grouped under one top-level claim. The FDA has stated that it believes the methodology will be particularly useful for presenting and reviewing information about infusion pumps (CDRH: FDA, 2010a).

An assurance case that addresses safety has been defined as a safety case (CDRH: FDA, 2010a). A top-level claim (infusion pump is comparably safe) is supported by arguments that demonstrate how and why the evidence (performance data) supports the top-level claim. In a safety case, the arguments are typically organised in a hierarchical

manner with multiple layers of sub-claims, each supported by the appropriate evidence. It is intended that these arguments are to be used to convince a qualified reviewers that the top-level claim (infusion pump is comparably safe) is valid (CDRH: FDA, 2010a). Weinstock and Goodenough (2009) have stated that much like a legal case; the assurance case lays out an argument and supporting evidence to show that safety claims are valid. The FDA has identified the following three main elements of an assurance case:

1. **Claim:** Statement about a property of the system or some subsystem.
2. **Evidence:** Information that demonstrates the validity of the claim. This can include facts (based on observations or established scientific principles), analysis, research conclusions, test data, or expert opinions.
3. **Argument:** Links the evidence to the claim. Arguments can be deterministic, probabilistic, or qualitative. The argument will describe what is being proved or established (the claim(s)), identify the items of evidence the manufacturer is appealing to, and the reasoning (inference, rationale) that the evidence is adequate to satisfy the claim. Arguments many also introduce sub-claims or assumptions which require further exposition.

It is argued by Weinstock and Goodenough (2009) that a goal-structured assurance case holds promise to make the regulatory approval process less daunting by providing a means for the regulatory authority to understand just what beneficial properties the manufacturer is claiming for the device and how the evidence shows that the device is safe and effective. A goal structured assurance case specifies a claim regarding a property of interest, provides evidence that supports that claim, and provides a detailed argument explaining how the evidence supports the claim. Rather than having to work through piles of evidence with little to no guidance, an assurance case provides the examiner with a structure that is easier to follow (Weinstock and Goodenough, 2009).

Weinstock and Goodenough (2009) have developed an assurance case for a generic infusion pump by adopting the GSN (Kelly, 1998). Figure 2-14 provides an example of a short assurance case developed in GSN.

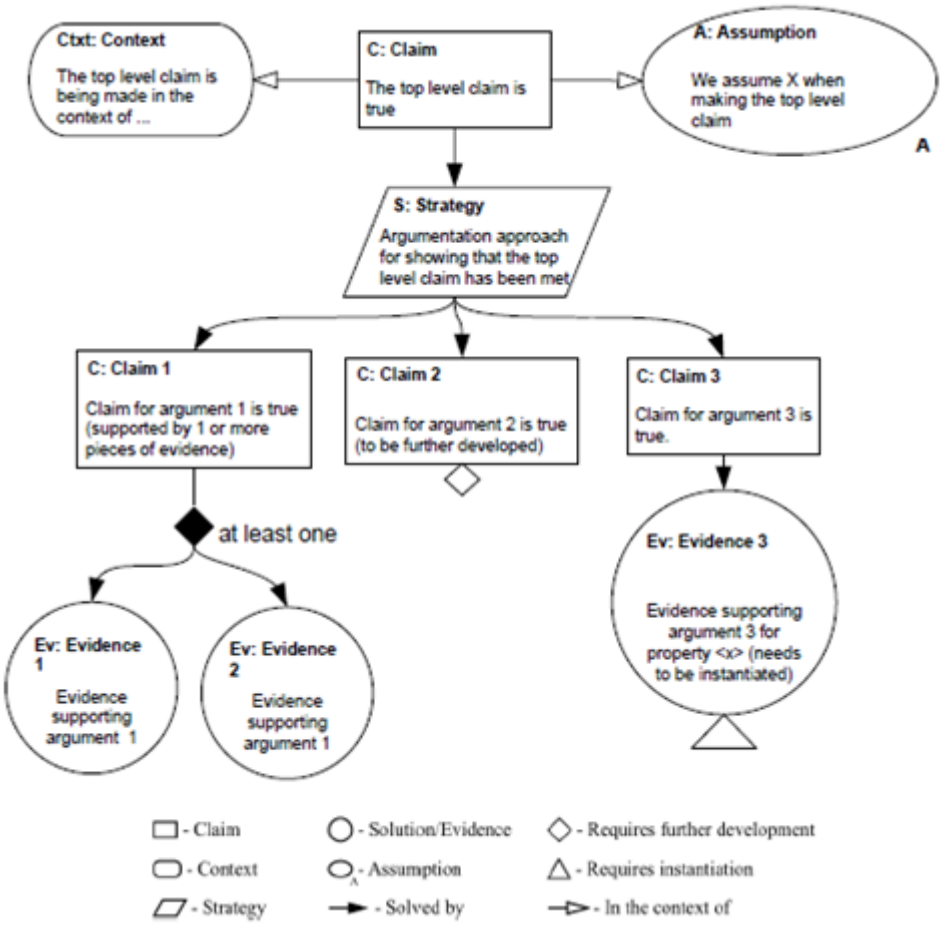

Figure 2-14: An example of a GSN argument (Weinstock and Goodenough, 2009)

2.2.5.6 Regulating the Approval of Medical Devices

Uniquely, medical devices are products that require rigorous regulation before they can be sold in the U.S. or countries that are member states of the EU. It is understood that manufacturers of medical devices are held to a higher standard than manufacturers of many other products due to the potential severity of the consequences of introducing inferior or unsafe products to the market-place (McAllister and Jeswiet, 2003).

In the U.S., medical devices are regulated by the Center for Devices and Radiological Health (CDRH) of the U.S. Food and Drug Administration (FDA). In the EU, the regulatory approval of medical devices relies on the use of notified bodies (NBs), which are independent commercial organizations that implement regulatory control over medical devices. It is understood that NBs have the ability to issue the CE mark, the

official marking required for certain medical devices (Kaplan *et al.*, 2004). Both the U.S. and EU regulatory approval systems classify medical devices pursuant to their inherent risks and accordingly assign different regulatory control mechanisms to each designated class of device (Chai, 2000).

In the U.S. approval system, medical devices are classified by the FDA into the following classes based on the intended use and risk the device presents to the patient [9]: Class I (low risk); Class II (medium risk); and Class III (high risk). In the EU, medical devices are grouped into the following classes (MHRA, 2009): Class I (generally regarded as low risk); Class IIa (generally regarded as medium risk); Class IIb (generally regarded as medium risk); and Class III (generally regarded as high risk). Examples of medical devices are for each of the aforementioned classes based on their risk are provided as follows: low risk (tongue depressors); medium risk (x-ray systems); and high risk (replacement heart valves).

Regulatory approval practices for the U.S. and EU have been described by Kaplan *et al*, (2004). It is understood that there are many similarities between the U.S. and EU regulatory processes, and there are important differences that impact the time and cost associated with the introduction of a new medical device in the U.S. and EU. It was noted that the main differences between the two processes were; the use of notified bodies in the EU, criteria for approval, and the process required in obtaining approval.

A comparative study of the medical device regulations in the U.S. and EU has been reported by Chai (2000). The study firstly reviews the U.S. and EU medical device classification systems and the requirements applicable to each class. Secondly, the U.S. and EU medical device regulations have been compared and contrasted according to their goals, implementation, and outcome. There were reported differences and similarities in the goals and implementation of the two regulatory approval systems, however it was also reported that it proved difficult to compare the outcome of the two approval systems' due to the lack of data. It was noted that due to the differences in the U.S. and EU regulatory systems, medical device manufacturers had to meet both sets of regulatory requirements in order for the device to be placed in the U.S. and EU markets.

2.3 Discussion

The discussion is presented in the order of the three research questions considered in this chapter. The following subsections discuss; how the definitions of design rationale have changed over the past ten years, the advancement in the state-of-the-art in design rationale representation frameworks; the capture tools that have been emerged since the seminal paper published by Regli *et al*. (2000), and the current capabilities of design rationale categorised in this chapter.

2.3.1 Definitions of Design Rationale

Before the year 2000, the design rationale research community have defined design rationale to include the reasons behind why design decisions regarding an artefact were made, the alternatives that were considered, a historical record of the reasons for making design decisions and representing the reasoning behind the design of an artefact. These definitions show that researchers in the design rationale community have considered design rationale to be notation for representing the design decisions that were undertaken during the development of an artefact.

More recently, since the year 2000, the design rationale research community have defined design rationale to be a potential solution to help designers identify issues with a design, a method for capturing design knowledge, a methodology for problem solving and decision-making in a design context and that design rationale can answer questions regarding the design of an artefact.

The more recent definitions of design rationale provided by the research community suggest that design rationale has evolved over the past ten years from a notation for representing design decisions to now being a methodological tool for problem solving and decision-making in a design context.

2.3.2 Representing and Capturing Design Rationale with the State-of-the-Art Methods of Representation and Computational Support Tools

Prior to the paper published by Regli *et al*. (2000), much attention had been focused on developing methods, notations and tools for recording rationales, the space or history of arguments surrounding the actual decision made. The prominent methods for representing design rationale were IBIS, PHI, QOC, and DRL.

From the year 2000 onwards, IBIS and QOC have become the basis for many new methods for representing design rationale. Methods such as Kuaba, TEAM and the design rationale model applied to health care have extended the original capabilities of these two prominent methods. IBIS remains as the prominent method for representing design rationale and is the methodological basis of many computational support tools. Many design rationale capture tools that have been developed since the year 2000 have adopted the IBIS structure or have extended it to apply it to the chosen application domain.

2.3.3 Current Capabilities of Design Rationale

The discussion on capabilities that design rationale currently has to offer follows the structure of a SWOT (Strengths, Weaknesses, Opportunities, and Threats) analysis framework. Firstly the strengths and weaknesses of the DR capabilities are considered and compared to each other using a quantitative analysis approach. The frequency of occurrences that DR researchers have mentioned a particular capability in peer reviewed journals has been used as this measure. Conversely, weaknesses are derived from the small frequency of mention by the DR research community in peer reviewed journal publications.

Secondly, the opportunities for new research that could further advance the understanding of the capabilities that DR currently offers are investigated. These opportunities have been derived from identifying whether the current DR capabilities

characterised as weaknesses could be translated into future strengths and whether the capabilities could include other types of actors than they currently serve.

Following this, the potential threats to the existing DR capabilities and continued advancement in DR research are presented. The potential threats have been identified by considering whether the current weaknesses constitute long term threats to DR research.

2.3.3.1 Strengths

Capabilities identified from the literature reviewed indicate that the major strengths of DR are communication, documentation, and representation. The capability ‘document’ has a frequency of seven occurrences. This is followed by the capabilities ‘communicate’ and ‘represent’ which both have four occurrences. These three sum to half the total capabilities.

2.3.3.2 Weaknesses

The remaining capabilities comprise of one or two occurrences. The capabilities which occur twice are; ‘answer’, ‘capture’, ‘explain’, ‘structure’, and ‘support’. Capabilities that occur once are; ‘design’, ‘determine’, ‘justify’, ‘provide’, and ‘teach’. These low numbers of occurrences may reflect that the DR research community do not consider them to be particularly important, or as not well served by DR, or as only served by a small part of DR.

Another weakness concerns the actors or users who utilise DR. Five out of the thirteen capabilities (‘capture’, ‘communicate’, ‘structure’, ‘support’ and ‘teach’) have identified designers to be the only actors concerned with the utilisation of DR. The remaining eight capabilities have no defined actors associated with the use of DR. This seems to be a weakness as there are other potential users of DR that are currently not mentioned in the literature which could benefit from using DR methods and tools. This is also emphasised by Carroll (2011) who explains that it is necessary for design rationale to be articulated by and accessible to anyone and everyone.

2.3.3.3 Opportunities

The preceding discussion on the frequency of capabilities leads to the question of whether low frequency capabilities could contribute to future opportunities for DR. A way to examine this question would be by being able to demonstrate a need for these capabilities inside and outside the DR community. However, these needs have not been categorised within the DR literature itself. Therefore, it is suggested that this is a gap which constitutes an important future research opportunity for DR practitioners.

Another opportunity for future research includes the targeting of new potential users of DR other than designers and the wider research and industrial communities in developing methods and tools that could be of benefit to the wider communities. If DR methods and tools could be utilised by users others than designers, this may expand the opportunities of receiving funding for future research and development. The DR community could perform an assessment of the types of actors involved in product development including who would potentially use the rationale and who would benefit from using it.

2.3.3.4 Threats

Despite over thirty years of research contribution and researchers efforts to develop DR methods and tools, the DR capabilities presented in this chapter have strongly emphasised only three capabilities (‘document’, ‘communicate’, and ‘represent’) out of the thirteen that were identified.

The main threat to future DR research and advancement that is faced by the DR community is the limited number of potential users who utilise DR. This suggests that the DR research domain could wither due to lack of future interest from funding bodies. The DR community need to address potential users and assess how these actors could benefit from using DR. DR methods and tools should be made available to a variety of users other than designers. For example, DR could be used in diverse industrial settings by manufacturers, regulatory bodies, and policy-makers.

By not demonstrating the capabilities of DR outside of the DR research community, DR will remain only useful to designers and not to others who may also benefit from using DR methods and tools.

This section has presented a discussion, using a SWOT analysis framework, on the capabilities that DR currently has to offer. The following sections in this chapter are as follows. A description of how the literature has answered the research questions is provided. Following this, gaps in existing knowledge that have been identified from the review of literature are outlined. Finally, a summary of the chapter is presented.

2.4 How the Literature Informed the Research Questions

This section presents answers to the three questions that were guiding this review of literature.

Firstly, this review sought to answer the questions; what is meant by design rationale, and how is it commonly defined? This review of literature has presented various definitions of design rationale and it is understood that design rationale is inherently linked to the explanation of a set of reasons or a logical basis for a course of action in the generic context of design. It is also understood that the term ‘design’ has various definitions but more importantly, there is no agreed definition of design in the literature therefore it poses some difficulty in concisely defining what design rationale is.

The second question posed was; what are the state-of-the-art in design rationale methods of representation and capture tools? There are four main methods for representing design rationale which are IBIS, PHI, QOC, and DRL. New frameworks for representing design rationale have been developed incorporating and extending the aforementioned methods to address their limitations. Many design rationale capture tools that have been developed since the year 2000 have adopted the IBIS structure or have extended it. Most recently, design rationale capture tools have been utilised for; meeting facilitation, satellite development, aerospace engineering, software design and development, engineering design, and safety critical systems.

The third and final question posed was; what are the current capabilities of design rationale? There were thirteen listed categories of design rationale capabilities that were identified from the literature reviewed. The thirteen categories of design rationale capabilities were; answer, capture, communicate, design, determine, document, explain, justify, provide, represent, structure, support, and teach. The design rationale capabilities presented in this chapter were analysed using a SWOT analysis framework. The SWOT analysis indicated that design rationale is strong on communication, documentation, and representation of design decisions. One of the weaknesses identified from the analysis highlighted that there are other potential users of design rationale that are currently not mentioned in the literature which could benefit from using design rationale. This presents an opportunity for the design rationale research community to assess the types of users who could potentially use design rationale and the benefits that it could provide. By not demonstrating the capabilities of design rationale to other potential users, design rationale will remain only useful to designers and not to others who may also benefit from its utilisation.

2.5 Research Gaps

The literature review has identified that there is currently a lack of published literature describing the use of design rationale with the medical device application domain. Sections 2.2.2 and 2.2.3, and in particular, Table 2-5 and Table 2-6, signify that design rationale representation frameworks and computational support tools have not been used to capture the design decisions of medical devices. It is intended that this significant gap in existing knowledge will provide the design rationale research and medical device communities with new incentives and insight into the possible integration of design rationale methods and tools with the regulatory approval of medical devices.

The review of literature has also recognised that currently there are no existing guidelines or recommendations for manufacturers of medical devices and regulatory approval authorities in order to utilise design rationale methods and support tools. Furthermore, there is an evident gap in knowledge surrounding how design rationale

could be utilised with the regulatory approval of medical devices. This gap has been derived from reviewing the published literature in this chapter and identifying that design rationale methods and tools have not been applied to the medical device domain, specifically with the regulatory approval of medical devices. The review of literature has indicated, among others, four significant gaps in existing knowledge that this research investigation is dedicated to addressing:

1. The utilisation of design rationale methods and tools with medical devices,
2. The feasibility of design rationale for use with the regulatory approval of medical devices,
3. How design rationale could be utilised with the development of medical devices for regulatory approval and the benefits it could provide, and
4. The steps required for medical device manufacturers and regulatory authorities to capture and represent the design decisions of medical devices.

2.6 Chapter Summary

This chapter has presented a review of literature in the domain of design rationale and particularly reviewed the capabilities which design rationale has to currently offer. The capabilities presented in this chapter were derived from the literature and compiled based on the similarity of the extracted verbs from the actions which describe what design rationale can do. This has provided the researcher with a basis for understanding the different actions that design rationale can perform and the prospect of utilising the capabilities during the succeeding stages of this research investigation.

The design rationale capabilities presented in this chapter were analysed using a SWOT analysis framework. The SWOT analysis indicated that design rationale methods and tools are strong on communication, documentation, and representation of rationale.
Additionally and significantly, several gaps in existing knowledge have been identified, the three research questions guiding this literature review have been answered, and the first objective of the research has been addressed. The following chapter details the research design through by which the primary research question shall be addressed.

CHAPTER 3

RESEARCH DESIGN

3 Research Design

This chapter identifies pertinent research approaches and provides the rationale underlying the selected research design and data collection techniques.

Based on the research questions and gaps in existing knowledge that were informed by the literature review in Chapter 2, this chapter presents the methodological approach utilised throughout this research to address the gaps and fulfil the objectives and aim of the research.

This chapter identifies the pertinent research approaches and provides the rationale behind the selected research design and data collection techniques. Available research approaches are discussed and the selected methodology is presented. The applicable research methods employed by the researcher have been outlined together with the rationale underlying the selected research design.

This chapter is structured as follows. Firstly, the designing of a research methodology is introduced. Secondly, the available research approaches and methods are presented and their applicability to the research investigation is assessed. Thirdly, the selection of the relevant methods and approaches are presented. This is followed by a description of the development of the research methodology which includes its initial development and detailed development stages. Following this, the strengths and weaknesses of the research design are discussed. Finally, this chapter summarises the research design and the methodology applied to the research investigation.

3.1 Research Methodology Design

During the initial phase of the research, the researcher considered it to be important to develop a structured and logical approach to conduct the research. In turn, this will provide further validation of the research. Furthermore, documenting the development of the research methodology and justifying the rationale underlying its development enhances its repeatability and reproducibility.

Robson (2002) has identified the following components that constitute a framework for research design: purpose (what is the study trying to achieve); theory (what theory will guide and inform the study); research questions (what questions is the research geared to providing answers); methods (what specific techniques will be used to collect data); and sampling strategy (where will the data be collected from). The relationship between these aspects is illustrated in Figure 3-1.

The framework (Figure 3-1) shows that there is some directionality regarding the whole process. The purposes and theory lead into, and help specify the research questions. Once details appear concerning the research questions, decisions regarding the methods that need to be used and sampling strategy can be made.

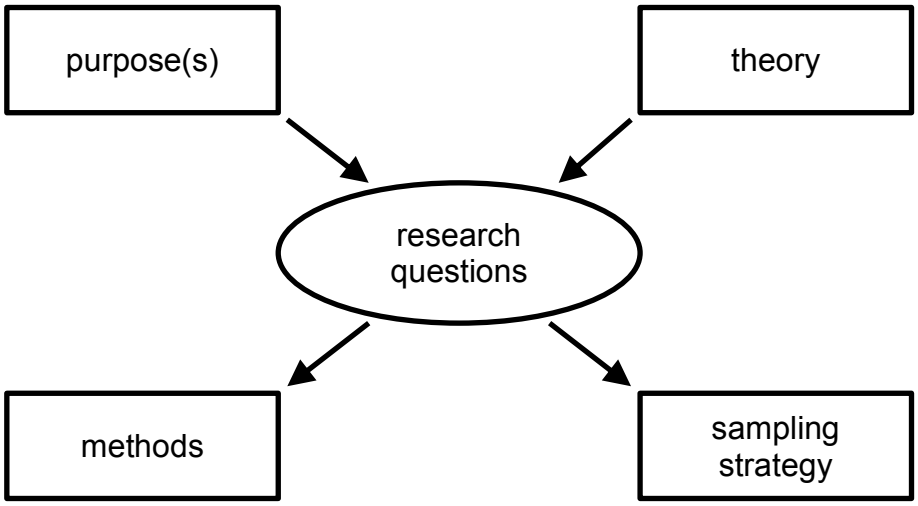

Figure 3-1: Framework for research design (Robson, 2002)

It has been suggested by Robson (2002) that when conducting research, there is a propensity for researchers to assume that there is no other option to their preferred approach.

Even though the applied research methods are determined by the research questions to some degree, there are still many ways to developing the research methodology. Robson (2002) has recognised that the methods or techniques employed must be appropriate for the research questions that require answering.

3.2 Research Approaches

There are two general approaches to research which are described as being either quantitative or qualitative (Robson, 2002).

It is understood that quantitative research assumes that everything in the social world can be described or numerically measured (McQueen and Knussen, 2002). One of the main advantages of quantitative research is that data can be collected and analysed in a rational manner that can be repeated. Quantitative research and quantitative data is more commonly gathered in laboratory experiments and surveys, represented in tables, graphs, charts, as in many of the social and all of the natural sciences (Booth *et al*., 2008). Robson (2002) likens this approach to a 'fixed' research design strategy whereby data are almost always in the form of numbers.

Qualitative research is more commonly associated with behavioural and social studies in which precise outcomes from the studies cannot be anticipated, therefore ways in which to measure data are undetermined. This research approach originates from the area of anthropology and is an investigative approach which utilises methods and tools such as; observations, surveys, structured interviews, semi-structured interviews, unstructured interviews, and analysis of documents and materials (Creswell, 2003).

Robson (2002) likens qualitative research to a 'flexible' research design strategy whereby the research design evolves during the data collection phases. This strategy shows substantial flexibility in anticipation that the design will emerge and develop during the collection of data. This is in contrast to the quantitative research approach which calls for a tight pre-specification of the design prior to data collection. Data collected using the flexible approach is described to be typically non-numerical (usually in the form of words); hence this type of approach is often referred to as a qualitative strategy. A comparison of the methods used in both the qualitative and quantitative research approaches is provided in Table 3-1 (Burns, 2000).

Table 3-1: Comparison of qualitative and quantitative research approaches (Burns, 2000)

	Qualitative	Quantitative
Assumptions	- Reality socially constructed. - Variables complex and interwoven; difficult to measure. - Events viewed from informant's perspective. - Dynamic quality to life.	- Facts and data have an objective reality. - Variables can be measured and identified. - Events viewed from outsider's perspective. - Static reality to life.
Purpose	- Interpretation. - Contextualisation. - Understanding the perspectives of others.	- Prediction. - Generalisation. - Casual explanation.
Method	- Data collection using observation and interviews. - Concludes with hypothesis and grounded theory. - Emergence and portrayal. - Inductive and naturalistic. - Data analysis by themes from informant's descriptions. - Descriptive write-up.	- Testing and measuring. - Commences with hypothesis and theory. - Manipulation and control. - Deductive and experimental. - Statistical analysis. - Statistical reporting. - Abstract impersonal write-up.
Researchers role	- Researcher as instrument. - Personal involvement. - Empathic understanding.	- Researcher applies formal instruments. - Detachment. - Objective.

Robson (2002) has described that in the flexible design research approach, rigorous data collection procedures are used, and multiple data collection techniques are typically employed. The data is then adequately summarised usually in tabular form and details of how the data are collected is provided. This approach includes detailed methods, a rigorous approach to data collection, data analysis, and report writing. Data can be collected from multiple sources such as documents, archival records, interviews, observations, and physical artefacts.

3.3 Research Methods

The following three influential design traditions within qualitative research have been identified by Robson (2002): grounded theory, ethnography, and case study. It has been recommended by Robson (2002) that the researcher should keep within one research tradition, however as the research investigation evolves, features from other research traditions may also be useful and incorporated into the research design. Additionally, the flexible research design strategy incorporates the use of multiple techniques to collect and analyse data.

A comparison of the key features of the grounded theory, ethnography, and case study methods is provided in Table 3-2. Descriptions of these methods are provided in the following subsections.

Table 3-2: Comparing research traditions in qualitative research (Robson, 2002)

	Grounded theory	**Ethnography**	**Case study**
Focus	Developing a theory grounded in data from the field	Describing and interpreting a cultural and social group	Developing an in-depth analysis of a single case or multiple cases
Discipline origin	Sociology	Cultural anthropology, sociology	Political science, sociology, evaluation, urban studies, many other social sciences
Data collection	Typically interviews with 20-30 individuals to 'saturate' categories and detail a theory	Primarily observation and interviews during extended time in the field	Multiple sources – documents, archival records, interviews, observations, physical artefacts
Data analysis	Open, coding, axial coding, selective coding, conditional matrix	Description, analysis, interpretation	Description, themes, assertions
Narrative form	Theory or theoretical model	Description of the cultural behaviour of the group	In-depth study of a 'case' or 'cases'

3.3.1 Grounded Theory

The central aim of the grounded theory study is to generate theory from data collected during the study (Robson, 2002). According to Robson (2002), grounded theory is particularly useful in new, applied areas where there is a lack of theory and concepts to describe and explain what is going on. Data collection, analysis and theory development and testing are interspersed throughout the study. The typical features of grounded theory are as follows (Robson, 2002):

1. applicable to a wide variety of phenomena;
2. commonly interview-based; and
3. a systematic but flexible research strategy which provides detailed prescriptions for data analysis and theory generation.

It has been suggested by Strauss and Corbin (1998) that by adopting the grounded theory approach, it is likely to offer insight, enhance understanding, and provide a meaningful guide to action. However, during the commencement of the research investigation, the researcher had not generated a theory or hypotheses. The areas of design rationale research and medical device regulatory approval are well established and there is available and accessible data. Therefore, the grounded theory method will not provide any substantial guidance during the course of the research investigation.

3.3.2 Ethnography

It has been described by Robson (2002) that the ethnographic study seeks to capture, interpret and explain how a group, organisation, or community live, experience and make sense of their lives and their world. Typically, it tries to answer questions about specific groups of people, or about specific aspects of the life of a particular group. Robson (2002) has listed the following typical features of ethnography to include:

1. selection of a group, organisation or community of interest or concern;
2. immersion of the researcher in that setting; and
3. use of participant observation.

The ethnography method is not applicable to the research investigation. The focus of the current study is on capturing and representing the design decisions of medical devices so that it can be used for regulatory approval. The research does not seek to capture, interpret, and explain how a group, organisation, or community live and experience their surroundings.

3.3.3 Case Study

It has been described by Huberman and Miles (2002) that the case study method is focussed on understanding the dynamics that are present in a single setting by utilising a combination of data collection methods. A case study is also strategy for doing research which involves an empirical investigation of a particular contemporary phenomenon within its real life context using multiple sources of evidence (Robson, 2002). The following typical features of the case study method have been outlined by Robson (2002):

1. selection of a single case (or a small number of related cases) of a situation, individual or group of interest or concern;
2. study of the case in its context; and
3. collection of information via a range of data collection techniques including observation, interview, and documentary analysis.

Robson (2002) has explained that case studies can follow an ethnographic or grounded theory approach, but are not required to. According to Huberman and Miles (2002), the case study method provides a more realistic and focussed view as compared to ethnography and the grounded theory approach. Gill and Johnson (1997) have also argued that the case study is relevant if there is a need to combine research with practice in the real world.

Case studies can be performed on a group, on an institution, on a neighbourhood, on an innovation, on a decision, on a service, on a programme and on many other things (Robson, 2002). A list of the different types of case studies is presented in Table 3-3.

Table 3-3: List of the types of case studies (Robson, 2002)

Case study type	Description
Individual case study	Detailed account of one person. Tends to focus on antecedents, contextual factors, perceptions and attitudes preceding a known outcome (e.g. drug use; immigrant status). Used to explore possible causes, determinants, factors, processes, experiences, etc., contributing to the outcome.
Set of individual case studies	As above, but a small number of individuals with some features in common are studied.
Community study	Study of one or more local communities. Describes an analyses the pattern of, and relations between, main aspects of community life (politics; work; leisure; family life; etc.). Commonly descriptive, but may explore specific issues or be used in theory testing.
Social group study	Covers studies of both small direct contact groups (e.g. families) and larger, more diffuse ones (e.g. occupational groups). Describes and analyses relationships and activities.
Studies of organisations and institutions	Studies of firms, workplaces, schools, trade unions, etc. Many possible foci, e.g. best practice; policy implementation and evaluation; industrial relations; management and organisational issues; organisational cultures; processes of change and adaptation; etc.
Studies of events, roles and relationships	Focus on a specific event. Very varied; includes studies of police-citizen encounters; doctor-patient interactions; specific crimes or 'incidents' (e.g. disasters); studies of roles conflicts; stereotypes, adaptations.

The case study method is considered by the researcher to be the most appropriate method for utilisation with the current study. The rationale underlying this selection is presented in the following section.

3.4 Research Strategy Selection

Consequential to comparing both the quantitative and qualitative research approaches, a qualitative research approach has been selected by the researcher and is to be adopted within the current research investigation. This selection is largely based on the empirical datasets required for the research investigation. It is anticipated that data will be emergent therefore a qualitative (flexible) research approach will offer the 'flexibility' needed to make any necessary modifications within the research design itself as and when required.

Based on the comparison of the research traditions that are available in qualitative research, utilisation of the case study method was found to be the most applicable research strategy for the research investigation. The case study method is used to answer the primary research question and fulfil the aim and objectives of the research. This selection is mainly based on the exploratory nature of the research, the empirical datasets required for the research such as information regarding the regulatory approval processes for medical devices, the research setting, and research focus. Robson (2002) likens the use of case studies to exploratory work.

The research will be conducted by utilising multiple analytical studies with the purpose of utilising them to develop the guidelines (Chapter 7). It is anticipated that the analytical case studies will provide insight into the development and implementation of the guidelines. The research investigation presented in this thesis is reporting on an in-depth analysis of multiple cases. These cases consist of collecting data from a variety of sources and analysing documentation in order to address the objectives of the research.

Based on the researcher's selection of the flexible research design strategy and the case study method, the methodology developed and followed for the research investigation is presented in the following section of this thesis.

3.5 Research Methodology Development

After considering the different research design approaches and methods and selecting the flexible research design strategy, this section presents the methodology that has been developed for the current study. The sequence of steps used in the initial development and detailed development stages of the methodology are illustrated and descriptions of each of the stages are provided.

3.5.1 Methodology Representation

The sequence of steps used to develop the initial and detailed stages of the methodology is represented using a set of descriptive process models. These models illustrate the initial and detailed stages as a set of linear and sequential activities.

The IDEFØ process modelling tool was chosen to illustrate the research methodology, as it possesses a clear definition and graphical representation, and has been successfully used as both and analysis tool and as a communication tool in a number of application areas (Sagoo *et al.*, 2009; Mayer *et al.*, 1992). The software used to create the models illustrating both the initial and detailed stages of the methodology was the 'BPwin Business Process Design Tool version 4.0'.

The IDEFØ modelling technique consists of five constituents to model the process; activity name, input, control, and mechanism. Details regarding the graphical syntax of these constituents can be found in Chapter 5 of this thesis, Sagoo *et al.* (2009) and Mayer *et al.* (1992). Creating a descriptive process model using the IDEFØ process modelling tool, as a rule, commences with the definition of the top level or context activity. This is followed by identification of the proceeding functions or activities (decomposition) which are grouped depending on their relationship or similarity. It is this process which constructs the hierarchy of the model.

3.5.2 Methodology Development: Initial Stage

The initial development stage of the research methodology is targeted at chapters 1, 2 and 3. These three chapters provide a vital foundation for the research investigation. Figure 3-2 illustrates the context activity for the steps used for modelling the initial stages of methodology developed for the research investigation. The input into the context activity is the research context. This is converted into the output – selected research design strategy. To convert the input into the required output, physical resources such as data collection and data analysis are required. Controlling the initial methodology is the availability of published literature.

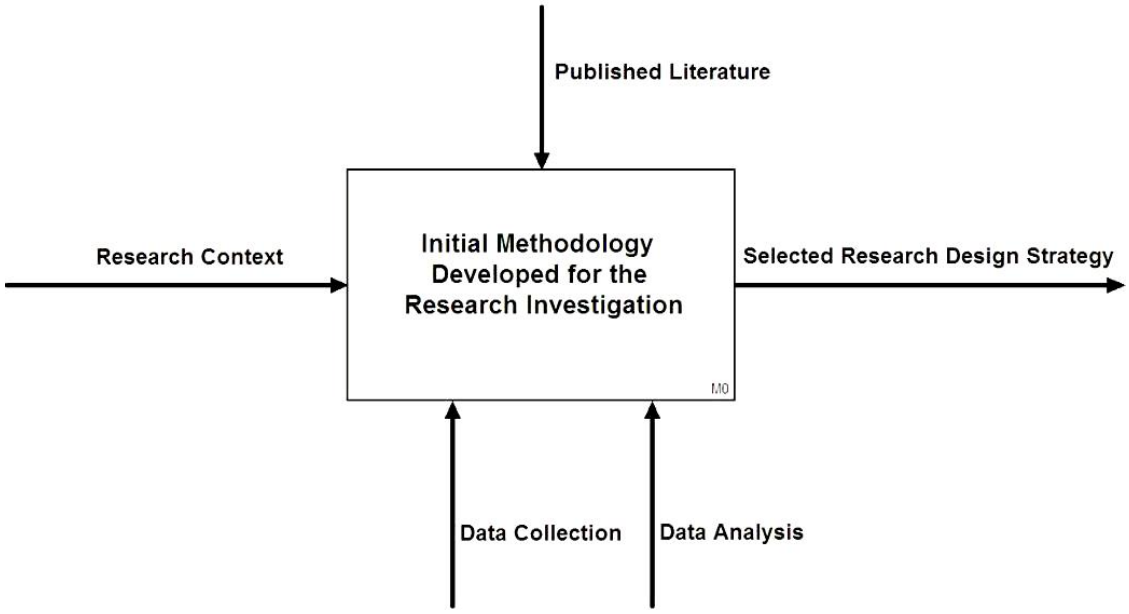

Figure 3-2: Initial development of the research methodology – context activity

The decomposition of the methodology (Figure 3-3) details the lower level activities that were undertaken in developing the initial methodology for the research investigation. Each of the individual activities from M1 to M5 has separate outputs signifying the results from each of the activities performed. These are direct inputs into the subsequent activities. Activity M6 converts this sequence of outputs into the final specified output, the selected research design strategy.

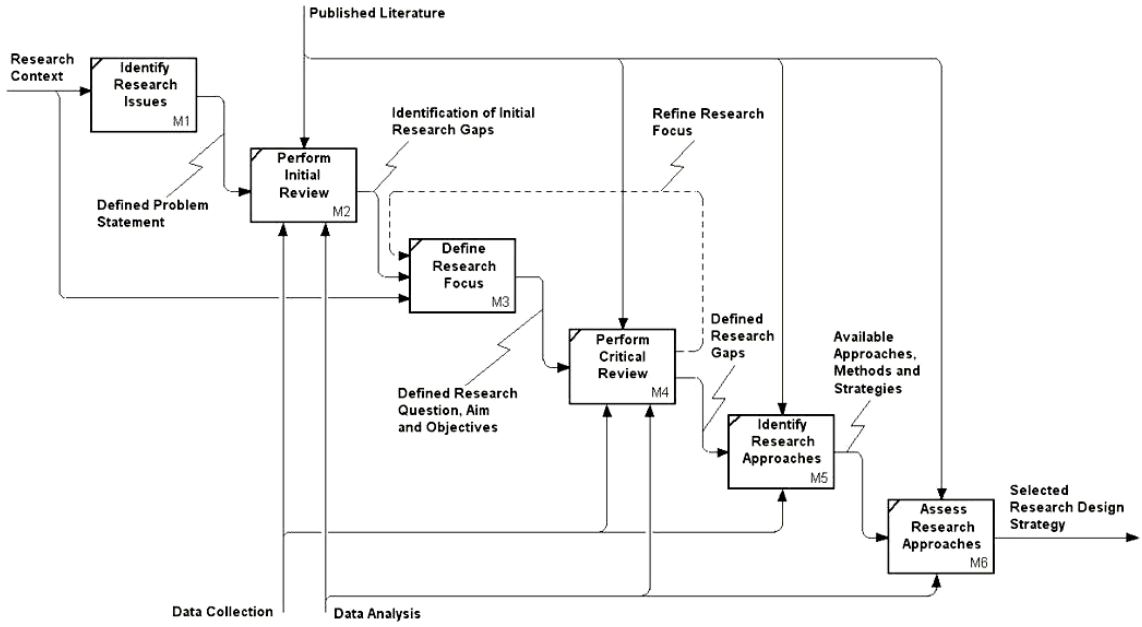

Figure 3-3: Initial development of the research methodology – decomposed activities

As illustrated in Figure 3-3, there are six activities (M1 to M6) that comprise the initial research methodology. These are: Identify Research Issues (M1); Perform Initial Review (M2); Define Research Focus (M3); Perform Critical Review (M4); Identify Research Approaches (M5); and Assess Research Approaches (M6).

Initial development of the research methodology firstly commences with identifying the research issues to be investigated by the research investigation (activity – M1). Input into the first activity (M1) is the research context. The output from this activity is the definition of the problem statement. This is a direct input into the following activity 'Perform Initial Review' (M2).

At activity M2, an initial review of literature is performed. Controlling this activity is the availability of published literature. Literature is searched, collected, and analysed and an initial set of research gaps are identified. As an output from activity M2, the initial research gaps identified from this initial literature review are a direct input into defining the focus of the research (M3).

At activity M3, the focus of the research investigation is defined based on the research context (primary input) and identification of the initial research gaps (output from M2).

The main outputs from this activity (M3) are the definition of the primary research question, research aim and research objectives. These are a direct input into the following activity (M4).

A critical review of literature on the state-of-the-art design rationale research is performed at the activity M4. Controlling this activity is the availability of published literature on design rationale research. Published literature is searched, collected, and analysed, and a set of comprehensive research gaps are defined. There are two outputs from this activity that are direct inputs into the following activity (M5) and the preceding activity (M3). As illustrated in Figure 3-3, the output returning to activity M3 (labelled refine research focus and shown as a dashed line) acts as an iterative loop to refine the research objectives.

Based on the defined research gaps from activity M4, at activity M5 the research design approaches are identified. The availability of published literature on research design approaches control this activity (M5). Data regarding the available research design approaches are collected from the available literature. This data details the available research approaches, methods and strategies, and is an output from this activity. This output is as a direct input into the final activity (M6).

At the final activity (M6), the available research approaches, methods, and strategies are assessed for application with the current research investigation. The advantages and applicability of the different approaches are identified from the published literature which controls this activity. The output from this activity is the selection of the research design strategy.

3.5.3 Methodology Development: Detailed Stage

The detailed development stage of the research methodology is targeted at chapters 4, 5, 6, 7, 8, and 9.

Figure 3-4 illustrates the context activity for the steps used for modelling the detailed methodology developed for the research investigation. The input into the context activity is the selected research design. This is converted into the output – verified research investigation. To convert the input into the required output, physical resources such as; data capture, data analysis, process modelling tool, and design rationale methods and tools are required. Controlling the detailed methodology is; the U.S. and EU medical device regulatory approval authorities, the availability of the medical device experts and researchers required for ensuring that validation can be undertaken, design rationale capabilities to identify the ability of design rationale to perform specific actions, and the availability of published literature to capture the necessary data required at the different stages of the research.

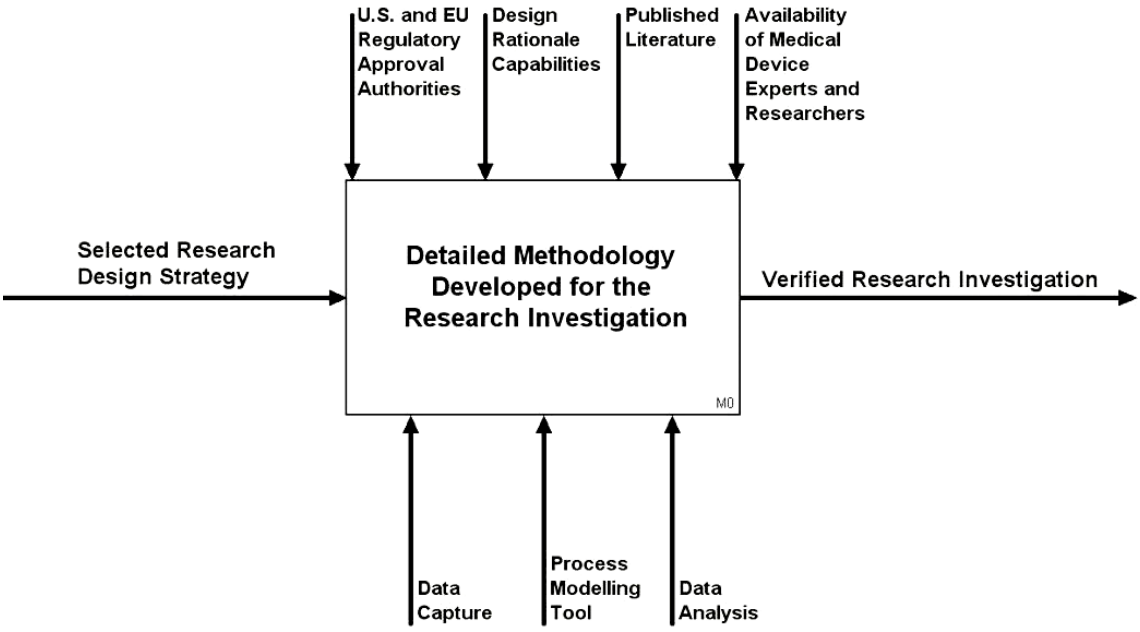

Figure 3-4: Detailed development and implementation of the research methodology – context activity

Decomposition of the methodology (Figure 3-5) details the lower level activities that are undertaken in developing the detailed methodology for the research investigation. Each of the individual activities from M1 to M5 represented in Figure 3-5 has separate outputs indicating the results from each of the activities performed. These are direct inputs into the following activities. Activity M6 converts this sequence of outputs into the final specified output, the verified research investigation.

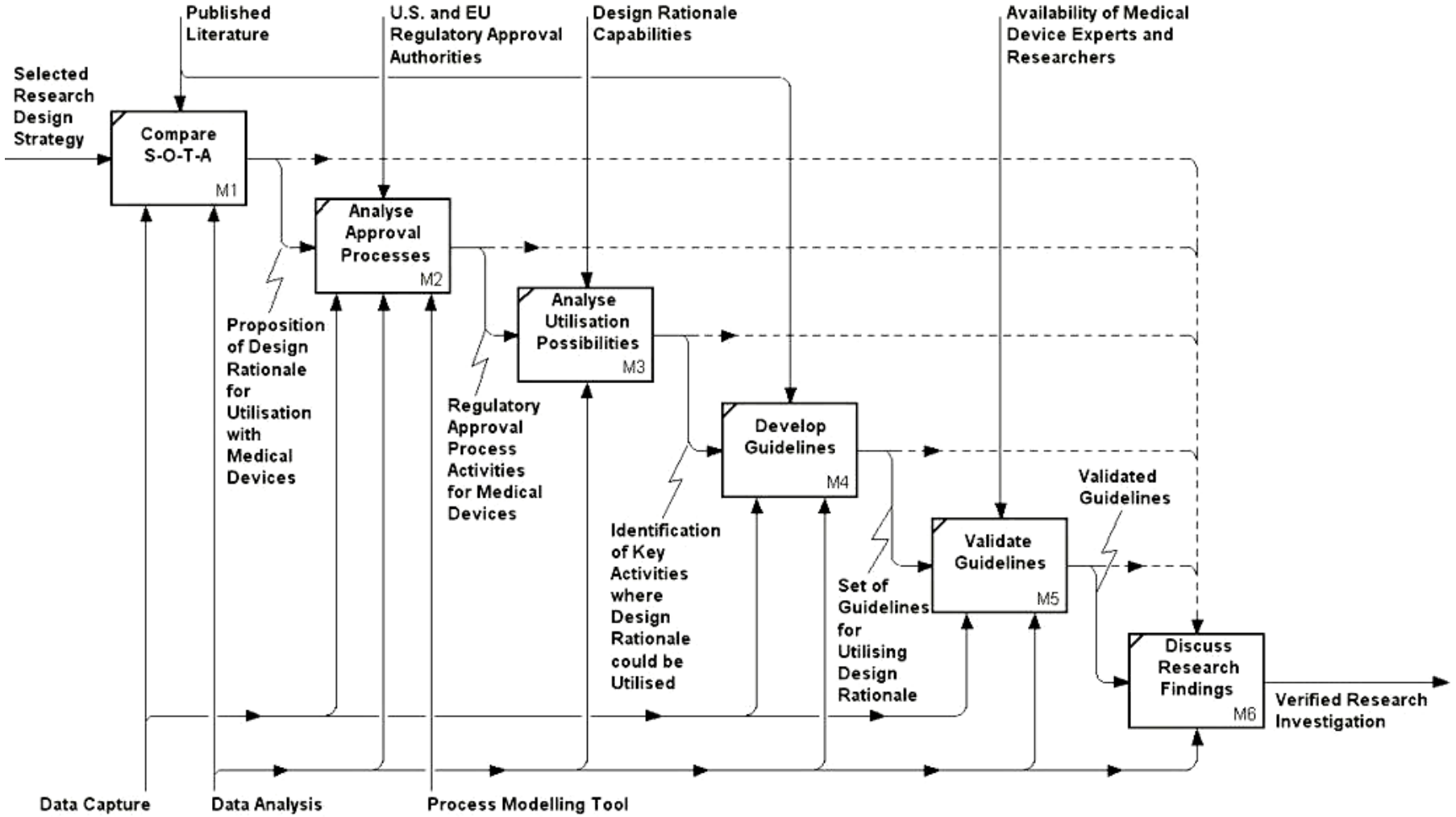

Figure 3-5: Detailed development and implementation of the research methodology – decomposed activities

The detailed development stage of the methodology (Figure 3-5) commences with a comparison of the state-of-the-art in design rationale research with the state-of-the-art in medical device design (M1). The activities following this are: Analyse Approval Processes for Medical Devices (M2); Analyse Utilisation Possibilities (M3); Develop Guidelines (M4); Validate Guidelines (M5); and Discuss Research Findings (M6).

The initial step of developing and implementing the detailed methodology for the research investigation (activity – M1) begins by comparing the state-of-the-art in design rationale research with the current state-of-the-art in medical device design. The initial input into activity M1, and the detailed methodology, itself is the selected research design strategy. At this activity (M1), data regarding the state-of-the-art in design rationale methods and existing best practices in the medical device domain are captured from the available published literature. The comparative analysis performed at this activity identifies the differences between the current best practices in medical device design and design rationale, establishes the vital benefits that design rationale could offer to the medical device community, and as an output from this activity, proposes the utilisation of design rationale with the regulatory approval of medical devices in addition to the existing best practices. This output is a direct input into the following activity (M2) and also acts as a control on the final activity (M6).

The second step of methodology (activity – M2) involved analysing the existing U.S. and EU regulatory approval processes for medical devices. Data regarding the current regulatory approval practices for placing medical devices in the U.S. and EU markets is captured from the websites and documentation provided by the U.S. and EU regulatory authorities for medical devices. Availability of the regulatory approval data for medical devices provided by the U.S. and EU regulatory authorities acts as a primary control on activity M2. The comparative analysis performed at this activity (M2) is dependent on the current regulatory approval information made available by the U.S. and EU regulatory authorities. To perform the analysis, a process modelling tool is used to transform the data obtained from the regulatory authorities into a set of descriptive models which represent the current regulatory approval processes for placing medical devices into the U.S. and EU markets. These models are then analysed and compared

with each other to identify the differences and similarities between the regulatory approval processes for medical devices in the U.S. and EU. The output from activity M2 is the classification of the U.S. and EU medical device regulatory approval process activities. This output is an input into the following activity (M3) and also controls the successful outcome of activity M6 (Discuss Research Findings).

At activity M3, an analysis of the possibilities of utilising design rationale with the U.S. and EU medical device regulatory approval process activities is performed. The output from activity M2 is a direct input into activity M3. At this activity (M3), the U.S. and EU medical device regulatory approval process activities (output from activity – M2) are mapped with the design rationale capabilities that were identified from the critical literature review in Chapter 2. These capabilities specify the ability of design rationale to perform designated actions, thereby controlling the different possibilities of how design rationale could be used with the individual activities that constitute both the U.S. and EU medical device regulatory approval processes. The mapping of the design rationale capabilities with the U.S. and EU regulatory approval process activities identifies the regulatory approval activities where design rationale could be utilised. These activities are then analysed to identify how the capabilities of design rationale could be utilised and what benefits design rationale could provide. The analysis performed at activity M3 identifies a set of possibilities for utilising design rationale with the key activities of the U.S. and EU regulatory approval processes that were identified from the analysis as an output from this activity.

Activity M4 develops the guidelines for utilising design rationale with the regulatory approval process activities for medical devices. The output from activity M3 is a direct input into this activity (M4) and provides the necessary basis for developing the guidelines. Data concerning the application of design rationale is captured and analysed from activity M3. The availability of published literature in the areas of; design rationale, medical device development, and regulatory approval control this particular activity (M4). The output from activity M4 is the guidelines for utilising design rationale with the regulatory approval of medical devices.

Once the guidelines have been developed (M4), medical device experts, and researchers are required for validating their utility and applicability at activity M5. The number of experts and researchers and the range of their expertise with respect to medical device development and regulatory approval control this activity (M5). Data concerning the validation is captured from the participating experts and researchers and analysed identifying the results from the validation activity. The output from activity M5 is the validated guidelines. This is a direct input into the final activity – discuss research findings (M6).

The final activity in the detailed methodology is to discuss the findings from the research investigation (M6). The input into activity M6 derives from activity M5 (validated guidelines), however the outputs from the previous activities (M1 to M4 and including M5) all control this final activity (M6). At this activity (M6), the findings from the different stages of the research (outputs from activities M1 to M5) are analysed in order to address the fulfilment of the research question, aim, and objectives. Once the findings from the different stages of the research are analysed and discussed, the final output from the detailed methodology developed for the research investigation (M6) is – a verified research investigation.

Detailed methods that have been developed and followed for the different stages of the research as illustrated in Figure 3-5 (activities M1 to M6) are presented in the following chapters of this thesis: M1 (Compare State-of-the-Art) – Chapter 4 (Comparing the State-of-the-Art in Design Rationale with Medical Device Design); M2 (Analyse Approval Processes) – Chapter 5 (Regulatory Approval of Medical Devices); M3 (Analyse Utilisation Possibilities) – Chapter 6 (Utilising Design Rationale with the Regulatory Approval of Medical Devices); M4 (Develop Guidelines) – Chapter 7 (Guidelines for Utilising Design Rationale with the Regulatory Approval of Medical Devices); M5 (Validate Guidelines) – Chapter 8 (Validation); and M6 (Discuss Research Findings) – Chapter 9 (Discussion and Conclusions). The reasoning behind this is so the individual methods and results can be repeated and reproduced, thereby validating the research findings.

3.6 Strengths and Weaknesses of the Research Design

The methodology developed and implemented for this research possesses both strengths and weaknesses in its design. These strengths and weaknesses are inherently linked to the available research approaches and methods selected which form the basis of the methodology developed for the current study. Strengths and weaknesses of the research design are discussed as follows.

3.6.1 Strengths

One of the major strengths of the selected and adopted research design approach is the specificity of the research investigation which addresses significant research gaps in two domains namely design rationale and medical device regulatory approval. The flexibility of the chosen research design allows the methodology to be developed and refined during the course of the research investigation. The development and refinement process also takes into account the results obtained from the different stages of the research, therefore assisting in the detailed methodology's development. Flexibility of the research design has provided the opportunity to develop the detailed methodology as the data emerges throughout the course of the research investigation. This ensures that, as the data emerges, it can be captured, analysed and methodically synthesised so that it can be used as an input into developing detailed methods for the following research activities.

The detailed methodology which incorporates the case studies, presented in the following chapters of this thesis, contains detailed methods that can be repeated, and as a consequence, the results can be reproduced accordingly. The adoption and use of the flexible research design approach has led to the emergence of data which consequently has reduced the amount of time that would have been spent in attempting to identify and capture the diverse datasets. As a result, this emergent data has alleviated time spent on data collection itself therefore presenting the researcher with the opportunity to capitalize on the time gained to analyse and synthesise data.

The research methodology implemented for this research investigation has been developed based on existing recognised approaches to research design. Due to the flexibility of the adopted research design approach and its limitations, data collection and analysis techniques from other research traditions may need to be incorporated into the methodology to provide a comprehensive understanding of the emergent data.

3.6.2 Weaknesses

The detailed methodology that has been specifically developed for the research investigation is based on the case study method and, as a result, has inherited some of its limitations. As with many qualitative research techniques, the case study method has been subject to criticism regarding its subjectivity, verification, and validity. However, the case study method can be more rigorous if all of the evidence is gathered and reported in an unbiased manner. In order to eliminate bias, the researcher has comprehensively documented the methods for data collection and analysis in an unbiased manner whereby these methods can be repeated thus ensuring the validity of the findings from the research.

Due to the specificity and novelty of the methodology developed for the research investigation, external validation of the detailed methodology has not been performed prior to its implementation. The detailed methodology has been specifically developed by the researcher based on data which has emerged throughout the course of the research therefore validation of the detailed methodology prior to its implementation proved difficult to perform.

A lack of collaboration with medical device manufacturers and regulatory authorities in identifying the requirements for the existing regulatory approval processes for medical devices in the U.S. and EU led to an increase in the amount of time spent searching and analysing the literature and documentation on the WWW.

3.7 Research Design Summary

Following the definition of the primary research question, aim, objectives, and research gaps presented in Chapters 1 and 2, this chapter has identified the approaches that are to be followed in order to accomplish these goals. The decision to adopt and implement a flexible approach to the research design through the use of the case study method has been justifiably discussed.

As illustrated at the detailed stage of the research methodology (decomposed activities) in Figure 3-5, the methodology will follow a sequential process in order to validate the research findings. This will be accomplished through:

- analysis of current literature to address and validate the research findings;
- continuous involvement with the case studies via documentary analysis and literature analysis; and
- workshops with medical device experts and researchers to validate the research findings.

Subsequent to the selection and definition of the research design presented in this chapter, the following chapters provide details of the research design's implementation.

CHAPTER 4

COMPARING THE STATE-OF-THE-ART IN DESIGN RATIONALE WITH MEDICAL DEVICE DESIGN

4 Comparing the State-of-the-Art in Design Rationale with Medical Device Design

This chapter presents a comparative analysis of the state-of-the-art in design rationale with the state-of-the-art in medical device design.

Literature concerning the state-of-the-art in design rationale research and medical device design were identified and reviewed in Chapter 2. The findings from the literature review are used to form the basis of the comparison presented in this chapter. This chapter compares the current capabilities of design rationale with the existing best practices in medical device design. This comparison establishes whether or not design rationale could be considered for utilisation with the medical device domain. This chapter addresses the second objective of the research. This chapter is structured as follows. Firstly, the methodology followed in order to perform the comparison is presented and described. Following this, the results obtained from the comparison are presented and analysed. Finally, this chapter concludes by summarising the findings from the analysis.

4.1 Comparison Methodology

The methodology followed for comparing the state-of-the-art in design rationale with the state-of-the-art in medical device design is presented in two stages as follows. Firstly, the ability of design rationale and assurance case practices to perform specific actions is identified and classified respectively. Secondly, an explanation of how the comparison was conducted is provided.

4.1.1 Classifying the Capabilities of Design Rationale and Assurance Case Practices

The design rationale capabilities (thirteen unique capabilities) that were identified from the literature reviewed in Chapter 2 (see section 2.2.4) are used in this chapter as a basis

for comparison. The capabilities for assurance case practices have been identified and captured from the seminal document published by Weinstock and Goodenough (2009). This is described as follows.

The process of identifying the capabilities offered by the assurance case practice involved reading the entire document and analysing it with the goal of being able to classify the capabilities (the ability to perform specific actions). Descriptions of the actions that assurance case practices are able to perform were taken directly from the document (Weinstock and Goodenough, 2009).

The actions were noted and compared with each other to distinguish them from one another in order to ensure that one action was not a synonym of another which was identified from the document. The outcome (end result of the action) was noted in the form of what can be accomplished by assurance case practices. The verb describing the action performed by the assurance case practice was extracted from the statement of the action. The verb was then used as the basis to derive the name of the capability. This information was then used to develop a list of capabilities for the assurance case practice.

4.1.2 Comparing the Design Rationale and Assurance Case Practices Capabilities

In order to conduct the comparison, the ability to perform specific actions of design rationale (design rationale capabilities identified and categorised in Chapter 2) is compared with the actions that assurance case practices have the ability to perform (assurance case practice capabilities presented in section 4.2.1). These capabilities of design rationale are compared with the identified capabilities of the assurance case practice. A matrix is used to list and compare the capabilities of both design rationale and assurance case practices as shown in Table 4-1.

Capabilities for design rationale are listed at the top of the table using the capability identification label (A to M to denote the thirteen capabilities) that was defined in

Chapter 2. At the left side of the table (Table 4-1), the capabilities for assurance case practices are listed according to the name of the capability. The star symbol (*) in the table (Table 4-1) indicates that the capabilities are represented by both design rationale and assurance case practices.

Table 4-1: Matrix for comparing the design rationale and assurance case capabilities

		Design rationale capability identification label (A to M)			
		A	**B**	**C**	**D**
Assurance case capability	**A**	*			
	B		*		
	C			*	
	D				*

The analysis of the results involves identifying the similar, same, or different capabilities that assurance case practices have to offer as compared to the capabilities of design rationale that have been previously identified (Chapter 2). The results from the comparison are presented and analysed in the following section of this chapter.

4.2 Results

Results obtained from the comparison of the design rationale capabilities and the capabilities for assurance case practices are presented as follows. First of all, the capabilities that have been identified for assurance case practices are presented. Second of all, these capabilities are compared with the design rationale capabilities.

4.2.1 Assurance Case Practice Capabilities

Capabilities for assurance case practices (the ability of assurance cases to perform specific actions) have been identified from Weinstock and Goodenough (2009) and are

listed in Table 4-2. Listed in the table (Table 4-2) are the actions that assurance case practices have the ability to perform, the extracted verb that has been used to define the action, the outcome of what that actions leads to, the name of the capability based on the verb, and an alphabetic capability identifier for each unique capability.

Table 4-2: List of identified assurance case practice capabilities

Actions	Verbs	Outcomes	Capability names	Capability identifier
To represent safety requirements.	Represent	Safety requirements are represented.	Represent	A
To document the device being manufactured.	Document	Device being manufactured is documented.	Document	B
To structure generic safety arguments.	Structure	Generic safety arguments are structured.	Structure	C

As shown in Table 4-2, there are currently three capabilities that assurance case practices have to offer which have been identified from the seminal document published by Weinstock and Goodenough (2009). These capabilities have been identified as: represent, document, and structure. The capabilities for assurance case practices identified and listed in Table 4-2 are used in the following subsection for the comparison.

4.2.2 Comparison of the Design Rationale Capabilities and Assurance Case Practice Capabilities

The capabilities that have been identified for assurance case practices in the previous subsection (represent, document, and structure) are compared with the thirteen capabilities of design rationale that were identified in Chapter 2. The thirteen capabilities of design rationale are presented in Table 4-3. The capabilities of design rationale are compared with the capabilities of assurance case practices in Table 4-4.

Table 4-3: List of design rationale capabilities

Capability names	Design rationale capability identifier
Answer	A
Capture	B
Communicate	C
Design	D
Determine	E
Document	F
Explain	G
Justify	H
Provide	I
Represent	J
Structure	K
Support	L
Teach	M

Table 4-4: Comparing the design rationale and assurance case practice capabilities

		Design rationale capabilities												
		A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**	**K**	**L**	**M**
Assurance case capabilities	**A**										*			
	B						*							
	C											*		

The comparison of the capabilities of design rationale and assurance case practice capabilities presented in Table 4-4 shows that the assurance case practice has three capabilities that are identical with three of the design rationale capabilities. These identical capabilities are; represent, document, and structure. However, the assurance case practice does not have any other capabilities that are unique. In comparison, design rationale has ten other capabilities that are unique in which they describe the ability of design rationale to be able to perform ten more specific actions than compared to assurance case practices. These ten capabilities consist of: Answer, Capture, Communicate, Design, Determine, Explain, Justify, Provide, Support, and Teach.

4.3 Chapter Summary

This chapter has presented a comparison of the state-of-the-art in design rationale with the state-of-the-art in medical device design.

The comparison consisted of comparing the design rationale capabilities that were identified from the literature reviewed in Chapter 2 with the capabilities identified from the existing best practices in medical device design, the assurance case practice for medical devices. Capabilities for the assurance case practices were identified and defined in this chapter in order to conduct the comparison.

Results from the comparison have highlighted that design rationale and assurance case practices for medical devices share the ability to perform three generic actions, although the differ in their specific outcomes.

Design rationale and assurance case practices both share the ability to represent, document and structure information that could be used to communicate the knowledge underlying the development of a medical device. In contrast, design rationale has the ability to perform an additional ten actions which signifies that it is further advanced than the current state-of-the-art in medical device design.

This chapter has addressed the second objective of the research.

CHAPTER 5

REGULATORY APPROVAL OF MEDICAL DEVICES

5 Regulatory Approval of Medical Devices

This chapter identifies the individual activities that constitute the U.S. and EU regulatory approval processes for medical devices and provides a comparative analysis of the two processes highlighting their similarities and differences.

Currently, there is a lack of models available in the published literature which represents the U.S. and EU medical device regulatory approval processes. In this chapter, descriptive models illustrating the U.S. and EU medical device regulatory approval processes have been constructed using a recognised process modelling tool. These models are derived from publicly available data obtained from the U.S. and EU regulatory authorities, individually analysed and compared with each other. The models illustrate the different stages that constitute the U.S. and EU regulatory approval of medical devices.

Individual activities that comprise the existing processes for regulating the approval of medical devices in the U.S. and EU are identified in this chapter. The third objective of the research is addressed in this chapter by revealing the individual process activities that are currently required for placing medical devices in the U.S. and EU markets.

This chapter is presented in the following stages. Firstly, the methodology followed for modelling and comparing the U.S. and EU medical device regulatory approval processes is described. This is followed by the results from the individual analysis of the two descriptive models, each representing the U.S. and EU medical device regulatory approval process respectively. Following this, the descriptive models are compared with each other and the findings from the comparison are discussed. Finally, the research questions guiding this chapter are addressed and a summary of the findings is provided.

5.1 Methodology

The methodology followed for modelling and comparing the U.S. and EU regulatory approval processes for medical devices is presented a follows.

Firstly, the research questions guiding the comparative analysis presented in this chapter are defined. Secondly, the selection and rationale underlying the process modelling tool is presented. This is followed by the methodology used for modelling and analysing both U.S. and EU regulatory approval process. Following this, the identification of data sources and data collection and analysis techniques are described. This is followed by an explanation of how the models are to be compared with each.

5.1.1 Defining the Research Questions

Each regulatory approval process presented in section 5.2 has been mapped in order to identify the main activities, analysed, and then compared with reference to the following questions:

1) What do the U.S. and EU regulatory approval processes for medical devices entail?
2) What are the different stages that constitute the U.S. and EU regulatory approval of medical devices?
3) What are the differences and similarities between the U.S. and EU regulatory approval processes?

5.1.2 Process Modelling Tool Selection

The IDEFØ modelling tool was chosen to model the regulatory approval processes. The justification for this choice can be found in section 5.1.3.3.

The IDEFØ process modelling technique consists of five constituents to model the process, as shown in Figure 5-1. These are: activity name (clarifies the objective of the activity), input (represents the information to be converted by a particular activity into an output), control (applies rules to regulate the imposing constraints of an activity), output (direct result of the information produced by an activity), and mechanism (physical resources required to perform the activity which can include people, equipment and software tools).

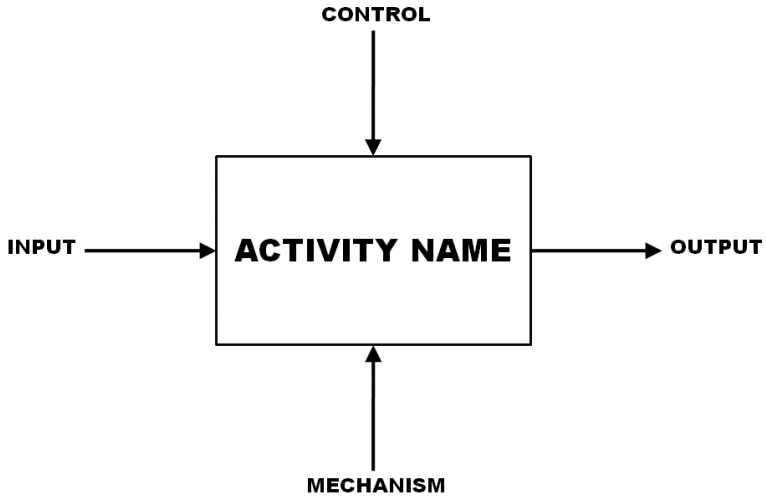

Figure 5-1: IDEFØ constituents

Creating a process model usually begins with raw data obtained from identified sources of information for a particular area of interest followed by identification of the activities performed.

A process model includes a set of activities arranged in a specific order, with clearly identified inputs and outputs (Zakarian and Kusiak, 2000). The top level or context activity (activity - A0 or M0) is primarily defined followed by identification of the proceeding functions or activities (decomposition). These are then grouped depending on their relationship or similarity. It is this process that constructs the hierarchy of the model to be analysed.

5.1.3 Modelling and Analysing the U.S. and EU Medical Device Regulatory Approval Processes

The steps for modelling and comparing the U.S. and EU medical device regulatory approval processes in this chapter have themselves been illustrated using the IDEFØ tool (Figure 5-2 and Figure 5-3). They are described in detail in the following subsections. Figure 5-2 illustrates the higher-level context activity (M0) and Figure 5-3 shows the lower-level decomposed activities (M1 to M6).

The inputs into the context activity were the descriptions of the existing U.S. and EU practices for the regulatory approval of medical devices. This was converted into the output – comparison of the U.S. and EU medical devices regulatory approval processes. To convert the input into the required output, physical activities, and resources such as data capture, data analysis and process modelling tool were required. Controlling the overall methodology were the availability of the required data and the modelling tool selection criteria for selecting the most appropriate process modelling tool.

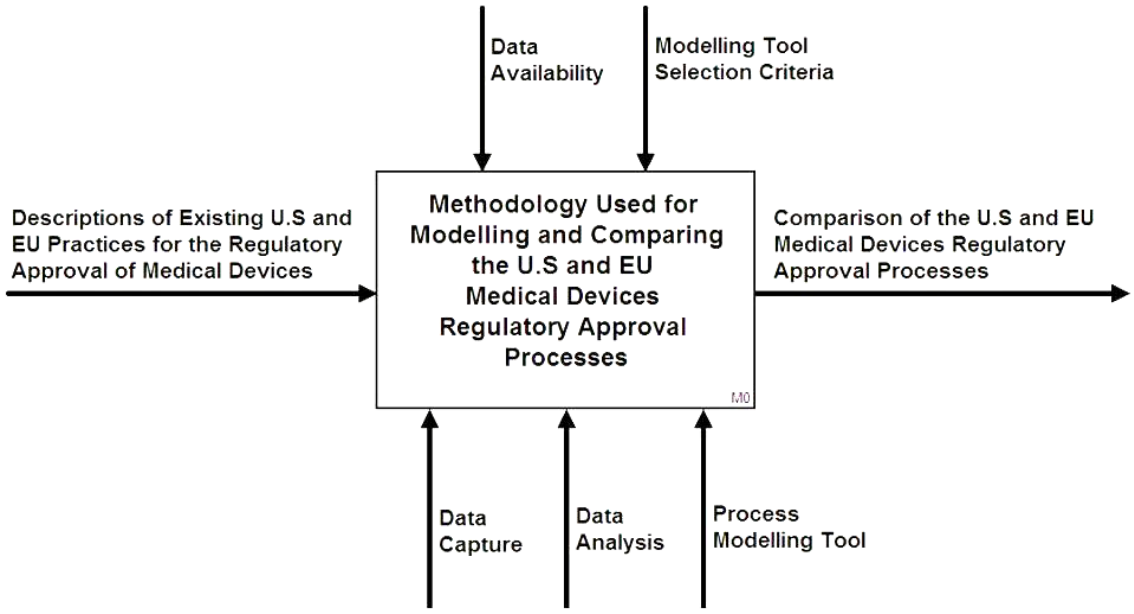

Figure 5-2: Context activity of the methodology (M0) – steps for modelling and comparing the U.S. and EU regulatory approval processes

The decomposition of the methodology (Figure 5-3) details the lower-level activities that were performed to create and compare the U.S. and EU medical devices regulatory approval process models.

Each of the individual activities from M1 to M6 had separate outputs signifying the results from each of the activities performed. These were direct inputs into the subsequent activities. Activity M6 converted this sequence of outputs into the final specified output, comparison of the U.S. and EU medical devices regulatory approval processes.

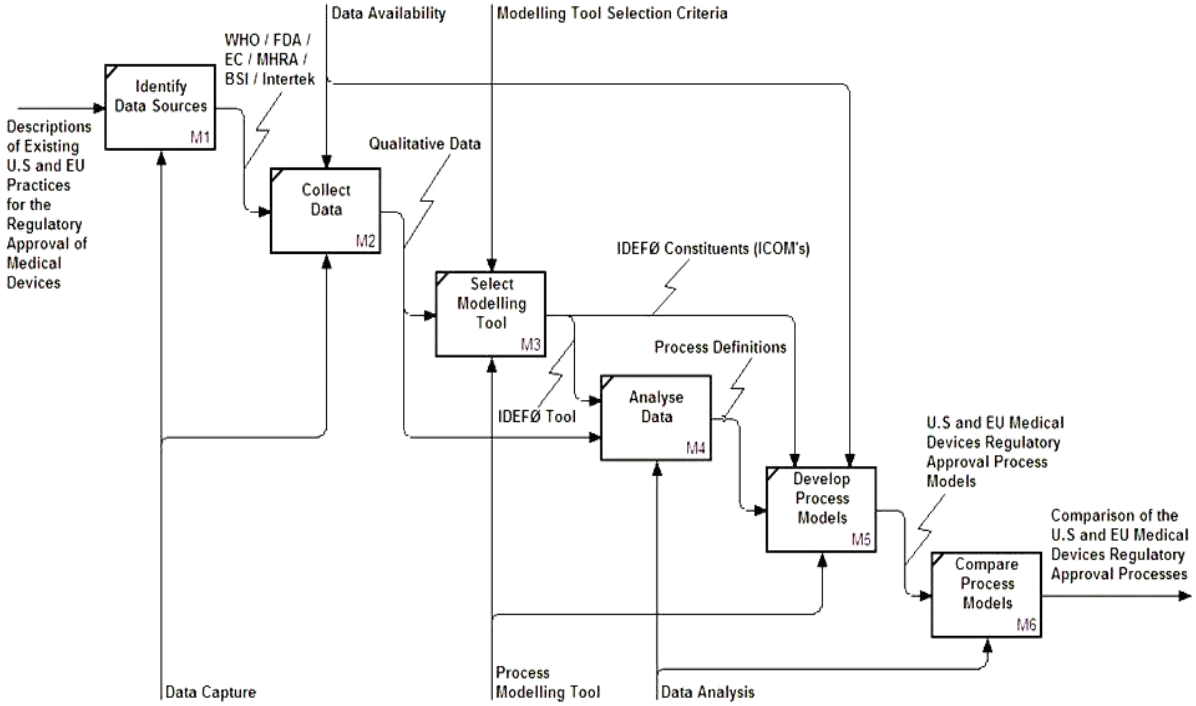

Figure 5-3: Decomposed activities of the methodology (M1 to M6) – steps for modelling and comparing the U.S. and EU regulatory approval processes

5.1.3.1 Identifying Data Sources

The sources of information that were identified (M1) and considered to be of direct relevance in providing the necessary data concerning the activities and requirements for the regulatory approval of medical devices in the U.S. and EU, are the output from activity M1 (Figure 3). These are listed in Table 5-1. Abbreviations listed throughout the chapter are specified in the appendix (Appendix B: Tabulation of Activities and Their Controls, Mechanisms and Outputs for the U.S. and EU Processes).

Table 5-1: List of identified data sources for medical device regulations in the U.S. and EU

Organisation	Abbreviation	Geographic Area	Role	Reference
World Health Organisation	WHO	International	Directing and coordinating authority for health within the United	(WHO, 2003)

			Nations system	
U.S. Food and Drug Administration	FDA	United States of America	Responsible for protecting the public health in the U.S.	[3]
European Commission	EC	Europe	Concerned with the regulatory framework of medical devices for market access	[4]
Medicine and Healthcare products Regulatory Agency	MHRA	United Kingdom	Responsible for the regulation of medicines and medical devices in the EU	[5]
British Standards Institute	BSi	United Kingdom	Inspection and certification of medical products	[6-7]
Intertek	-	International	Inspection and certification of medical products	[8]

5.1.3.2 Data Collection

Data was collected (M2) from the sources identified in the preceding activity (M1). Table 5-2 presents a list of the source documents collected. Data collected and directly referenced from the websites of the U.S. and EU regulatory authorities for medical devices can be found in section 5.1.3.4.

Table 5-2: List of documents containing data for medical device regulations in the U.S. and EU

Document Name	Organisation	Date	Reference
Medical Devices: Guidance Document, Classification of Medical Devices	EC	2010	European Commission (2010)
Bulletin No.17: Medical Devices and Medicinal Products	MHRA	2009	MHRA (2009)
Medicines & Medical Devices Regulation: What you need to know	MHRA	2008	MHRA (2008a)
Bulletin No.4: Conformity Assessment Procedures (Medical Device Regulations)	MHRA	2008	MHRA (2008b)
Bulletin No.2: The CE Mark	MHRA	2007	MHRA (2007)
Council Directive 93/42/EEC on Medical Devices (MDD)	EC	2007	European Commission (2007)
Guidance Notes for Manufacturers of Class I Medical Devices (EC Medical Devices Directives)	MHRA	2006	MHRA (2006a)
Bulletin No.8: Information About the EC Medical Devices Directives	MHRA	2006	MHRA (2006b)
Bulletin No.10: The Classification Rules	MHRA	2006	MHRA (2006c)
Bulletin No.18: The Medical Devices Regulations: Implications on Healthcare and Other Related Establishments	MHRA	2006	MHRA (2006d)
Design Control Guidance for Medical Device Manufacturers	FDA	1997	CDRH:FDA (1997)
Medical Device Quality Systems Manual: A Small Entity Compliance Guide.	FDA	1996	[9]; CDRH:FDA (1996)
Certification for Medical Devices	BSi	-	[6]
CE Marking for Medical Devices	BSi	-	[7]

5.1.3.3 Modelling Tool Selection

Modelling tools were considered and assessed for constructing the two regulatory approval process models (M3) in order to graphically illustrate the U.S. and EU regulatory approval processes. Controlling this activity was the modelling tool selection criteria (definition, concept, motivation, theory, graphical representation, and analysis tool).

5.1.3.4 Data Analysis

On completion of the data collection activity (M2) and modelling tool selection (M3), the outputs from activities M2 and M3 were direct inputs into activity M4 – 'Analyse Data'.

In M4, a detailed analysis of the qualitative data was performed in order to define the individual activities performed by the device manufacturers and regulatory authorities in the two processes that are required for medical device approval in the U.S. and EU.

The activities that constituted the U.S. and EU regulatory approval processes were primarily identified from the data sources (Table 5-1 and Table 5-2). The sequence of steps required for the regulatory approval of medical devices in the U.S. and EU was noted. This information was then used to define the activities (Table 5-3 and Table 5-4).

Having defined these activities, for each activity the inputs, outputs, factors controlling the regulatory approval activities (controls), and the physical resources required to undertake those activities (mechanisms) were defined.

Table 5-3 shows the data sources used for each defined activity for the U.S. regulatory approval process.

Table 5-3: List of the U.S. data sources used in the data analysis

IDEFØ Activity Name	Inputs	Controls	Outputs	Mechanisms
A1 – Define Device [10]	Medical Device Intended for Human Use [11]	Device Definition [14] (contained in 21 CFR 862-892)	Defined Medical Device [10]	FDA Website [14]; Device Manufacturer [10]
A2 - Classify Device [10]	Defined Medical Device [10]	Device Classification Criteria [14]; Regulatory Controls [15]	Classified Device: Class I [14]; Classified Devices: Classes II and III [14]	CDRH Classification Database [14]; Device Manufacturer [10]
A3 – Select Marketing Process [14]	Classified Devices: Classes II and III [14]	Device Classification Criteria [14]; Regulatory Controls [15]; Marketing Clearance Requirements [10]	Premarket Notification 510(k) Requirements and Premarket Approval Application (PMA) Requirements [10]	FDA Website [11]; Device Manufacturer [10]
A4 – Prepare Marketing Application [10]	Premarket Notification 510(k) Requirements and Premarket Approval (PMA) Requirements [10]	Marketing Clearance Requirements [10]; Quality System Regulations (QSR) [16]	Device Data and Documentation [10]	Device Manufacturer [10]; Clinical Trials [10]; Clinical Performance Data [10]; Quality Management System (QMS) [16, 19]
A5 - Submit Marketing Application [10]	Device Data and Documentation [10]	Application Submission Requirements [11]	Device Marketing Application [10]	FDA Website (MHRA, 2008b); Device Manufacturer [10]
A6 – Review Device Application	Device Marketing Application	PMA Regulations (21 CFR 814;	Device Approvable Letter [13]	FDA Personnel [13]

[11-13]	[10]	510(k) Regulations FD&C Act; Refuse to File policy) [13]		
A7 – Register Device Details [10]	Device Approvable Letter [13]; Classified Device: Class I [14]	Marketing Clearance Requirements [10]; Premarket Requirements [10]	Medical Device Registered for Intended Use in the U.S. with the FDA [10]	Device Manufacturer [10]; FDA Website [11]
A8 – Market Device [10]	Medical Device Registered for Intended Use in the U.S. [10]	Marketing Clearance Requirements [10]; Post market Requirements [10]; Quality System Regulations (QSR) [10]; Medical Device Reporting (MDR) Regulations [10]	Medical Device Registered and Approved for Intended Use in the U.S. [10]	Device Manufacturer [10]; FDA Personnel [13]

Table 5-4 shows the data sources used for each defined activity for the EU regulatory approval process.

Table 5-4: List of the EU data sources used in the data analysis

IDEFØ Activity Name	Inputs	Controls	Outputs	Mechanisms
A1 – Classify Device [6-8]	Intended Purpose of Medical Device (European Commission, 2010)	Classification Rules in Annex IX of Medical Device Directive (MDD) 93/42/EEC (European Commission, 2007; 2010)	Classified Device: Class I (ns/nm) [7] (European Commission, 2007); Classified Devices: Classes I (s/mf), IIa, IIb and III [7] (European	Device Manufacturer (European Commission, 2010); EU Competent Authority Website (such as MHRA for UK Notified

			Commission, 2007)	Bodies Listed Under the Medical Devices Directives) [17]
A2 – Implement Quality Management System (QMS) [6-7]	Classified Devices: Classes I (s/mf), IIa, IIb and III [7] (European Commission, 2007)	Annex II or V of Medical Device Directive (MDD) 93/42/EEC [9]; ISO Standard 13485:2003 [7]	QMS Compliance [7]	Device Manufacturer (European Commission, 2010)
A3 – Prepare Technical Documentation [6-7]	Classified Device: Class I (ns/nm) [7] (European Commission, 2007); QMS Compliance [7]	Medical Device Directive (MDD) 93/42/EEC [7]; Risk Management Requirements [7]	Technical File or Design Dossier (Device Data and Documentation) [6-8]	Device Manufacturer (European Commission, 2010); Clinical Data [7]
A4 – Select and Appoint EU Notified Body [6-7]	Technical File (Device Data and Documentation) [6-8]	Located in EU [7]	Appointed EU REP [7] for Classified Device: Class I (ns/nm); Appointed EU REP [7] for Classified Devices: Classes I (s/mf), IIa, IIb and III	Device Manufacturer [7]; EU Competent Authority Website such as MHRA for U.K. Notified Bodies Listed Under the Medical Devices Directives) [17]
A5 – Audit: QMS, Technical File and Dossier [6-7]	Appointed EU REP [7] for Classified Devices: Classes I (s/mf), IIa, IIb and III	Medical Device Directive (MDD) 93/42/EEC [6, 17] (European Commission,	CE Certificate [7] for Class I Devices (s/mf); CE Certificate [7] for Class IIa, IIb and III Devices	EU Notified Body [7]

		2010)		
A6 – Register Device Details [6-7]	CE Certificate [7] for Class I Devices (s/mf); Appointed EU REP [7] for Classified Device: Class I (ns/nm)	Medical Device Directive (MDD) 93/42/EEC [6, 17] (European Commission, 2010)	Registered All Class I Medical Devices [7]	Device Manufacturer [6-7]; EU Competent Authority [7]
A7 – Market Device [6-7]	Registered All Class I Medical Devices [6]; CE Certificate [6] for Class IIa, IIb and III Devices	Medical Device Directive (MDD) 93/42/EEC [6-7, 17]; CE Mark (MHRA, 2008a; European Commission, 2010); Declaration of Conformity [6-7]; Post Market Surveillance (MHRA, 2006a)	Medical Device Certified and Approved for Intended Purpose in the EU (MHRA, 2008a)	EU Notified Body [7]; Device Manufacturer [6-7]

5.1.3.5 Process Model Development

The process models illustrating the U.S. and EU regulatory approval processes for medical devices presented in this chapter were developed (M5) using the IDEFØ modelling tool which was selected at activity M3 (Figure 5-3).

The software used to create the models (methodology for developing the models and the actual U.S. and EU regulatory approval process models) was the 'BPwin Business Process Design Tool version 4.0'. The models were developed by firstly creating the context activity followed by the decomposition of activities.

5.1.3.6 Comparison of U.S. and EU IDEFØ Models

The final activity in the methodology (M6) compared the developed U.S. and EU regulatory approval process models constructed in the previous activity (M5).

Two methods were utilised to form an overall comparison of the U.S. and EU regulatory approval processes for medical devices.

Firstly, the IDEFØ process models for each of the aforementioned regulatory approval processes were analysed, described, and compared with reference to each of the individual activities performed.

Secondly, the IDEFØ constituents (inputs, controls, outputs, and mechanisms) were described and compared. The comparison was the final output from the sequence of activities in the methodology as illustrated in Figure 5-3 (M1 to M6).

5.2 Results: U.S. and EU Medical Devices Regulatory Approval Process Models

The following subsections present the U.S. and EU medical devices regulatory approval process models that have been created using the IDEFØ process modelling technique.

5.2.1 Higher Level Context Activity of the U.S. Medical Devices Regulatory Approval Process Model

The higher level context activity, represented by the IDEFØ technique, of a process model for regulating the approval of medical devices for the U.S. market is shown in Figure 5-4.

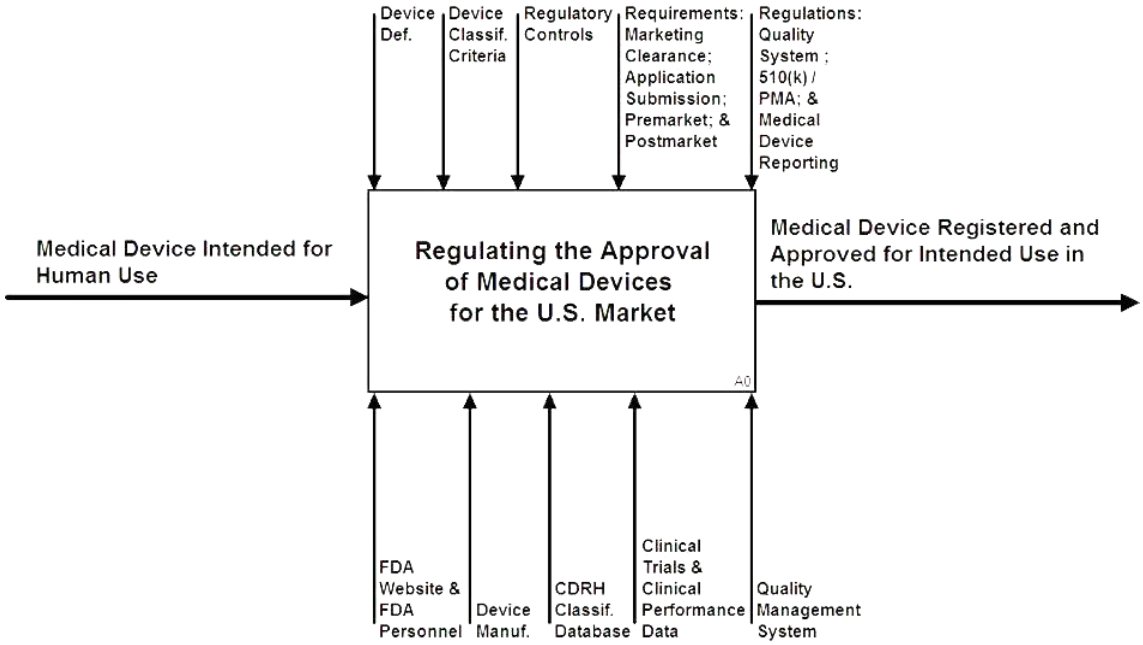

Figure 5-4: Context activity of the U.S. medical devices regulatory approval process

The direct input into the context activity (A0) was a medical device intended for human use. This input was converted into the output – 'Medical Device Registered and Approved for Intended Use in U.S'. As illustrated in Figure 5-4, there are seven mechanisms or physical resources, and ten constraints (controls) required to regulate the approval of medical devices for the U.S. market. The context activity is shown decomposed in Figure 5-5.

5.2.2 Decomposition of the U.S. Medical Devices Regulatory Approval Process Model

The U.S. medical devices regulatory approval process (Figure 5-5) commences with the definition of the medical device (A1). The activities that follow this are; classify device (A2), select marketing process (A3), prepare marketing application (A4), submit marketing application (A5), review device application (A6), register device details (A7), and market device (A8). These activities are described in detail in the following subsections using the IDEFØ modelling tool constituents (inputs, controls, outputs, and mechanisms).

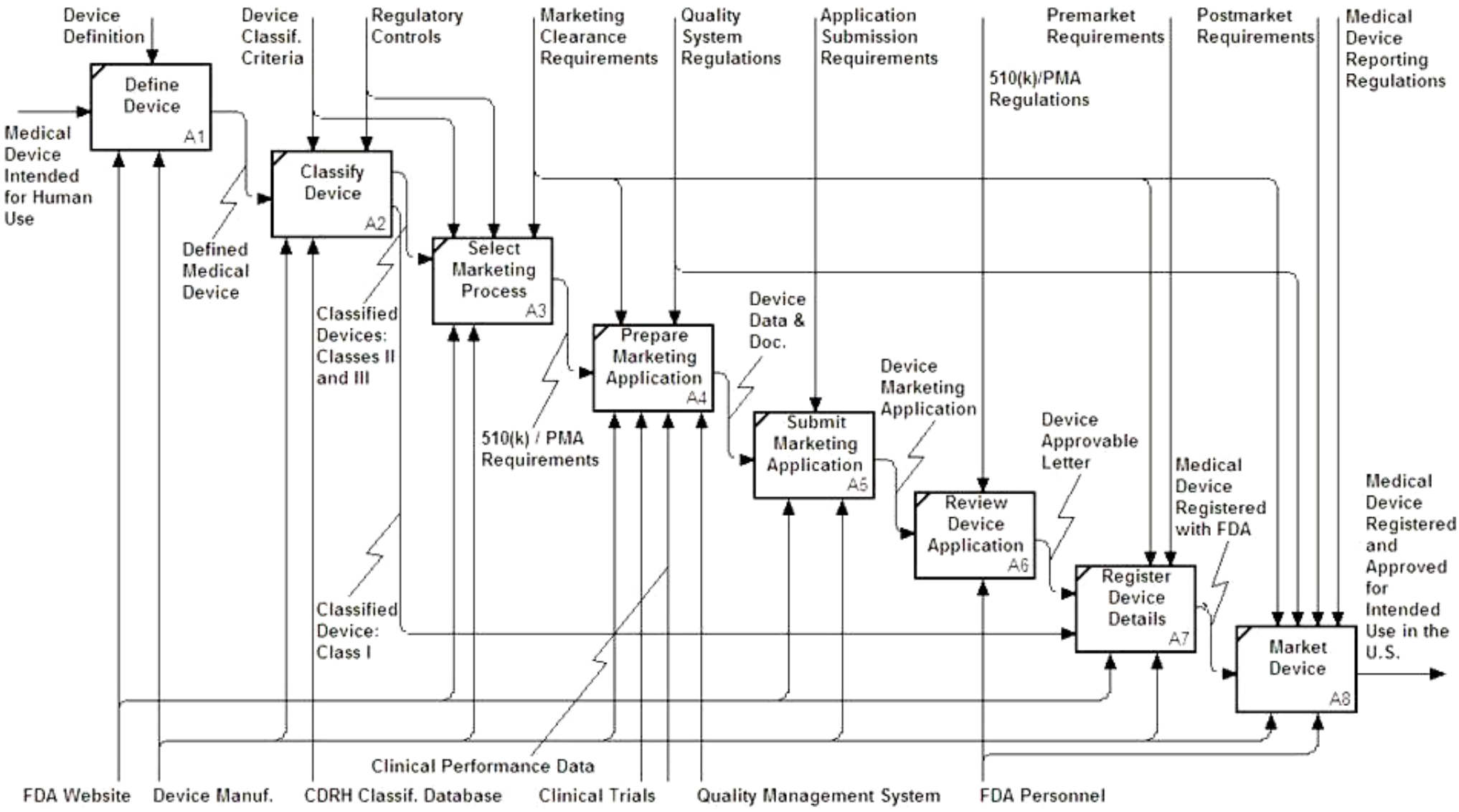

Figure 5-5: Decomposition of the U.S. medical devices regulatory approval process

5.2.2.1 Define Device

Figure 5-6 shows activity A1 and illustrates the input, control, output, and mechanisms. Activity A1 – 'Meets Device Definition' is defined by the FDA [10] to be the primary step in the medical device marketing process in the U.S. According to the FDA [10], this is to ensure that the manufactured medical device intended for human use (input into activity A1) conforms to the definition of a medical device provided in section 201(h) of the FD&C Act. The FDA states that the definition [14] provides a clear distinction between a medical device and other FDA regulated products such as drugs. In order to market a device, the device manufacturers' are required to ensure that their intended product for the medical device market meets with the definition of a medical device.

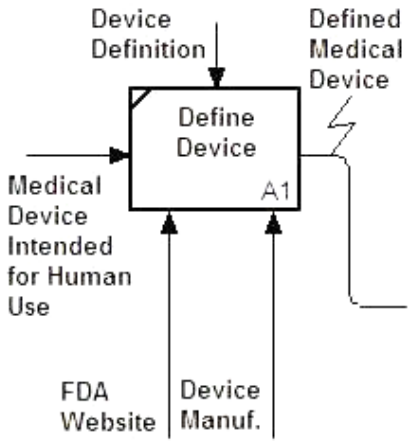

Figure 5-6: Activity A1 – define device

5.2.2.2 Classify Device

Figure 5-7 illustrates the second activity in the process (A2). This activity identifies how the FDA determines the classification of the medical device to be placed on the market. The FDA classifies medical devices into three different classes (I, II and III), whereby the regulatory control increases from class I medical devices to class III. Class I devices are restricted by general controls; class II devices are restricted by special controls; class III devices require premarket approval.

General controls are described by the FDA to be the basic provisions that provide the FDA with the means of regulating devices to ensure their safety and effectiveness [15]. They include provisions that relate to adulteration; misbranding; device registration and listing; premarket notification; banned devices; notification, including repair, replacement, or refund; records and reports; restricted devices; and good manufacturing practices. It is further described that the general controls apply to all three classes of medical devices; however, they are the only level of controls that apply to class I devices [15].

The FDA has stated that class II devices are those for which general controls alone are insufficient [15]. In addition to the general controls, the special controls include special labelling requirements, mandatory performance standards, and post market surveillance. The FDA considers that the device classification identifies the level of regulatory control that is necessary to assure the safety and effectiveness of a medical device [10]. In order to identify the device classification of a medical device to be placed on the U.S. market, device manufacturers' are advised by the FDA to use the CDRH (Center for Devices and Radiological Health) Classification Database [14] to search for similar products that are regulated by the FDA. The product classification database is described to contain products that the FDA considers to be devices, and contains medical device names and associated information developed by the CDRH.

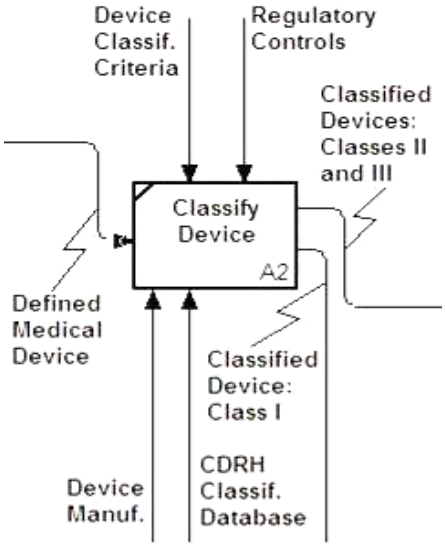

Figure 5-7: Activity A2 – classify device

5.2.2.3 Select Marketing Process

Figure 5-8 illustrates the select marketing process activity (A3). At this activity, the device manufacturers are required by the FDA to select the appropriate marketing approval process in order to obtain market approval for the device. A major control on this particular activity (A3) is the marketing clearance requirements for both class II and III devices.

The FDA has highlighted [12] that for most class II devices, a premarket notification 510(k) is required, and for most class III devices, a premarket approval application (PMA) is required for obtaining market clearance. It is further explained by the FDA [14] that most class I devices and a few class II devices are exempt from the premarket notification [510(k)] requirements subject to the limitations on exemptions. However, it is also noted that these devices are not exempt from other general controls. According to the FDA, all medical devices must be manufactured under a quality assurance program, be suitable for the intended use, be adequately packaged and properly labelled, and have establishment registration and device listing forms on file with the FDA [14]. The FDA has listed the devices by class that are exempt from the 510(k) and Good Manufacturing Practices (GMP)/Quality Systems [19].

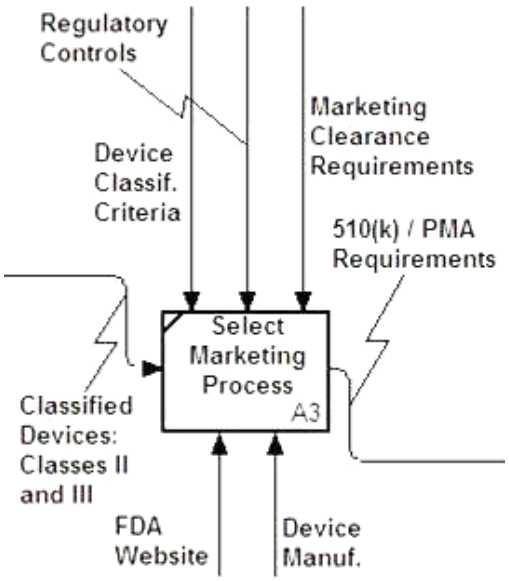

Figure 5-8: Activity A3 – select marketing process

5.2.2.4 Prepare Marketing Application

At activity A4, (Figure 5-9) the device manufacturers' are required to prepare the marketing application based on the selected marketing process. The type of marketing application (510(k) or PMA) is based on the class of device (class II or III).

The device manufacturers' are required to develop the necessary documentation containing the device data and information which is needed to submit the application for device approval in the following activity A5 – 'Submit Marketing Application'.

The FDA state that for some 510(k) submissions and most PMA applications, clinical performance data is required to obtain marketing clearance [10]. If the device is classified as class I or II, and if it is not exempt, a 510k will be required for marketing [14].

The FDA also state that products requiring PMA's are class III devices and are high risk devices that pose a significant risk of illness or injury, or devices found not substantially equivalent to class I and II predicate through the 510(k) process [16]. The PMA process is described to be more involved and includes the submission of clinical data to support claims made for the device.

The clinical trials are to be conducted by the device manufacturers. These must conform to the FDA's Investigational Device Exemption (IDE) regulation (marketing clearance requirements). Additionally, the device manufacturers' are required to implement a quality management system (QMS) that is in accordance to the FDA's quality systems regulation (QSR).

The QSR includes requirements related to the methods used in and the facilities and controls used for: designing, purchasing, manufacturing, packaging, labelling, storing, installing, and servicing of medical devices [16]. The manufacturing facilities of the device manufacturers' must undergo inspections by the FDA to assure compliance with the requirements of the QSR [16].

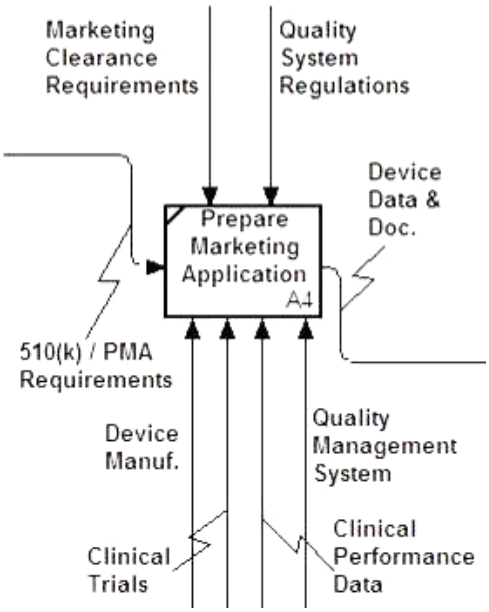

Figure 5-9: Activity A4 – prepare marketing application

5.2.2.5 Submit Marketing Application

Activity A5 is illustrated in Figure 5-10. At this activity, the device manufacturers are required to submit the applicable marketing application to the FDA using the FDA website. The FDA has specified three types of 510(k) submissions for marketing clearance: Traditional, Special, and Abbreviated [12]. For PMA submissions, the FDA has defined the following five methods; Traditional PMA, Modular PMA, Streamlined PMA, Product Development Process, and Humanitarian Device Exemption (HDE).

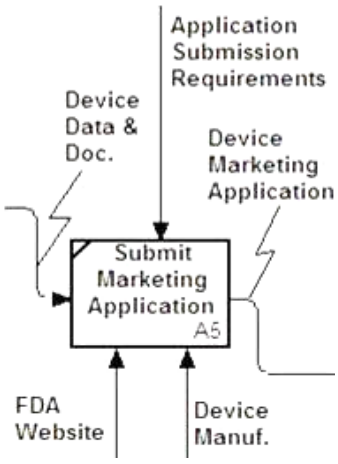

Figure 5-10: Activity A5 – submit marketing application

5.2.2.6 Review Device Application

Activity A6 is shown in Figure 5-11. This activity requires the reviewing of the medical device marketing application by the FDA. The device application is reviewed at this stage by personnel in the CDRH department at the FDA. The review of the application by the FDA is performed in conformance to the regulations found in 21CFR814 [13].

The application review process consists of the following four steps: (1) administrative and limited scientific review by FDA staff to determine completeness (filing review); (2) an in-depth scientific, regulatory, and quality system review by the appropriate FDA personnel; (3) a review followed by the recommendations of the appropriate advisory committee (panel review); and (4) the final deliberations, documentation, and notification of the decision made by the FDA.

If the application is considered successful by the FDA, the application is then filed for review. The filing of an application means that FDA has made a threshold determination that the application is sufficiently complete to begin an in-depth review [13].

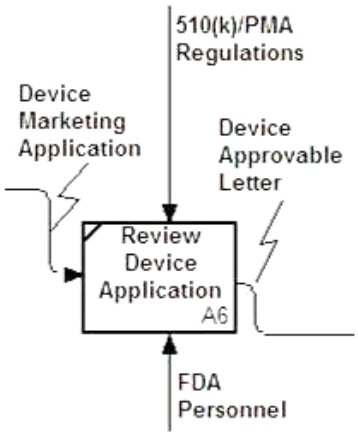

Figure 5-11: Activity A6 – review device application

5.2.2.7 Register Device Details

Figure 5-12 shows activity A7 – 'Register Device Details'. Activity A7 requires the device manufacturer to register the manufacturing company and list the type of device

they plan to market with the FDA [10] using the FDA website. The FDA states that all registration and listing information (annual, initial or updates) are to be submitted electronically unless a waiver is granted to the device manufacturer.

Before marketing clearance can be obtained, the device manufacturer has to assure that the device is properly labelled in accordance with the FDA's labelling regulations.

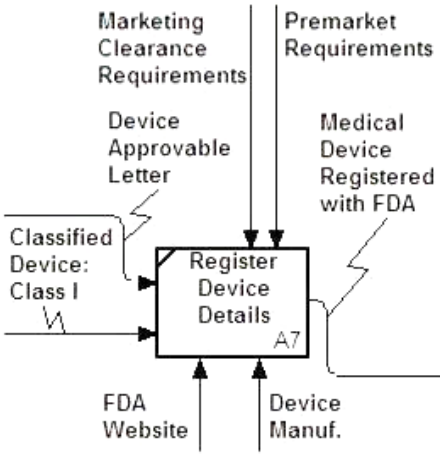

Figure 5-12: Activity A7 – register device details

5.2.2.8 Market Device

The final activity requires the device manufacturers to place the medical device in the U.S. market. (A8). Once the device is on the market, there are post market requirements (surveillance controls) with which a medical device manufacturer as well as other firms involved in the distribution of devices must conform to [10]. These requirements include the QSR and medical device reporting regulations (MDR).

MDR regulation is an adverse event reporting program for medical devices [10]. This includes the implementation of tracking systems, reporting of device malfunctions, serious injuries, or deaths, and registering the establishments where devices are produced or distributed with the FDA.

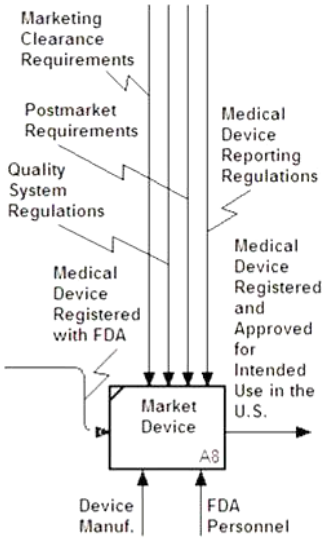

Figure 5-13: Activity A8 – market device

5.2.3 Higher Level Context Activity of the EU Medical Devices Regulatory Approval Process Model

The higher level context activity, represented by the IDEFØ technique, of a process model for regulating the approval of medical devices for the EU market is shown in Figure 5-14.

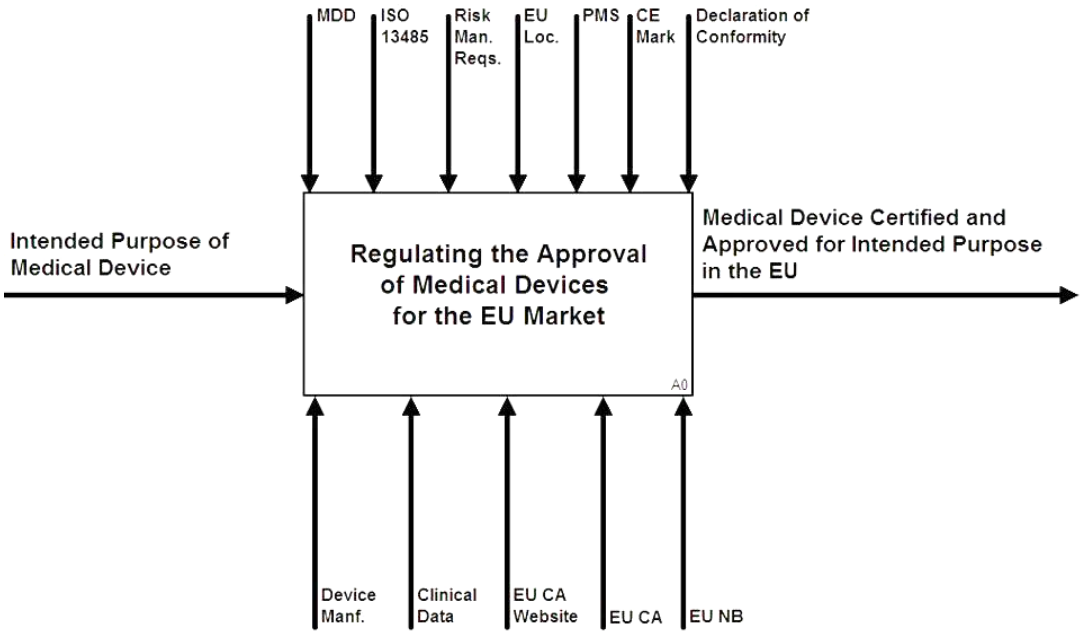

Figure 5-14: Context activity of the EU medical devices regulatory approval process

The direct input into the context activity (A0) was the intended purpose of the medical device. This input was converted into the output – 'Medical Device Certified and Approved for Intended Purpose in the EU'.

As illustrated in Figure 5-14, there were five mechanisms or physical resources, and seven constraints (controls) required to regulate the approval of medical devices for the EU market. The context activity is shown decomposed in Figure 5-15.

5.2.4 Decomposition of the EU Medical Devices Regulatory Approval Process Model

The decomposition of the IDEFØ model for the EU medical devices regulatory approval process (Figure 5-15) commences with the classification of the medical device (A1).

The activities that follow this are; implement quality management system (QMS) (A2), prepare technical documentation (A3), appoint EU notified body (A4), audit QMS including technical file (device documentation) and design dossier (A5), register device details (A6), and market device (A7).

The activities are described in detail in the following subsections using the IDEFØ modelling tool constituents (inputs, controls, outputs, and mechanisms).

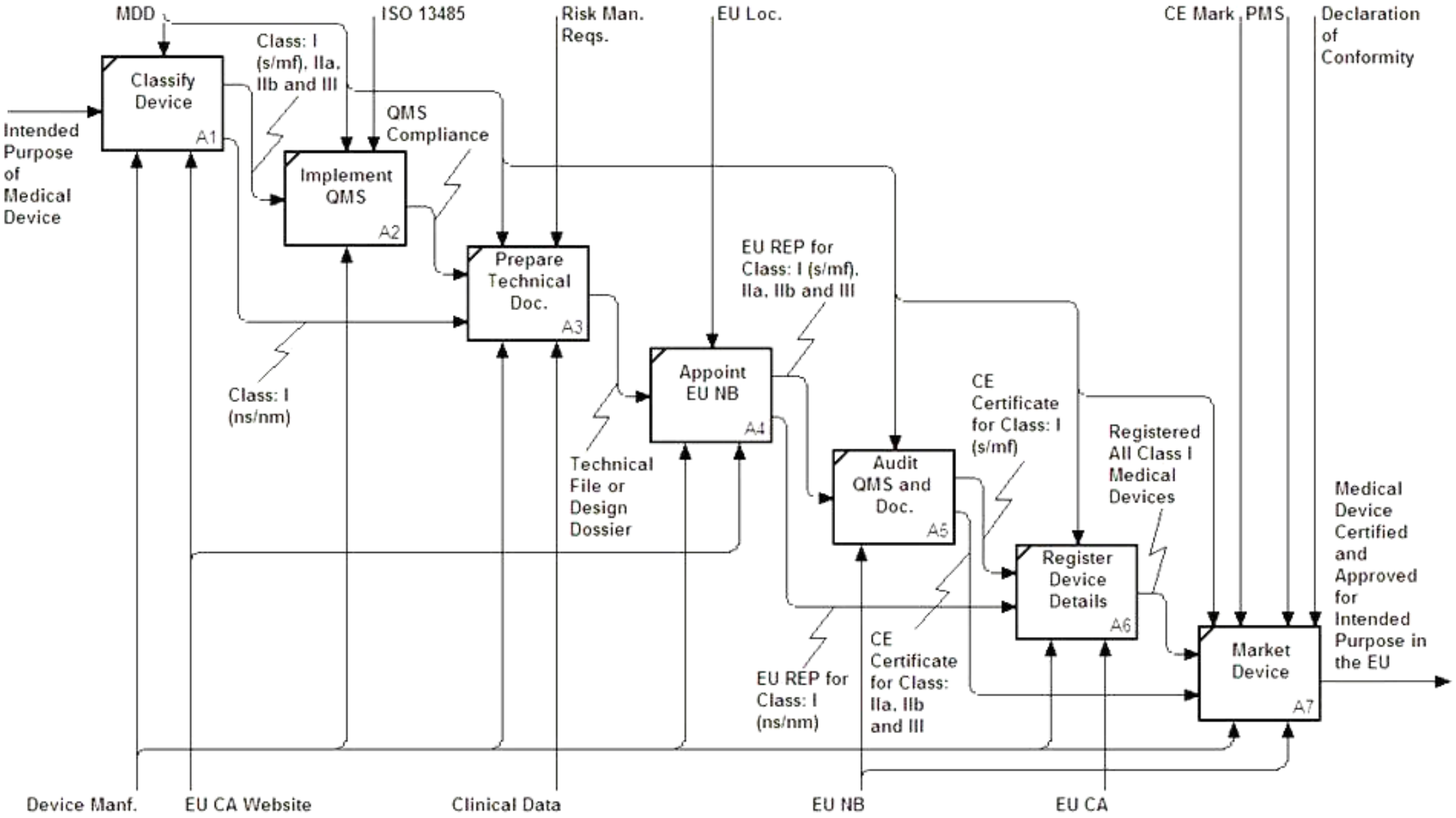

Figure 5-15: Decomposition of the EU medical devices regulatory approval process

5.2.4.1 Classify Device

Figure 5-16 shows activity A1 – 'Classify Device'. Medical device manufacturers' are required to classify the device to be placed in the EU market using the classification rules defined in Annex IX of the Medical Device Directive (MDD) 93/42/EEC [6] (European Commission, 2007; 2010). This classifies a device according to its properties, function, and intended purpose (MHRA, 2008b).

Devices that are covered by the MDD are grouped into four classes (MHRA, 2006c) designed to reflect the perceived risk associated with the devices (MHRA, 2008b). These classes are: class I (low-risk devices), class IIa (medium-risk devices), class IIb (medium-risk devices), and class III (high-risk devices). Devices classified as class I are grouped according to whether they are sterile and/or have a measuring function (s/mf) or they are non-sterile and/or have no measuring function (ns-nm). It is described by the Medicines and Healthcare products Regulatory Agency (MHRA) (MHRA, 2008b; 2006c) that at this particular activity (A1), it is for the device manufacturers' to determine the classification of the medical device to be placed on the market.

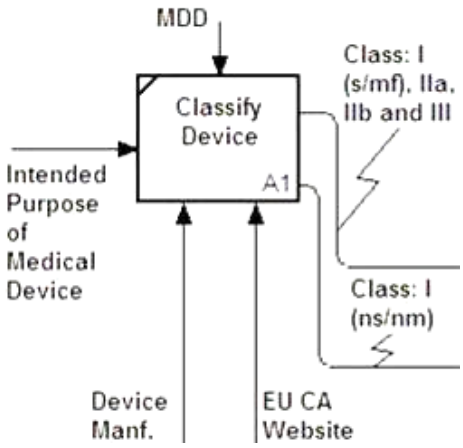

Figure 5-16: Activity A1 – classify device

5.2.4.2 Implement Quality Management System

Activity A2 (Figure 5-17) requires for the device manufacturers' to implement a quality management system (QMS) for the intended medical device to be placed on the EU

market. As illustrated in Figure 5-17, only medical devices that are classified as class I (s/mf), IIa, IIb and III are required to have a QMS implemented by the device manufacturers'. Manufacturers of devices classified as class I (ns-nm) are not required to implement a QMS.

The QMS is to be implemented by the device manufacturer in accordance with the MDD [6-7] or the equivalent ISO 13485:2003 standard. Many companies in the EU apply the ISO 13485 standard to achieve QMS compliance [7]. As part of QMS compliance, device manufacturers are required to have their quality systems and technical documentation reviewed by an EU NB (A5) before they are able to place their products on the market [18].

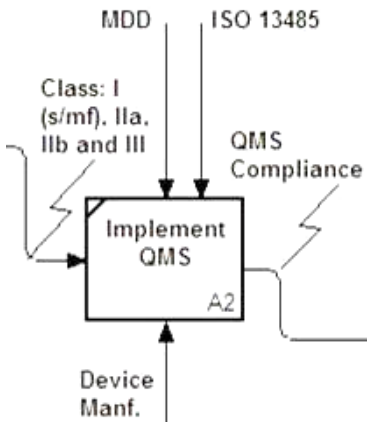

Figure 5-17: Activity A2 – implement QMS

5.2.4.3 Prepare Technical Documentation

At activity A3 (Figure 5-18), the device manufacturers' are required to prepare the technical documentation for the medical devices to demonstrate the conformity of the device with the MDD [7]. Devices have to meet the essential requirements set out in the MDD taking account of the intended purpose of the devices concerned (MHRA, 2008a).

Technical documentation has to cover the following aspects of the medical device: device description; raw materials and component documentation; intermediate product and sub-assembly documentation; final product documentation; packaging and labelling

documentation; and design verification which includes the results of qualifications tests and design calculations relevant to the intended use of the device (MHRA, 2008a). Clinical data and manufacturing testing records are also required as part of the technical documentation. Manufacturing and test records are required to show compliance with the defined procedures and specifications. It has been noted that many class I devices do not require a special clinical investigation to establish data on performance and safety or side effects (MHRA, 2008a). However, it is also noted that manufacturers should review the intended use of the medical device and any medical claims being made to ensure that there are adequate supporting test results.

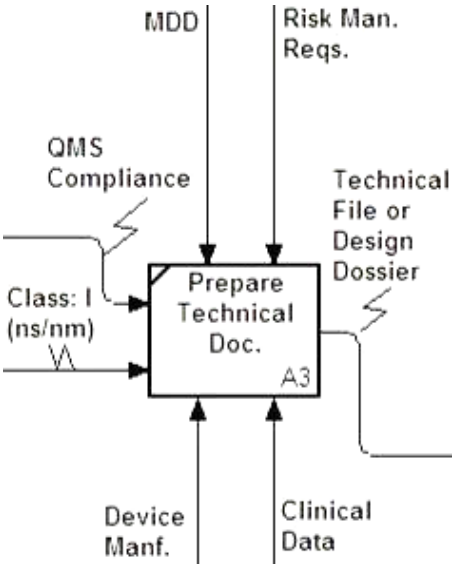

Figure 5-18: Activity A3 – prepare technical documentation

5.2.4.4 Appoint EU Notified Body

In activity A4 (Figure 5-19), device manufacturers are required to select and appoint an authorised representative to handle the regulatory issues regarding medical devices [7]. The EU location of the appointed notified body is controlling this activity (Figure 5-19). The appointed EU NB must be registered with an EU CA and located in the EU. Medical device manufacturers in the EU can register with any of the designated EU CA's. Device manufacturers should use the website of an appointed EU CA to search and identify the available notified bodies to handle the regulatory issues under the MDD [17].

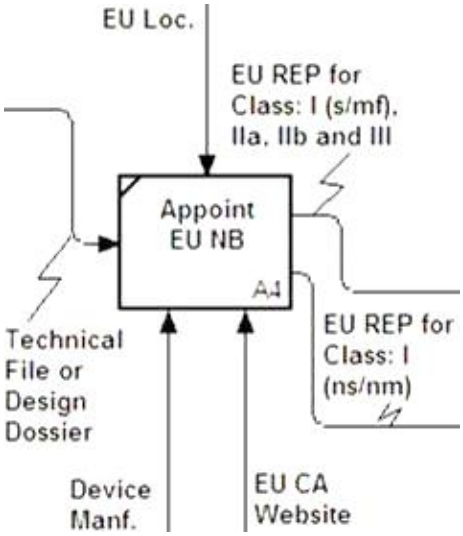

Figure 5-19: Activity A4 – appoint EU notified body

5.2.4.5 Audit Quality Management System and Documentation

At activity A5 (Figure 5-20), manufacturers' of devices in class I (s/mf), IIa, IIb and III are required to have their technical files, device documentation, and QMS and/or design dossiers audited by the appointed EU NB. The device manufacturers should establish and maintain documented procedures and records at their premises for audit inspection by the EU NB. For manufacturers' of devices that are classified as class I (ns/nm), auditing is not required. The audit is conducted by the EU NB according to MDD to ensure that the device, its documentation, technical file, and QMS show conformance to MDD.

On successful completion of the audit by the EU NB, a CE certificate for the device is issued to the device manufacturer by the EU NB which performed the audit [7]. The issuing of the CE certificate indicates that the CE mark can now be placed on the device by the manufacturer. The CE mark means that a medical device manufacturer is satisfied that the device conformed to the relevant essential requirements in the MDD and that it is fit for its intended purpose (MHRA, 2007). This is a legal requirement for devices intended for the EU market and it also indicates that the medical device can be placed anywhere in the EU market without further control.

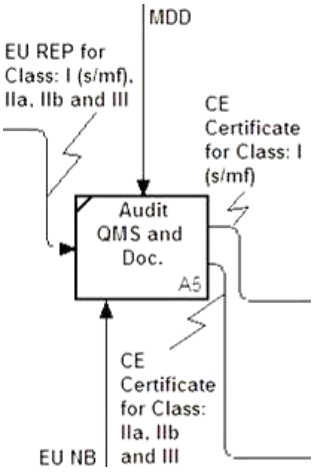

Figure 5-20: Activity A5 – audit QMS and documentation

5.2.4.6 Register Device Details

Activity A6 (Figure 5-21) requires the manufacturers' of all class I (s/mf and ns/nm) devices to register the details of the devices and the manufacturing organisation with an EU CA [7]. This is to be completed in accordance to the MDD. For all medical devices of classes IIa, IIb and III, device manufacturers are not required to register the device and manufacturer details. The MDD states that any device manufacturer who, under their own name, places medical devices on the market shall inform the competent authorities of the member state in which they have their registered place of business of the address of the registered place of business and the description of the devices concerned (European Commission, 2007).

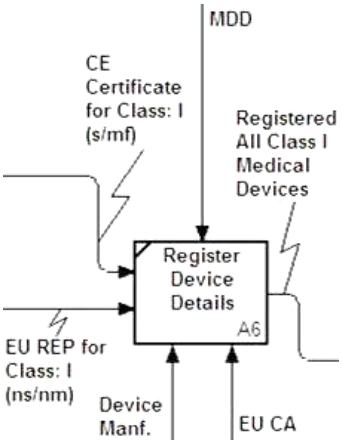

Figure 5-21: Activity A6 – register device details

5.2.4.7 Market Device

Activity A7 (Figure 5-22) is primarily for the device manufacturers' to 'place the medical device on the EU market'. The term 'placing on the market' has been defined by the EC (European Commission, 2007) to mean; 'the first making available in return for payment or free of charge of a device other than a device intended for clinical investigation, with a view to distribution and/or use on the Community market, regardless of whether it is new or fully refurbished'.

The MDD states that the manufacturer must draw up a written declaration of conformity (European Commission, 2007). This declaration of conformity must cover one or more medical devices manufactured, clearly identified by means of product name, product code, or other unambiguous reference, and must be retained by the manufacturer (European Commission, 2007). For implementing post market surveillance (PMS) for medical devices, it is described (MHRA, 2008a) that device manufacturers' are to maintain a vigilance system to notify the regulatory authorities of incidents that might lead to serious health consequences, or to a systematic recall of a device.

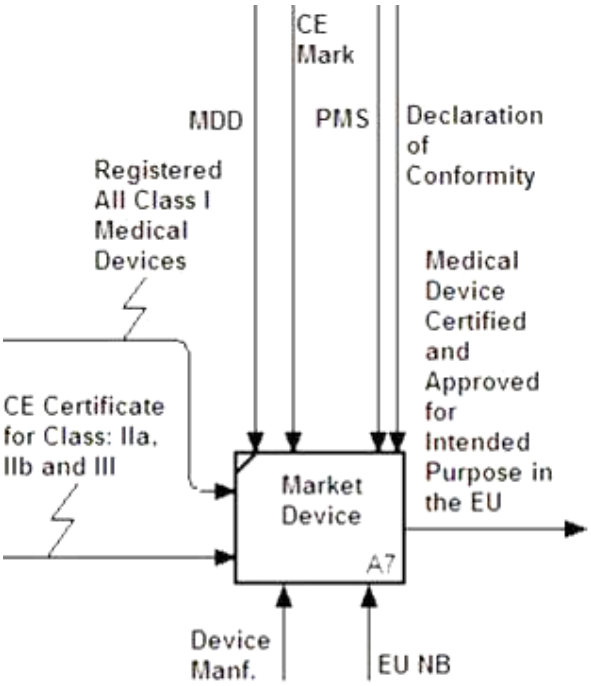

Figure 5-22: Activity A7 – market device

5.3 Discussion: Comparing the U.S. and EU Processes

The decomposed activities and outputs for both the U.S. and EU regulatory approval processes for medical devices, represented by the IDEFØ technique, have been used as the initial point for comparison. Following this, the physical resources and factors controlling device approval for both processes are compared and contrasted.

5.3.1 Decomposed Activities and Outputs

Three pairs of activities in the U.S. and EU processes appeared to have identical goals. These activities are 'Classify Device' (U.S. A2 | EU A1), 'Register Device Details' (U.S. A7 | EU A6), and 'Market Device' (U.S. A8 | EU A7). The goals are: device manufacturers' are to identify the device classification of their device intended for regulatory approval, device manufacturers' are to register the device details with the necessary regulatory approval authorities, and the device manufacturers' are to place the medical device in either the U.S. or EU market. However, the physical resources and factors controlling device approval for each of the activities differ.

The device classification activity in U.S. process (U.S. A2) shows that device manufacturers' are to utilise the CRDH device classification database to identify similar products that are regulated by the FDA. In the EU, device manufacturers' are to use the website of the EU CA as an initial point of reference to identify the appropriate documentation relating to medical device classification.

The registration of the device details in the U.S. process requires the device manufacturers' to use the FDA's website to register the details of the device and manufacturer. In the EU, only manufacturers of class I devices are required to register the details of the device and organisation with an EU CA.

Placing of the medical device in the U.S. requires the device manufacturers' to notify the FDA personnel that the device has been placed onto the market and that there is conformance with the post market requirements specified by the FDA. Device

manufacturers of class IIa, IIb and III in the EU are required to notify the EU NB that vigilance systems are in place before the device is placed onto the EU market.

Two pairs of activities in the U.S. and EU processes appear to have similar goals. Similarity of these goals is evident within the two pairs of the U.S. and EU activities. The first pair is 'Prepare Marketing Application' and 'Prepare Technical Documentation' (U.S. A4 | EU A3), and the second pair is 'Review Device Application' and 'Audit QMS and Documentation' (U.S. A6 | EU A5).

Preparation of the device marketing application in the U.S. (U.S. A4) requires the device manufacturers' to ensure that clinical trials have been conducted, if necessary, any clinical performance data is collated, and that the quality management system is established within the manufacturing organisation.

At the preparation of the technical documentation activity in the EU (EU A3), device manufacturers' are required to have clinical data, if necessary, as part of the technical documentation. Outputs from both activities are the technical documentation of the devices. In the U.S., the output is specified as device data and documentation, and in the EU the output is specified as a technical file (applicable to devices in class: I (s/mf and ns/nm), IIa and IIb) or design dossier (applicable to class III devices only).

Reviewing of the device application activity in the U.S. (U.S. A6) is similar to the auditing of the QMS and documentation activity in the EU (EU A5). At these activities, regulatory authorities in the U.S. (FDA) and in the EU (EU NB) are required to review the device documentation submitted by the device manufacturers'. However, the outputs from these activities differ. In the U.S. process, the output (U.S. A6) is a device approvable letter given by the FDA to the device manufacturer on successfully completing the review. In the EU, there are two outputs. These are a CE certificate for class I devices (s/mf) and a CE certificate for devices designated in classes IIa, IIb and III. CE certificates are issued by the EU NB to the device manufacturer on successful completion of the audit.

In contrast, several activities are uniquely found in either the U.S. or EU approval process. For the U.S. these are ‘Define Device’ (U.S. A1), ‘Select Marketing Process’ (U.S. A3), and ‘Submit Marketing Application’ (U.S. A5). For the EU process, activities that are unique are ‘Implement QMS’ (EU A2) and ‘Appoint EU NB’ (EU A4).

In the U.S. process, device manufacturers’ are primarily required to ensure that their device intended for the U.S. market meets with the definition of a medical device as defined by the FDA. Selection of the marketing process by the device manufacturer in the U.S. is based on the classification of the device to be placed onto the U.S. market. The device marketing application is submitted to the FDA by the device manufacturer using the FDA website.

In the EU process, the device manufacturers’ are required to implement a QMS which is in accordance to the MDD. It is this QMS which is then audited by the EU NB (EU A5). The appointing of the EU NB is a requirement for medical device manufacturers in the EU. The EU NB must be registered with an EU CA. This activity is not required in the U.S. process as the FDA is the principal regulatory authority responsible for regulating medical devices.

5.3.2 Physical Resources Required for Device Approval

Four physical resources required for device approval in the U.S. and EU processes appear to be similar. These are device manufacturers, clinical trials, and clinical data, the websites of the U.S. and EU regulatory authorities, and the regulatory authorities.

Device manufacturers’ are required to undertake the majority of the activities when placing medical devices in the U.S. and EU markets. Clinical data from any clinical trials that are conducted by the device manufacturers’ are required by the regulatory authorities to establish if the device works well in people and is safe to use. The U.S. and EU medical device regulatory authority websites are specified for use by the FDA and the EU competent authorities at the initial activities of both the U.S. and EU

regulatory approval processes. Information relating to the regulatory approval of medical devices can be found at the websites by the device manufacturers'. Regulatory authorities in the U.S. and EU are required to review and audit the device approval applications and device documentation prior to the device being placed onto the market by the manufacturers, and also after the device has been marketed to ensure conformity to the post market regulations.

However, there are two physical resources that are required for device approval in the U.S. which are unique to this process. These are the CDRH device classification database and quality management system. The CDRH device classification database is to be used by device manufacturers' in order to identify predicate devices. This is specified by the FDA and remains unique to the U.S. process. In the U.S. process, the quality management system is a physical resource whereas in the EU, the implementation of the QMS is an individual activity (EU A2). Manufacturers' in the U.S. are required to establish and follow the quality management systems according to the QSR to ensure that their devices meet the applicable requirements. In the EU, the QMS is to be implemented after the device classification activity (EU A1).

5.3.3 Factors Controlling Device Approval

Two factors controlling device approval in the U.S. and EU processes appear to be similar. These are medical device reporting regulations in the U.S. and post market surveillance in the EU.

In the U.S., medical device reporting is a method for the FDA to receive medical device adverse events from medical device manufacturers', importers and user facilities. This is so that adverse events that have occurred concerning the use of the medical device can be detected and corrected. In the EU, device manufacturers' are required to implement a documented procedure to review the experience gained from devices on the market. Any necessary corrective actions that are required are to be recorded as part of the documentation.

Several factors controlling device approval are uniquely found in either the U.S. or EU processes. For the U.S. process these are; device definition, device classification criteria, regulatory controls, marketing clearance requirements, quality system regulations, application submission requirements, 510(k) or PMA requirements, premarket requirements, and post market requirements. For the EU process these are; MDD, ISO standard 2003:13485, risk management requirements, EU location, CE mark, and declaration of conformity.

5.4 Chapter Summary

Answers to the three research questions that were guiding this chapter are summarised followed by the fulfilment of the third research objective.

Firstly, this chapter sought to identify what the U.S. and EU regulatory approval processes for medical devices entailed? In this chapter, models of the U.S. and EU regulatory approval processes for medical devices captured using the IDEFØ process modelling tool were presented. These models were created based on publicly available information which was obtained from the U.S. and EU medical device regulatory authorities.

The second research question posed was; what are the different stages that constitute the U.S. and EU regulatory approval of medical devices? The models created in this chapter identified the individual activities of the U.S. and EU approval processes, the outputs from the activities performed, the physical resources required to perform the individual activities, and the factors which control the successful placement of the medical device on the intended market.

The third research question posed was; what are the differences and similarities between the U.S. and EU regulatory approval processes? The U.S. and EU regulatory approval process models presented in this chapter were compared and contrasted using the modelling tool constituents as a basis for comparison. Comparison of the U.S. and EU

models revealed differences and similarities between the two processes, and identified the features that were unique to each process.

Differences included the types of physical resources and factors controlling device approval for each activity that comprised both processes. The inputs and outputs from the activities in each process also differed. Primary input into the U.S. process focussed on the medical device intended for human use, whereas the input into the EU process focussed on the intended purpose of the medical device. The final output from the U.S. process was concerned with the registration and approval for the intended use of the device in the U.S. market. In contrast to this, the final output from the EU process concerned itself with the certification and approval for the intended purpose of the medical device in the EU market. Similarities included three pairs of activities in both the U.S. and EU processes which appeared to have identical goals. These goals primarily require medical device manufacturers' to identify the device classification, register the details of the intended device for market with the designated regulatory authorities, and place the medical devices in either the U.S. or EU markets.

This chapter has identified the existing processes for medical device approval in the U.S. and EU. Also, this chapter has revealed the different process activities that are currently required for placing medical devices in the U.S. and EU markets thereby fulfilling the third objective of the research. The following chapter investigates the utilisation of the design rationale capabilities identified in Chapter 2 with the U.S. and EU medical device regulatory approval process activities that have been revealed in this chapter.

CHAPTER 6

UTILISING DESIGN RATIONALE WITH THE REGULATORY APPROVAL OF MEDICAL DEVICES

6 Utilising Design Rationale with the Regulatory Approval of Medical Devices

This chapter provides details of an analysis which investigates the possibilities of utilising design rationale with the U.S. and EU regulatory approval processes for medical devices.

This chapter analyses the possibilities of utilising design rationale with the different activities that constitute both the U.S. and EU regulatory approval processes for medical devices. In this chapter, the design rationale capabilities that were derived from the literature reviewed in Chapter 2 are mapped with the U.S. and EU medical device regulatory approval process activities that were identified in the previous chapter (Chapter 5).

This chapter identifies the relevant U.S. and EU regulatory approval process activities where design rationale could be utilised and outlines the benefits it could provide to medical device manufacturers and regulatory authorities. Additionally, this chapter provides the necessary basis for forming the guidelines presented in the following chapter (Chapter 7). The analysis reported in this chapter addresses the gaps in existing research (Chapter 2) by analysing ways in which design rationale could be utilised with the regulatory approval of medical devices. The fourth objective of the research is addressed in this chapter.

This chapter is presented as follows. First of all, the methodology followed in order to identify and analyse the U.S. and EU regulatory approval process activities is presented. This is followed by the results from the analysis which identifies the relevant U.S. and EU regulatory approval process activities where design rationale could be utilised. Following this, the proposition of the regulatory approval of medical devices as a novel area of application is discussed which includes the implications that this could present on the future of design rationale research. Finally, this chapter is summarised.

6.1 Analysis Methodology

6.1.1 Defining the Research Questions

The analysis presented in this chapter is guided by the following research questions that have been defined:

1) How could design rationale be utilised with the U.S. and EU regulatory approval processes for medical devices?
2) What benefits could design rationale potentially provide for medical device manufacturers and regulatory authorities?

6.1.2 Identifying U.S. and EU Regulatory Approval Process Activities

Descriptive models developed using the IDEFØ process modelling technique have illustrated the individual activities and the physical resources required to perform those activities that are required for placing medical devices in the U.S. and EU markets.

These process models have been used in this chapter to recognise the individual activities required for regulating the approval of medical devices in the U.S and EU. It is these individual activities that have been investigated to identify if design rationale could be utilised.

The alphanumerical activity identifier (AX – whereby X denotes the activity number) and the names of the individual activities that comprise both the U.S. and EU regulatory approval processes for medical devices are listed in Table 6-1.

As listed in Table 6-1, there are eight activities that comprise the U.S. process and seven activities that comprise the EU process for regulating the approval of medical devices.

Table 6-1: List of U.S. and EU medical device regulatory approval process activities

Activity identifier	U.S. process activity name	EU process activity name
A1	Define Device	Classify Device
A2	Classify Device	Implement Quality Management System (QMS)
A3	Select Marketing Process	Prepare Technical Documentation
A4	Prepare Marketing Application	Appoint EU Notified Body
A5	Submit Marketing Application	Audit QMS and Documentation
A6	Review Device Application	Register Device Details
A7	Register Device Details	Market Device
A8	Market Device	*(Not applicable for EU process)*

6.1.3 Utilising Design Rationale

Mechanisms are specified in the IDEFØ technique to represent the physical resources required to perform activities and can include software tools. Design rationale consists of methodological approaches and computational support tools based on those approaches. This chapter focuses specifically on the concept of design rationale as a physical resource that could be utilised with the activities that comprise both the U.S. and EU regulatory approval processes for medical devices.

In order to utilise design rationale with the individual regulatory approval activities, it was considered essential to identify design rationale's ability to perform actions that would be relevant and of benefit to the medical device manufacturers and regulatory authorities during the device approval process. These actions have been defined as capabilities of design rationale whereby thirteen capabilities have been identified. These thirteen capabilities of design rationale are listed in Table 6-2. Provided in Table 6-2 are the names of the DR capabilities and their identification labels (listed alphabetically from A to M).

The individual activities comprising both the U.S. and EU regulatory approval processes for medical devices (Table 6-1) and the DR capabilities (Table 6-2) are the

datasets used in the analysis which is described in the following subsection of this chapter.

Table 6-2: List of design rationale capabilities

Capability identification label	Design rationale capability name
A	Answer
B	Capture
C	Communicate
D	Design
E	Determine
F	Document
G	Explain
H	Justify
I	Provide
J	Represent
K	Structure
L	Support
M	Teach

6.1.4 Analysing the Possibilities of Utilising Design Rationale with the U.S. and EU Regulatory Approval Process Activities

The activities comprising both the U.S. and EU regulatory approval processes were individually tabulated according to each process. These activities for both the U.S. and EU processes (Table 6-1) were separately listed as rows in two tables beginning with the first activity (A1) continuing through to the final activity of that process (U.S. process | activity A8, and EU process | activity A7).

The thirteen design rationale capabilities (Table 6-2) were listed as columns in each of the two corresponding tables representing the U.S. and EU processes and their constituent activities. These capabilities of design rationale were used to designate design rationale's ability to perform specific actions and to map them against the regulatory approval activities.

Each of the thirteen design rationale capabilities was then mapped with the individual activities for both the U.S. and EU regulatory approval processes. This mapping addressed whether or not each capability of design rationale was applicable and could support each activity for per U.S. or EU process, and if it could, what were the available benefits of utilising design rationale at that particular activity? Evidence to provide the rationale for the resulting responses to the aforementioned questions has been established from the regulatory approval process activity description including the requirements for that activity, and the description of the design rationale capability stating the action that design rationale can perform.

6.2 Results

Results from the analysis of utilising the design rationale capabilities with the regulatory approval activities for medical devices in the U.S. and EU are presented in the following subsections of this chapter. Firstly, the process used for mapping the design rationale capabilities with the individual activities for both the U.S. and EU approval processes is described. This provides details on how the results from the analysis are presented.

Secondly, the design rationale capabilities are mapped with both the U.S. and EU regulatory approval process activities respectively. The mapping identifies the individual activities where the capabilities of design rationale could be utilised. The activities where design rationale could be utilised are then individually analysed to identify which of the thirteen design rationale capabilities are applicable, how they could be utilised at a particular activity and the benefits that they could provide.

6.2.1 Mapping Design Rationale Capabilities with the U.S. and EU Regulatory Approval Activities

The names of the individual activities in both processes (eight activities in the U.S. process | A1 to A8; and seven activities in the EU process | A1 to A7) were separately tabulated individually by U.S. and EU process and mapped with the thirteen design

rationale capabilities. These tables are presented in the following sub-sections of this chapter.

An example showing the mapping of the design rationale capabilities with the U.S. regulatory approval process activities is presented in Table 6-3. Table 6-3 shows that the regulatory approval process activities were alphanumerically listed as rows in the first column (activities A1 to A8). The design rationale capabilities were listed as columns beginning with capability 'A' (answer) incrementing alphabetically to capability 'M' (teach). Symbols were used to indicate the applicability of the design rationale capabilities at each activity. The 'X' symbol denotes that the design rationale capability was not applicable at the activity and the tick mark symbol indicates that the design rationale capability could be used at the activity.

The example shown in Table 6-3 illustrates that capabilities 'A' (answer), 'B' (capture) and 'M' (teach) were not applicable for the first two activities (A1 and A2) in the U.S. regulatory approval process for medical devices. The table (Table 6-3) also shows that capability 'B' (capture) was not applicable at activity A8 but capabilities 'A' (answer) and 'M' (teach) were applicable at this activity.

This mapping is performed for both the U.S. and EU regulatory approval processes and is presented in Table 6-4 and Table 6-5 in the following subsections of this chapter.

Table 6-3: An example of the mapping of the design rationale capabilities with the U.S. regulatory approval process activities

U.S. process activity name	Design rationale capabilities		
	A	B...	... to M
A1 – Define Device	X	X	X
A2 – Classify Device...	X	X	X
... to A8 – Market Device	✓	X	✓

6.2.2 Utilising Design Rationale Capabilities with the U.S. Regulatory Approval Process Activities

The thirteen design rationale capabilities were mapped with the eight activities that comprise the U.S. medical devices regulatory approval process in Table 6-4.

Results from the analysis highlight that there were there three main activities (A4 | Prepare Marketing Application; A6 | Review Device Application; and A8 | Market Device) in the U.S. regulatory approval process for medical devices where the capabilities of design rationale could be applicable. However, the results also indicate that not all of the design rationale capabilities were applicable at these three activities. The names of the capabilities that were applicable differed at these three activities.

There were twelve out of the thirteen design rationale capabilities that were found to be applicable at activity A4 (Prepare Marketing Application). Eleven identical capabilities were found to be applicable at activities A6 (Review Device Application) and A8 (Market Device).

The three activities (A4, A6, and A8) where the capabilities of design rationale where found to be applicable are individually analysed in the following subsections. Benefits of utilising the applicable design rationale capabilities with the three activities in the U.S. process are also outlined.

Table 6-4: Utilising design rationale capabilities with the U.S. regulatory approval process for medical devices

U.S. process activity name	Design rationale capabilities												
	A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**	**K**	**L**	**M**
A1 – Define Device	X	X	X	X	X	X	X	X	X	X	X	X	X
A2 – Classify Device	X	X	X	X	X	X	X	X	X	X	X	X	X
A3 – Select Marketing Process	X	X	X	X	X	X	X	X	X	X	X	X	X
A4 – Prepare Marketing Application	X	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
A5 – Submit Marketing Application	X	X	X	X	X	X	X	X	X	X	X	X	X
A6 – Review Device Application	✓	X	✓	✓	✓	✓	✓	✓	✓	✓	✓	X	✓
A7 – Register Device Details	X	X	X	X	X	X	X	X	X	X	X	X	X
A8 – Market Device	✓	X	✓	✓	✓	✓	✓	✓	✓	✓	✓	X	✓

6.2.2.1 Prepare Market Application

At activity A4, medical device manufacturers could utilise design rationale as part of the marketing application to provide the regulatory authority in the U.S. (U.S. Food and Drug Administration – FDA) with explicit rationale behind the design and development of the medical device intended to be placed on the U.S. market.

At this activity, the capabilities of design rationale could be utilised by device manufacturers in the following twelve ways: (1) to show how the reasoning, design knowledge and designers decisions were captured when designing a medical device; (2) to communicate the design aspects of the medical device such as the design relationships, design space, information and logical reasoning; (3) to make the reasoning behind the design of the medical device explicit for device application review; (4) to show how the reasoning underlying the design of the medical device was determined; (5) to show how the design decisions, design history, decision-making processes, design and logical reasoning that were made during the design of the medical device were documented; (6) to provide explanations of how the medical device was designed; (7) to provide justification of the argument behind the design decisions made during the design of the medical device; (8) to provide historical evidence of the medical device design process; (9) to represent the reasoning underlying the design of the medical device; (10) to show how the decision-making process and designers decisions were structured during the design of the medical device; (11) to show the reasoning and argumentation behind the design of the medical device by using a communication support system; and (12) to teach the FDA about how the medical device was designed using structured methods for capturing design knowledge as it is generated.

6.2.2.2 Review Device Application

When reviewing the device application at activity A6 (Review Device Application), the capabilities of design rationale could be utilised in the following eleven ways by the FDA: (1) to answers questions concerning the design of the medical device; (2) to understand and review the design relationships, design space, information and logical

reasoning; (3) to identify the explicit reasoning behind the design of the medical device; (4) to realise how the reasoning underlying the design of the medical device was determined; (5) to review how the design decisions, design history, decision-making processes, design and logical reasoning that were made during the design of the medical device were documented; (6) to examine explanations of how the medical device was designed; (7) to view the justification of the argument behind the design decisions that were made during the design of the medical device; (8) to review historical evidence of the medical device design process; (9) to view the representation of the reasoning underlying the design of the medical device; (10) to understand how the decision-making process and designers decisions were structured during the design of the medical device; and (11) to gain knowledge of how the medical device was designed.

6.2.2.3 Market Device

Activity A8 (Market Device) was found to have eleven design rationale capabilities that could be applied at this activity which were identical to those capabilities applicable in activity A6. Although the identical design rationale capabilities were found to be applicable at both activities (A6 and A8), the manner in which they could be utilised at activity A8 differs from the way in which they could be applied at activity A6.

At activity A8, the capabilities of design rationale could be utilised by both the medical device manufacturers and the FDA in the following eleven ways: (1) to answers questions concerning a device malfunction after the device has been placed on the market; (2) to communicate the design relationships, design space, information and logical reasoning for a medical device that has been recalled from the market; (3) to understand the reasoning behind the design of a medical device that has been recalled; (4) to determine the reasoning underlying the design of a medical device that has been recalled; (5) to understand the design history of a medical device that has been recalled; (6) to provide an explanation of how a medical device was designed in the event of a device recall; (7) to review the justification of the argument behind the design decisions that were made during the design of the medical device that has been recalled; (8) to view the historical evidence of a medical device that has been recalled; (9) to review the

representations of the reasoning underlying the design of a medical device that has been recalled; (10) to show how the decision-making processes and designers decisions were structured during the design of a medical device that has been recalled; and (11) to learn about the design and development of a medical device that has been recalled from the U.S. market after receiving regulatory approval.

6.2.2.4 Benefits of Utilising Design Rationale with the U.S. Regulatory Approval Process Activities

There are various possible benefits available to both the medical device manufacturers and the FDA for utilising design rationale and its existing capabilities with three of the regulatory approval process activities for medical devices in the U.S. (A4 | Prepare Marketing Application; A6 | Review Device Application; and A8 | Market Device). These postulated benefits have been derived from analysing the ways in which design rationale could be utilised with the three U.S. regulatory approval process activities for medical devices (A4, A6, and A8). The possible benefits are summarised as follows.

The use of design rationale with the preparation of the marketing application (A4) could provide benefits to the device manufacturers. Device manufacturers could fully document the rationale of the design and development of the medical device that has been manufactured for regulatory approval in the U.S. This captured and documented design rationale for the medical device could be used by different personnel in the organisation who are involved with the development and regulatory approval aspects of the device before the marketing application is submitted to the FDA. Utilising the capabilities of design rationale with the marketing application could provide benefits to the device manufacturers and the FDA by communicating the final design of the medical device and its rationale. This rationale could be reused in the future by device manufacturers to diagnose a problem with an existing device and to identify possible solutions. If the design rationale is captured and documented in parallel with the design of the medical device, this could provide the medical device manufacturers with a method of addressing and resolving issues during the development stages of the device

prior to market approval which could provide significant cost savings due to device recalls, major rework, and possible litigation costs.

Using documented design rationale as part of the device application review (A6) could benefit the FDA. The FDA could use the documented design rationale of the device as part of the device application to validate the device's safety and effectiveness, to understand how the device was designed and to raise any queries related to the design of the device before it is approved for sale in the U.S. market. By utilising design rationale as a way to review the device application, the FDA could reduce the amount of time spent on reviewing vast device design documentation as this could be represented by design rationale. As a result, this could also decrease the time taken to approve a device and the overall time taken for manufacturers to place a medical device on the U.S. market. By querying the design rationale of a medical device during the application review, the FDA could also gain insight into the possible issues related with the device and to prevent them from occurring before the device has been placed on the market, thereby increasing the quality and safety of the device intended for the U.S. market.

Design rationale could provide significant benefits once the device has been placed on the U.S. market (A8). A major benefit of utilising design rationale with activity A8 of the U.S. regulatory approval process for medical devices is to address design issues with a device that has been recalled from the U.S. market. This is where the reuse of design rationale could assist the medical device manufacturers and the FDA to promptly identify the root cause of the problems associated with the recalled device and to propose solutions that address the issues. The opportunities available for the reuse of a design documented using design rationale are significantly increased than compared to a device designed without utilising design rationale.

6.2.3 Utilising Design Rationale Capabilities with the EU Regulatory Approval Process Activities

The thirteen design rationale capabilities were mapped with the seven activities that comprise the EU medical devices regulatory approval process in Table 6-5.

There were there three activities in the EU process (A3 | Prepare Technical Documentation; A5 | Audit QMS and Documentation; and A7 | Market Device) which highlighted that design rationale could be utilised based on its current capabilities. Results from the analysis have indicated that not all of the thirteen design rationale capabilities were applicable at these three activities.

There were twelve design rationale capabilities that were found to be applicable at activity A3 (Prepare Technical Documentation). Eleven capabilities were found to be identically applicable at activities A5 (Audit QMS and Documentation) and A7 (Market Device).

The following subsections individually analyse the three activities (A3, A5, and A7) where the capabilities of design rationale where found to be applicable and presents the benefits of utilising design rationale with the three activities in the EU regulatory approval process.

Table 6-5: Utilising design rationale capabilities with the EU regulatory approval process for medical devices

EU process activity name	Design rationale capabilities												
	A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**	**K**	**L**	**M**
A1 – Classify Device	X	X	X	X	X	X	X	X	X	X	X	X	X
A2 – Implement QMS	X	X	X	X	X	X	X	X	X	X	X	X	X
A3 – Prepare Technical Doc.	X	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
A4 – Appoint EU NB	X	X	X	X	X	X	X	X	X	X	X	X	X
A5 – Audit QMS and Doc.	✓	X	✓	✓	✓	✓	✓	✓	✓	✓	✓	X	✓
A6 – Register Device Details	X	X	X	X	X	X	X	X	X	X	X	X	X
A7 – Market Device	✓	X	✓	✓	✓	✓	✓	✓	✓	✓	✓	X	✓

6.2.3.1 Prepare Technical Documentation

At activity A3, medical device manufacturers wanting to place their medical devices in the EU market could utilise design rationale when preparing the technical documentation.

Twelve capabilities of design rationale could be utilised at activity A3 in the following ways: (1) to show how the reasoning, design knowledge and designers decisions were captured when designing a medical device; (2) to communicate the design aspects of the medical device; (3) to make the reasoning behind the design of the medical device explicit; (4) to show how the reasoning underlying the design of the device was determined; (5) to show how the design decisions, design history, decision-making processes that were made during the design of the medical device were documented; (6) to provide explanations of how the medical device was designed; (7) to provide justification of the argument behind the design decisions made during the design of the device; (8) to provide historical evidence of the device design process; (9) to represent the reasoning underlying the design of the device; (10) to show how the decision-making process and designers decisions were structured during the design of the device; (11) to show the reasoning and argumentation behind the design of the device by using a communication support system; and (12) to teach the EU medical device regulatory authorities about how the device was designed using structured methods for capturing design knowledge.

6.2.3.2 Audit Quality Management System and Documentation

Eleven design rationale capabilities could be utilised in the following ways by the regulatory authorities for medical devices in the EU when auditing the QMS and device documentation at activity A5: (1) to answers questions concerning the design of the device; (2) to review the design relationships, design space, information and logical reasoning; (3) to identify the reasoning behind the design of the device; (4) to realise how the reasoning underlying the design of the device was determined; (5) to review how the design decisions, design history, decision-making processes, design and logical reasoning that were made during the design of the medical device were documented; (6)

to examine explanations of how the device was designed; (7) to view the justification of the argument behind the design decisions that were made during the design of the device; (8) to review historical evidence of the device design process; (9) to view the representation of the reasoning underlying the design of the device; (10) to understand how the decision-making process and designers decisions were structured during the design of the device; and (11) to gain knowledge of how the device was designed.

6.2.3.3 Market Device

Activity A7 was found to have eleven design rationale capabilities that could be applied when placing the medical device in the EU market.

At this activity (A7), the eleven capabilities of design rationale could be utilised by both the device manufacturers and the medical device regulatory authorities in the EU in the following ways: (1) to answers questions concerning a device malfunction after the device has been placed on the EU market; (2) to communicate the design relationships, design space, information and logical reasoning for a device that has been recalled from the EU market; (3) to understand the reasoning behind the design of a device that has been recalled; (4) to determine the reasoning underlying the design of a device that has been recalled; (5) to understand the design history of a device that has been recalled; (6) to provide an explanation of how a device was designed in the event of a device recall; (7) to review the justification of the argument behind the design decisions that were made during the design of the medical device that has been recalled; (8) to view the historical evidence of a device that has been recalled; (9) to review the representations of the reasoning underlying the design of a device that has been recalled; (10) to show how the decision-making processes and designers decisions were structured during the design of a device that has been recalled; and (11) to learn about the design and development of a device that has been recalled from the EU market after receiving regulatory approval.

6.2.3.4 Benefits of Utilising Design Rationale with the EU Regulatory Approval Process Activities

There are a range of benefits available to both the device manufacturers and the regulatory authorities in the EU for utilising design rationale with the three regulatory approval process activities for medical devices in the EU (A3 | Prepare Technical Documentation; A5 | Audit QMS and Documentation; and A7 | Market Device). These benefits are summarised as follows.

Utilising design rationale with the preparation of the technical documentation (A3) could provide benefits to the device manufacturers. Device manufacturers could document the design rationale of the manufactured device as part of the technical documentation for regulatory approval in the EU. This could be used by personnel in the organisation who are involved with the development and regulatory approval aspects of the medical device before the technical documentation is submitted to the EU regulatory authorities. Utilising the design rationale capabilities with the preparation of the technical documentation could provide benefits to the device manufacturers and the EU regulatory authorities by communicating the final design of the device and its rationale. If required, this rationale could be reused by device manufacturers to diagnose a problem with an existing device and to identify possible solutions. Capturing and documenting design rationale in parallel with the design of the device could provide the device manufacturers with a way of addressing and resolving issues during the design and development stages of the device. This could provide significant cost savings due to device recalls, major device rework and any potential litigation costs.

Utilising design rationale with the auditing of the QMS and device documentation (A5) could benefit the regulatory authorities in the EU. The EU medical device regulatory authorities could review the design rationale of the device as part of the device documentation to understand how the device was designed and to raise any queries related to its design before it is approved and certified for sale in the EU. Utilising design rationale as a way to audit the QMS and device documentation, the regulatory authorities could reduce the amount of time spent on auditing documentation. This could also decrease the time taken to approve and certify a device and also decrease the

overall time taken for manufacturers to place a device on the EU market. Querying the design rationale of a device during the audit could provide insight for the regulatory authorities into the possible issues related with the device. This could assist them in preventing them from occurring before the device has been placed on the EU market.

Design rationale could provide significant benefits once the device has been placed on the EU market (A7). A major benefit of utilising design rationale with activity A7 of the EU regulatory approval process for medical devices is to address design issues with a device that has been recalled from the EU market. At this activity (A7), the reuse of design rationale could assist the device manufacturers and the regulatory authorities in the EU to identify the root cause of the issues that are associated with a device that has been recalled.

6.3 Discussion

The discussion is structured in two parts. Firstly, it discusses the proposition of the regulatory approval of medical devices as a novel area of application for design rationale. This is followed by a discussion on the implications that this could present on the future of design rationale research. Discussion on the novel area of application for design rationale addresses the possible utilisation of design rationale with the regulatory approval of medical devices and presents future challenges that need to be addressed by the design rationale research community. The prospective research that is required in order for design rationale to be utilised with the regulatory approval of medical devices is discussed.

6.3.1 Novel Area of Application for Design Rationale

Utilisation of design rationale methods and computational support tools to capture and represent the design decisions of medical devices, so that they can be used with regulatory approval, presents a novel area of application for design rationale, and in particular, the design rationale research community. Accessing a new application

domain for design rationale presents both challenges and benefits for the design rationale research and medical device communities.

In order for medical device manufacturers and regulatory authorities to be able to utilise design rationale methods and tools with the regulatory approval of medical devices, there are several challenges that need to be overcome by the design rationale research community. These challenges include; identifying or developing the most appropriate design rationale methods or frameworks to capture and represent the design decisions of medical devices, integrating design rationale with existing medical device development and regulatory approval practices, identifying the utility and usability of design rationale with the medical device domain, identifying how well design rationale can be put to use with the regulatory approval of medical devices, understanding the requirements and problems currently faced by the medical device community, and providing evidence to the medical device community of the value of design rationale solutions through formal empirical evaluations.

As well as the future challenges facing the design rationale research community, accessing a new application domain could potentially provide many benefits for design rationale research. These benefits are suggested and include; developing and applying dedicated design rationale methods and tools to a highly technical and heavily regulated application domain, dissemination of design rationale research within a new application domain, new opportunities for acquiring funding to advance design rationale research, opportunity for design rationale to have an impact on the way medical devices are currently developed and regulated in the U.S. and EU, and opportunities to liaise and work in conjunction with medical device manufacturers and regulatory authorities thereby disseminating design rationale research to a wider audience.

6.3.2 Implications on Future Design Rationale Research

Accessing a novel area of application such as the medical device domain has implications on future design rationale research. Firstly, design rationale researchers need to work closely with medical device manufacturers and regulatory authorities in

identifying design issues with medical devices that can have a negative impact on them being successfully approved for the U.S. and EU markets. Secondly, researchers need to identify the stakeholders who could benefit from using design rationale and classify how they could use design rationale and integrate it with their existing working practices. Further research needs to be conducted to identify how designers in the medical device domain retrieve and reuse design information and how this design information should be structured so that it can be used for regulatory approval purposes.

Due to the highly technical and scientific nature of complex medical devices such as MRI scanners, researchers need to identify if the existing state-of-the-art in design rationale representation frameworks and tools are feasible for utilisation with such complex medical instrumentation. If not, this could lead to an area of new research in developing bespoke methods and tools or further extending existing ones that enable the capture and representation of the design decisions of medical devices so that it can be used with the regulatory approval activities as identified in this chapter.

6.4 Chapter Summary

This chapter identified the relevant U.S. and EU regulatory approval process activities where design rationale could be utilised and highlighted the potential benefits available to medical device manufacturers and regulatory authorities. This chapter has analysed each of the process activities that constitute the U.S. and EU regulatory approval processes for medical devices and identified the individual activities where design rationale could be utilised. The benefits that are offered to medical device manufacturers and regulatory authorities by utilising design rationale with the current regulatory approval processes for medical devices have been outlined.

This chapter has fulfilled the fourth research objective by analysing how design rationale could be utilised with the regulatory approval of medical devices. Based on the results obtained from the analysis presented in this chapter, the following chapter presents the guidelines that have been developed.

CHAPTER 7

GUIDELINES FOR UTILISING DESIGN RATIONALE WITH THE REGULATORY APPROVAL OF MEDICAL DEVICES

7 Guidelines for Utilising Design Rationale with the Regulatory Approval of Medical Devices

This chapter presents the guidelines that have been developed for utilising design rationale with the regulatory approval of medical devices.

The regulatory approval process activities that were identified as applicable and proposed for utilisation in the previous chapter (Chapter 6), have formed the basis for developing the guidelines that are presented in this chapter. These guidelines provide a generic step-by-step approach for medical device manufacturers and regulatory authorities on how to use design rationale with three key regulatory approval activities.

This chapter reports on the development of the guidelines that can be used by medical device manufacturers and regulatory authorities to capture, represent and review the design decisions in the case of a medical device. In this chapter, the fifth objective of the research is addressed.

This chapter is structured and presented as follows. The focus and the context of the guidelines are firstly defined. Secondly, the methodology followed for developing the guidelines is described. This is followed by the guidelines themselves which present the different stages of the guidelines and the generic steps that have been defined. Following this, the chapter is summarised.

7.1 Focus and Context of the Guidelines

7.1.1 Guidelines Focus

The focus of the guidelines is placed on three key activities that constitute the application of design rationale with the regulatory approval of medical devices. These three key activities were identified from the analysis performed in Chapter 6. In Chapter 6, the analysis identified that design rationale could be utilised with the regulatory approval of medical devices in the following three ways:

1. When developing a medical device or preparing the designated marketing application (U.S.) and technical documentation (EU), medical device manufacturers could capture and represent the design decisions of a medical device.
2. During the review of the marketing application (U.S.) or audit of the quality management system and technical documentation (EU), the regulatory authorities could review the rationale underlying the design decisions that were undertaken during the development of a medical device.
3. Once the medical device has been placed onto the market, design rationale could be used by medical device manufacturers to resolve and/or prevent design issues with a device that has been recalled.

Figure 7-1 illustrates the integration of design rationale and the interconnections of the three key activities addressed by the guidelines presented in this chapter.

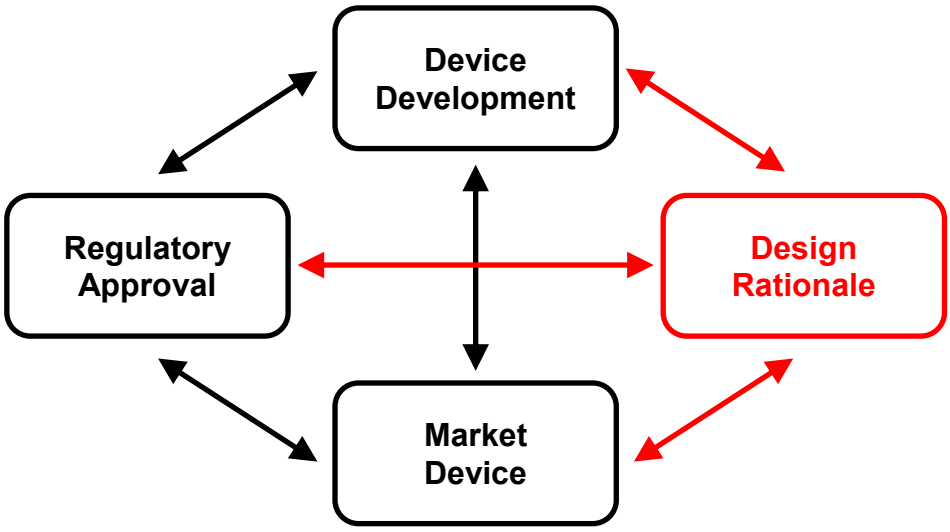

Figure 7-1: Focus of design rationale integration with the designated medical device regulatory approval activities

The guidelines are primarily intended for medical device regulatory authorities in the U.S. and EU, medical device manufacturers, in particular, designers, engineers, regulatory approval specialists, and project managers involved in the development and regulatory approval of medical devices. However, other technical specialists, such as

those involved in device research and development, quality management, and manufacturing, could find the guidelines of use.

It is anticipated that manufacturers involved in medical device development will benefit by adopting the guidance provided by the guidelines in order to incorporate design rationale with their existing working practices.

The guidelines may also be particularly useful for designers and researchers in other application domains, where little guidance exists on the utilisation of design rationale to communicate design decisions.

7.1.2 Goal of the Guidelines

The goal of the guidelines is to provide guidance and support in order to communicate design decisions in the case of a medical device.

7.1.3 Guidelines Intentions

The intentions of the guidelines are to:

1. Provide a descriptive step-by-step approach on how to utilise design rationale to capture and represent the design decisions of a medical device.
2. Describe the factors that need to be considered when reviewing the design decisions of a medical device.
3. Explain the steps necessary in order to utilise design rationale to resolve and/or prevent a design issue with a medical device.

Having defined the focus, goal and intentions of the guidelines in this section, the following section describes the steps that have been followed in order to develop the guidelines.

7.2 Guidelines Development Methodology

The methodology followed for developing the guidelines to utilise design rationale with the regulatory approval of medical devices is presented in this section as follows. First of all, the constituents that have formed the basis for the guidelines are described. This is followed by a description of how the structure of the guidelines has been fundamentally created.

7.2.1 Forming the Guidelines

There are two main constituents that have formed the basis for developing the guidelines. The first is the regulatory approval process activities that were identified from the analysis presented in Chapter 6 and discussed in section 7.1.1.

The analysis in Chapter 6 investigated the possibilities of utilising design rationale with the U.S. and EU regulatory approval processes for medical devices and identified three key activities where design rationale could be utilised and the intended users who would benefit from its utilisation. Significantly, the analysis also identified how design rationale could be utilised at each of the three activities and how it could be integrated into the existing working practices by medical device manufacturers and regulatory authorities in the U.S. and EU.

In addition, the second constituent that has been used to form the guidelines is published literature in the areas of design rationale and medical device practices. Descriptions regarding design rationale capture and representation, issue resolution, solution synthesis, and reviewing argumentation-based notations for medical device applications, have been extracted directly from the literature and synthesised to form the guidelines.

The literature used and referenced in this chapter was identified and reviewed in Chapter 2 of this thesis. Data was extracted from the literature listed in Table 7-1. The authors, the title of the published article and a description of the articles are provided (Table 7-1).

Table 7-1: List of identified literature that has been used to form the guidelines

Authors (date)	Article title	Description of articles
Bracewell *et al*. (2009)	Capturing design rationale	Provided descriptions of how design rationale can be captured & represented.
Weinstock and Goodenough (2009)	Towards an Assurance Case Practice for Medical Devices	Explored the use of assurance cases for justifying claims of medical device safety.

The process of extracting and synthesising the data from the literature involved the following stages. Firstly, the articles were fully examined as described in Chapter 2 (section 2.1.3). The parts of the articles that were considered relevant in supporting the formation of the guidelines were manually highlighted so that they could be referred to as and when necessary without repeating the process of fully examining them.

Secondly, the highlighted texts were then extracted from the articles and categorised into three categories, each representative of the three key activities and goals that are the focus of the guidelines. The categories (activity names), guidelines goals, and the reference to the literature indicating the data source that has been used to address each of the objectives is listed in Table 7-2.

Table 7-2: List of derived categories

Category name	Guidelines goals (no.)	Authors (date)
Device Development	Capture and represent the design decisions of a medical device (1)	Bracewell *et al*. (2009)
Regulatory Approval	Factors that need to be considered when reviewing medical devices (2)	Weinstock and Goodenough (2009)
Market Device (Device Recall)	Utilising design rationale to resolve and/or prevent a design issue (3)	Bracewell *et al*. (2009)

The published literature was selected and used as a basis to form the guidelines based on, firstly, the information relevant to development of the guidelines that the articles offer, and secondly, the success of the DRed design rationale tool developed and employed into industrial practice and the FDA's recent recommendations to use assurance case practices to demonstrate the safety of medical devices. Figure 7-2 illustrates an actual representation of captured rationale using the DRed tool in the aerospace industry.

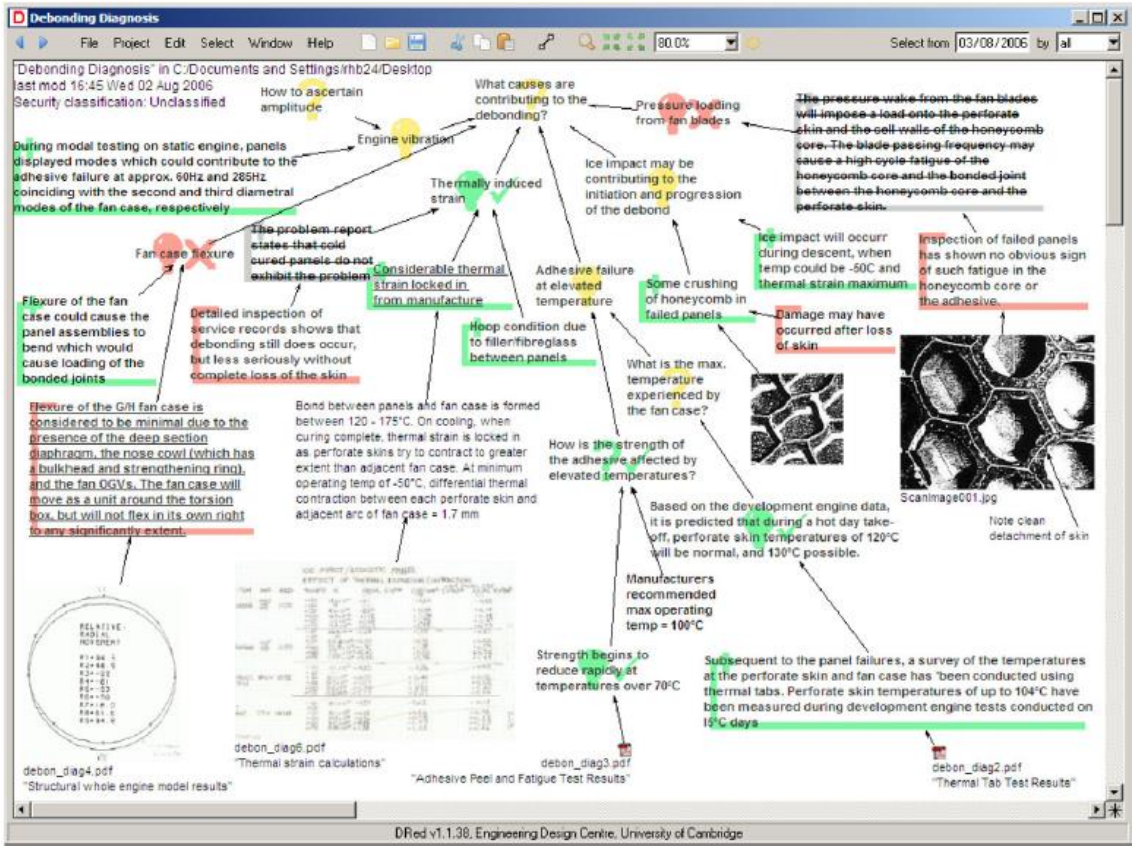

Figure 7-2: DRed representation of captured rationale (Bracewell *et al.*, 2009)

The descriptions extracted from the literature (Bracewell *et al*., 2009; Weinstock and Goodenough, 2009) have been adapted and generically arranged in order for them to be applicable for forming the guidelines which are mainly aimed at medical device manufacturers and regulatory authorities, who are the intended users. For example, Bracewell *et al*. (2009) have presented an account of how design rationale was routinely captured in the aerospace industry. From the literature itself, this account has been

extracted, arranged, and written in the form of what a designer needs to do in order to capture the design rationale of a generic product, in the instance of the guidelines presented in this chapter, a medical device.

The guidelines themselves do not make reference to the extracted descriptions or the literature that they were extracted from, however the explicit listing of the literature referenced (Table 7-1) and derivation of the categories (Table 7-2) indicates how the guidelines have been formed. The referenced literature can be referred to for more information.

On completion of the data extraction and categorisation, a structure for the guidelines was created and is described in the following subsection.

7.2.2 Creating the Guidelines Structure

In order for the guidelines to be developed so that they can be followed by medical device manufacturers and regulatory authorities, a coherent structure containing different stages has been created to illustrate who should utilise design rationale (user) and where (activity) it is to be utilised. This structure is founded on the three key activities, the intended users of the guidelines, and the goal and intentions of the guidelines.

The guidelines have been structured and defined into the following three stages:

- **Stage 1:** describes the approach in which to capture and represent the design decisions of a medical device. This initial stage of the guidelines is intended for medical device manufacturers.
- **Stage 2:** outlines the factors that need to be considered when reviewing the design decisions of a medical device. This stage is intended for the regulatory authorities.
- **Stage 3:** explains how to utilise design rationale to resolve and/or prevent a design issue with a medical device that has been recalled from the market. This final stage of the guidelines is intended for medical device manufacturers.

The three stages that comprise the guidelines are illustrated in Figure 7-3. Figure 7-3 shows how the guidelines are structured into three sequential stages. These sequential stages emphasize that there is directionality offered by the guidelines which is representative of the regulatory approval processes which were modelled in Chapter 5. In Figure 7-3, the three key activities which have formed the basis for the guidelines are named and highlighted and the intended users of the guidelines are listed.

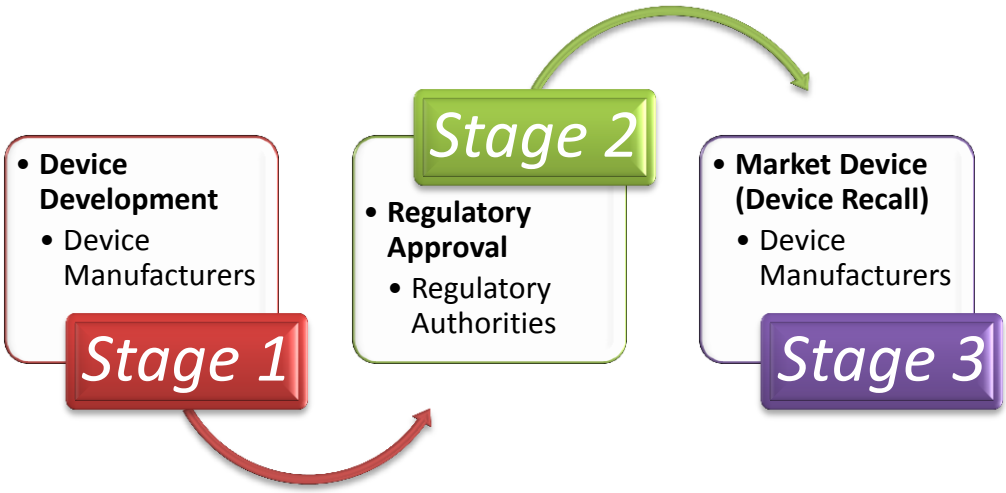

Figure 7-3: Stages comprising the guidelines structure

Within the three separate stages, each of which reflects the key activities and goals addressed by the guidelines, the guidelines themselves have been structured (written) as 'steps'. The steps indicate the actions that are required by the intended user of the guidelines in order to utilise design rationale to either; capture and represent the design decisions of a medical device, review the design decisions of a medical device, diagnose a problem with a device, and design a solution to resolve and/or prevent the problem from reoccurring.

Each of the steps within the individual three stages is labelled (named to indicate the action that is to be undertaken) and assigned a numerical identifier beginning with the number 1 and ending with the final number in the sequence of steps (Step 1 to Step 'n'). For ease of clarity, the guidelines have been written and complied using bullet points

and indentation to show the numerous steps that comprise each stage. The three stages have also been individually named as follows:

Stage 1 - Capturing and Representing the Design Decisions of a Medical Device
Stage 2 - Reviewing Design Decisions
Stage 3 - Diagnosing a Problem and Designing a Solution

In order to illustrate how the guidelines have been structured according to the development approach presented in this section, an example is provided below:

- **Stage 1:** Capturing and Representing the Design Decisions of a Medical Device
  - ***Step 1:*** *Identify design rationale representation framework*
    - [Description of how medical device manufacturers are to identify the state-of-the-art in design rationale representation frameworks]
  - ***Step 2:*** *[Name of guidance step]*
    - [Description of how medical device manufacturers are to perform the necessary action required at this step]

This section has presented the methodology that has been developed and followed in order to develop the guidelines that are to be used for utilising design rationale with the regulatory approval of medical devices. The following section in this chapter presents the guidelines.

7.3 The Guidelines

In this section, the guidelines that have been developed for utilising design rationale with the regulatory approval of medical devices are presented. The guidelines consist of three stages, each describing the individual steps necessary in order to utilise design rationale to capture and represent the design decisions in the case of medical devices. These guidelines are primarily intended for medical device manufacturers and regulatory authorities.

The guidelines are presented as follows. An overview of the guidelines is initially provided which describes the intent of the guidelines. This is followed by a description

on how to use the guidelines with existing working practices. Following this, the three stages of the guidelines are presented in the following order. Firstly, Stage 1 of the guidelines provides guidance on how to capture and represent the design decisions of a medical device. Secondly, Stage 2 of the guidelines describes the steps necessary in order to review the design decisions of a medical device. Finally, Stage 3 of the guidelines provides details on how to utilise design rationale to resolve and/or prevent a design issue with a device that has been recalled from the market.

7.3.1 An Overview of the Guidelines

The guidelines provide a generic top-level approach to utilising design rationale with the regulatory approval of medical devices. This top-level approach does not provide a detailed description (how to use specific representation frameworks and computational support tools), but instead provides a generic step-by-step approach in which the intended users of the guidelines can follow in order to gain an understanding of how the concept of design rationale can be utilised with three key activities that constitute the regulatory approval processes for medical devices in the U.S. and EU.

The guidelines are divided into the three numerical stages, each of which targets the following three key regulatory approval activities: (Stage 1) Device Development; (Stage 2) Regulatory Approval; and (Stage 3) Market Device (Device Recall). Each of the stages is intended for the following users: (Stage 1) Medical Device Manufacturers; (Stage 2) Regulatory Authorities; and (Stage 3) Medical Device Manufacturers (Regulatory Authorities). The individual stages of the guidelines incorporate the use of primary ‘guidance steps’ which are sequenced in numerical order. These indicate the order in which to perform the necessary actions in order to: (Stage 1) Capture and Represent the Design Decisions of a Medical Device; (Stage 2) Review Design Decisions; and (Stage 3) Diagnose a Problem and Design a Solution.

A schematic illustrating the overview of the guidelines is presented in Figure 7-4. In the schematic (Figure 7-4), the 3 stages that are the focus of the guidelines are presented (stages 1, 2 and 3). The schematic details the stage number and name, activity name,

and implementation responsibility (designated personnel required to perform the activity – medical device manufacturers and/or regulatory authorities). Figure 7-4 shows that the stages are to be sequentially performed beginning at stage 1 and it also illustrates the interrelationships between the three stages and their crossover elements.

Firstly, the design decisions for a medical device are to be captured and represented by the device manufacturers during its development by using stage 1 of the guidelines. These captured design decisions are then to be submitted by the device manufacturers with the existing device documentation to the relevant regulatory authorities (directional arrow labelled | 1-2).

Secondly, these design decisions along with the appropriate device documentation are to be reviewed by the regulatory authorities (stage 2). If the regulatory authorities are not satisfied with any aspect of the captured and represented design decisions, or if there is any dispute with any of the decisions made by device manufacturers, the regulatory authorities can request that device manufacturers make the necessary changes to satisfy regulatory requirements (arrow | 2-1).

The two directional arrows between stages 1 and 2 (arrows | 1-2 and | 2-1) indicate that iterations could occur when regulatory authorities are reviewing the design decisions. The primary implementation responsibility at stage 2 is directed at the regulatory authorities. However the device manufacturers will be notified of any inconsistencies with the design decisions by the regulatory authorities at this stage. Once the device has been approved for market, the device manufacturers can then place the device onto the market (arrow | 2-3).

Once placed onto the market, if a problem is identified with the device or it is recalled from the market by the regulatory authorities and/or device manufacturers, both device manufacturers and regulatory authorities could reuse the previously captured design decisions to identify the root cause of the problem for which the device was recalled (stage 3 of the guidelines). Primarily at stage 3, it is the responsibility of the device

manufacturers to diagnose a problem and to design the corrective solution to resolve the issue surrounding the device recall.

Once the problem has been diagnosed and a solution has been designed and the new design decisions have been captured and represented, the device manufacturers can then submit the updated design decisions to the regulatory authorities notifying them of the changes made to the devices design (arrow | 3-2). The regulatory authorities can then review the design decisions (stage 2) before either reapproving the device for market, or rejecting it from further market access.

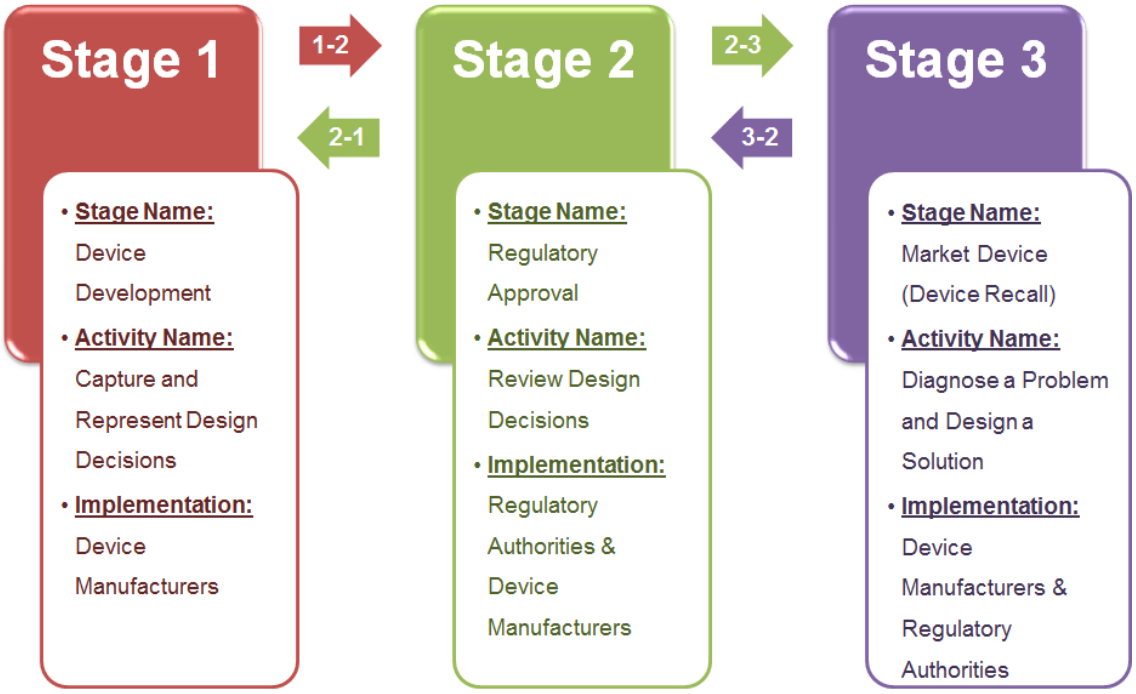

Figure 7-4: Schematic of the guidelines for utilising design rationale with the regulatory approval of medical devices

7.3.2 How to Use the Guidelines

It is intended that the guidelines be used by medical device manufacturers and regulatory authorities in conjunction with existing working practices and in addition to the different regulatory approval routes for medical devices in the U.S. and EU. It should be noted that as a consequence, the extent with which and the approach in which the guidelines are to be adopted is very much at the user's discretion.

The generic practice of capturing and representing the design decisions of a medical device is explained step-by-step in Stage 1 of the guidelines. This should be of general interest as well as of use for understanding how to generically capture and represent the design decisions of an artefact or product.

The steps specified in Stage 2 of the guidelines give details on the actions required in order to review the design decisions of a medical device. The steps defined in Stage 2 will help to assure that the regulatory authorities can understand the structure by which the design decisions of a medical device have been represented.

Stage 3 of the guidelines details the steps necessary in order to utilise design rationale to diagnose a problem with a medical device that has been recalled from either the U.S. or EU markets. This stage of the guidelines also presents the different steps required to design a solution.

7.3.3 Stage 1 of the Guidelines – Capturing and Representing the Design Decisions of a Medical Device

Stage 1 of the guidelines provides the steps necessary for medical device manufacturers to capture and represent the design decisions that were undertaken during the development stages of a medical device.

It is intended that these captured design decisions could be structured by using a design rationale representation framework and be used as part of the device documentation required for regulatory approval in the U.S. and EU. Once captured, this rationale for the developed device could be referred to in the future as and when necessary by the medical device manufacturers. The guidelines presented in Stage 1 provide the basic guidance steps in order for medical device manufacturers to capture and represent the design decisions of a medical device.

Stage 1:

Capturing and Representing the Design Decisions of a Medical Device

- ***Step 1:*** *Select the product or device that has been, or is currently being developed.*
  - To begin the process of capturing and representing the design decisions for a medical device, first select the specific device that is being developed or has been developed and requires regulatory approval in order to be placed onto the market.
- ***Step 2:*** *Identify the team members that are/were involved in the design and development of the product or device.*
  - Collect the names and details of all the personnel involved in the development of the device. Each of the personnel involved during the design and development stages of the medical device will have data or access to the data concerning the design and development stages of the device. This data will have the rationale underlying the design and development of the device.
- ***Step 3:*** *Organise a team of personnel (ideally, the team members that are/were involved in the design and development of the product or device) to perform the task of capturing and representing the design decisions.*
  - In order to capture and represent the design decisions for a medical device, there needs to be an individual or a group of people in order to perform the task. Team members should ideally consist of designers, engineers, and project managers who were involved during the device's development stages.
- ***Step 4:*** *Gather all of the design data concerning the product or device from the team members in '**Step 2**' and any other identifiable data sources.*
  - The rationale underlying the design and development of the device can be found in and sourced from engineering drawings, documents, emails, models, databases, including colleagues.
- ***Step 5:*** *Organise the design data into different categories, each category reflecting an integral part (component, module) of the product or device.*

- Once the design data has been gathered, divide the datasets into categories which highlight the different integral parts of the device. This is to simplify the design decisions into key parts of the device that will make it easier for reviewers to follow and analyse. Also, this makes it useful for traceability at a later date if the design on a particular part of the device is altered. The rationale for this particular change can be amended without having to alter the entire design argument.

- ***Step 6:*** *Identify and classify the design decisions undertaken during product or device development according to the designated categories defined in '**Step 5**'.*
  - Go through the design data of the device to identify the design decisions that were taken during the device's development and classify each of the decisions based on an integral part of the device. This classification helps to determine which decisions were made regarding each unique part of the device.
- ***Step 7:*** *Identify the available design rationale representation frameworks and computational support tools.*
  - There are a variety of state-of-the-art design rationale representation frameworks available and subsequent computational support tools based on the representation notations. Information of these frameworks can be found in the literature and online (WWW). The representation frameworks that are widely used are: Issue-Based Information System (IBIS), Procedural Hierarchy of Issues (PHI), Questions, Options, and Criteria (QOC), and Decision Representation Language (DRL).
- ***Step 8:*** *Select the relevant design rationale representation framework and computational support tool to represent the design decisions of the selected product or device.*
  - Once the state-of-the-art in design rationale representation frameworks have been identified, a selection of the most relevant framework is required. The selection can be made based on the current domain coverage of the frameworks or by identifying the structure that is most relevant to represent the design decisions for a medical device.
- ***Step 9:*** *Select one of the designated categories which reflect an integral part of the product or device.*

- This is to be used in the following step for representing the design decisions of the integral part of the device.

- ***Step 10:*** *Identify the initial steps in representing the design argument and subsequent decisions as suggested by the underlying theory of the selected design rationale representation framework.*
  - To represent the design decisions for a medical device by using design rationale, the theory of the representation framework needs to be understood. Different frameworks begin the representation in their own unique ways and follow a structure that is bespoke. For example, the IBIS methodology requires the definition of a top-level issue. Each framework has its own way of constructing and representing a design argument.
- ***Step 11:*** *Construct the design argument, directly with the computational support tool, according to the structure of the selected design rationale representation framework by using the design decisions that were extracted from the available design data.*
  - More recently, computational support tools based on existing representation framework notations are available on the WWW and can be downloaded. These tools can be used to directly construct a design argument which shows the design decisions taken during the development of a medical device without having to use a paper-based system. This saves time and effort on the part of the team who are performing the task of design decision capture and representation.
- ***Step 12:*** *Repeat '**Step 11**' for the different categories which are related to the different integral parts of the product or device.*
  - This step is to be repeated for each of the different integral parts of the device so as to capture and represent the different parts that constitute the whole device.
- ***Step 13:*** *Verify the design decisions for each of the integral parts of the product or device.*
  - On completion of capturing and representing the design decisions for the medical device, these decisions require verification before they are to be used and submitted with the device documentation for regulatory approval. To

accomplish the verification of the design decisions, show the captured design decisions to the team involved in the development of the device to confirm the decisions before being released to the regulatory authorities. This could be considered to be an internal verification process within the medical device manufacturing company.

- ***Step 14:*** *Save and retain all soft copies and hard copies of the captured design decisions that have been represented using design rationale.*
  - Use the computational support tool to save and print the captured design decisions and keep all copies for future use, as they may be required at a later time, for example, if the design changes or the device is recalled from the market.
- ***Step 15:*** *Compile and add the design rationale documentation (design decisions represented by utilising design rationale) with the existing design documentation required for regulatory approval purposes.*
  - Embed the captured and represented design decisions within the existing documentation required for regulatory approval as additional information for the regulatory authorities.
- ***Step 16:*** *Submit all relevant product or device documentation to the required regulatory authorities as specified in the regulatory requirements.*
  - All device documentation required for regulatory approval should be submitted to the regulatory authorities as specified.

7.3.4 Stage 2 of the Guidelines – Reviewing Design Decisions

Stage 2 of the guidelines details the individual steps required for the regulatory authorities, in particular of medical devices, to review the design decisions that were captured by the medical device manufacturers and represented using design rationale representation frameworks.

The steps presented in this stage of the guidelines outline the factors that need to be considered when reviewing the design decisions of a medical device. In order for design rationale to be utilised with the regulatory approval of medical devices, adopting design

rationale to represent the design decisions of a medical devices necessarily requires that there be way to review them. In order to accept design rationale documentation as part of the regulatory approval documentation and practices for medical devices, the reviewer must be able to understand it, be convinced that the design decisions are concise, and supported by the necessary evidence.

The guidelines in Stage 2 provide the fundamental steps in order for the regulatory authorities in the U.S. and EU to review the design decisions that were undertaken by medical device manufacturers during the development of a medical device.

Stage 2:

Reviewing Design Decisions

- ***Step 1:*** *Verify that the design rationale documentation is structurally complete and that the node phrasing in each representation is correct.*
  - Check to see that every node can be traced back to the top-level claim and that each 'leaf' node is either evidence or reference to some previously reviewed design rationale documentation.
- ***Step 2:*** *Validate the claims being made.*
  - Ensure that the claims are expressed as simple predicates and that evidence is a noun phrase (not stated as a claim). Checking that claims and evidence nodes are correctly phrased guards against confusion when later considering the substance of the design rationale documentation.
- ***Step 3:*** *Review the design arguments and design decisions for all of the integral parts and components of the medical device.*
  - Review the design rationale documentation to consider whether the design decisions and resulting arguments are persuasive. An argument is persuasive if each claim follows from the claims or evidence supporting it.

Persuasiveness is best achieved when the associations between claims are made obvious.

- ***Step 4:*** *Check for the incompleteness of design arguments, design decisions, and supporting evidence.*
  - Ensure that the design argument and design decisions, including the claims and evidence are complete. If a design argument breaks claims into sub-cases and argues each of the sub-cases separately, the design argument is defective if all the sub-cases are not actually addressed.
- ***Step 5:*** *Check the design rationale for robustness.*
  - Verify if a claim is supported by independent arguments/evidence (e.g., by test results and by modelling analysis). If so, the claim is more likely to hold, since a defect in one branch of the supporting argument will not impair the validity of the other branches. To the extent that proposed supporting arguments are not independent, the claim is more weakly supported than it might at first appear.

7.3.5 Stage 3 of the Guidelines – Diagnosing a Problem and Designing a Solution

Stage 3 of the guidelines describes the steps necessary in order to utilise design rationale to diagnose a problem with a medical device that has been recalled from either the market. This stage of the guidelines also presents the different steps required to design a solution in order to resolve the identified problem and/or prevent the problem from reoccurring.

The guidelines in Stage 3 provide the essential steps for medical device manufacturers to utilise design rationale to identify a problem with a medical device, resolve the issue so that it does not reoccur, and demonstrate to the regulatory authorities that the device is safe and effective for use.

Stage 3:

Diagnosing a Problem and Designing a Solution

- ***Step 1:*** *Define the problem focus that is associated with the product or device.*
  - First step in diagnosing the problem associated with the device that has been recalled is to define the problem statement. This statement should specify the exact nature of the device recall. The problem can be identified from the reason behind the recall of the device from the market by the regulatory authorities or actual users of the device, i.e. from the public domain or clinicians and physicians.
- ***Step 2:*** *Identify personnel involved in the design and development of the product or device that has been recalled from the market.*
  - Collect the names and details of all the personnel involved in the development of the device. Each of the personnel involved during the design and development stages of the medical device will have data or access to the data concerning the design and development stages of the device. This data will have the rationale underlying the design and development of the device.
- ***Step 3:*** *Select personnel to perform the task of diagnosing the problem and designing a solution.*
  - In order to diagnose the reported problem and design a solution for the recalled medical device, there needs to be an individual or a group of people in order to perform the task. Team members should ideally consist of designers, engineers, and project managers who were involved during the device's development stages.
- ***Step 4:*** *Prepare a problem report which describes the problems associated with the recalled product or device.*
  - The problem report should explicitly state the exact nature of the problem associated with the device that has been recalled from the market. This report should provide details such as; reason for recall, when and how the problem

was identified, how many products have been affected, any serious injuries as a result of the device recall, and list any possible causes for the problem.

- ***Step 5:*** *Retrieve all design documentation and any previously captured rationale of the product or device that has been recalled.*
  - Gather all of the necessary documentation that is associated with the recalled device and any previously captured rationale as this is to be used to trace the history of the design and development of the device.
- ***Step 6:*** *Review the design documentation and any previously captured rationale.*
  - Perform a thorough review and analysis of the design documentation to identify the design decisions that were made during the development stages. Extract these decisions from the design documentation during the review. Segregating the design decisions for the different parts that comprise the device is a useful way to organise the decisions based on individual parts or components.
- ***Step 7:*** *Identify the available design rationale representation frameworks and computational support tools.*
  - There are a variety of state-of-the-art design rationale representation frameworks available and subsequent computational support tools based on the representation notations. Information of these frameworks can be found in the literature and online (WWW). The representation frameworks that are widely used are: Issue-Based Information System (IBIS), Procedural Hierarchy of Issues (PHI), Questions, Options, and Criteria (QOC), and Decision Representation Language (DRL).
- ***Step 8:*** *Select the relevant design rationale representation framework and computational support tool to represent the design decisions (diagnosis of the problem and design of the solution) of the selected product or device.*
  - Once the state-of-the-art in design rationale representation frameworks have been identified, a selection of the most relevant framework is required. The selection can be made based on the current domain coverage of the frameworks or by identifying the structure that is most relevant to represent the design decisions taken to diagnose a problem and to design a solution for a medical device.

- ***Step 9:*** *Form theories about the potential causes of the problem and highlight all known design issues.*
  - Begin to form some theories about what some of the potential causes of the problem could be and list them in an order of likelihood. Start searching for evidence to support or refute the theories. Make a list of the known design issues with the devices, if any are known and made available.
- ***Step 10:*** *Depending on the selected design rationale representation framework, define the top-level issue to be resolved – for example, "What is causing the issue of…"*
  - To represent the design decisions for a medical device by using design rationale, the theory of the representation framework needs to be understood. Different frameworks begin the representation in their own unique ways and follow a structure that is bespoke. For example, the IBIS methodology requires the definition of a top-level issue. Each framework has its own way of constructing and representing a design argument. At this step, define the top-level issue, i.e. what is causing the reported problem.
- ***Step 11:*** *Construct the design argument, using the formed theories as an initial basis, directly with the computational support tool according to the structure of the selected design rationale representation framework.*
  - Use the computational support tool, which is based on an existing design rationale representation framework to directly construct a design argument showing the design decisions taken to diagnose the reported problem with the recalled.
- ***Step 12:*** *Generate the various hypotheses regarding the diagnosis of the problem (top-level issue).*
  - Use the representation frameworks structure in order to construct the argument showing the various hypotheses that have been generated regarding the diagnosis of the problem.
- ***Step 13:*** *Develop the respective pro and con statements to support or refute each of the generated hypotheses providing adequate evidence in support of each statement.*

- Build the design argument showing the process of diagnosing the problem using answers and pro and con statements to either support or refute each of the generated hypotheses.

- ***Step 14:*** *Resolve all issues with an answer and/or pro and con statements.*
  - Do not leave any unresolved issues. Ensure all issues are resolved with either an answer that is linked with a pro or con statement.
- ***Step 15:*** *Verify the diagnosis of the problem with the recalled product or device.*
  - Go through each of hypotheses and resultant decisions to verify that all raised issues have been resolved and that the top-level issue has been resolved. In the case of the diagnosis, the question as to what has caused the design problem has been answered using evidence in support.
- ***Step 16:*** *Highlight that the top-level issue is resolved or it is insoluble.*
  - If the top-level issue cannot be resolved for any reason, label it as insoluble. This will provide indication that further studies need to be conducted to address the issue.
- ***Step 17:*** *To design a solution in order to resolve the diagnosed problem, define a new top-level issue – for example, "How to stop…"*
  - Raise a top-level issue that aims to address the questions of how to solve the reported problem. The solution is directly related to the reported problem, in that it aims to solve the problem that has been identified and diagnosed with the device.
- ***Step 18:*** *Generate various hypotheses regarding the possible resolution of the defined top-level issue.*
  - Use the representation frameworks structure in order to construct the argument showing the various hypotheses that have been generated regarding possible solutions to address the diagnosed problem.
- ***Step 19:*** *Develop the respective pro and con statements to support or refute each of the generated hypotheses providing adequate evidence in support of each statement.*
  - Build the design argument showing the process of diagnosing the problem using answers and pro and con statements to either support or refute each of the generated hypotheses.

- ***Step 20:*** *Verify the solution.*
  - Go through each of hypotheses and resultant decisions to verify that all raised possible solutions have been address and that the top-level issue has been resolved. In the case of designing a solution, the question as to how to stop the problem from reoccurring has been answered using evidence in support.
- ***Step 21:*** *Prepare a narrative description of the solution, complete with details such as rework procedures required to apply the solution to the device(s) or products that have been recalled from the market.*
  - Being narrative, these descriptions are best written as standard word-processed reports.
- ***Step 22:*** *Inform the regulatory authorities of the changes made to the product or device and submit the generated rationale documentation of the diagnosis and solution with the any other documentation as required by the regulatory authorities.*
  - Inform the regulatory authorities that the problem with the recalled device has been diagnosed and a solution has been designed and implemented so the problem will not reoccur again.

7.4 Discussion

This section presents a discussion on the descriptive guidelines that have been developed and presented in the preceding section this chapter.

The descriptive guidelines have been structured into three stages and consist of numerous guidance steps for each of the three stages. There are sixteen steps present in stage 1 of the guidelines, five steps for stage 2, and a total of twenty-two steps which comprise stage 3 of the guidelines. These steps have been derived from the literature and present the necessary actions required by medical device manufacturers and regulatory authorities to utilise design rationale with the regulatory approval of medical devices. Each of the three stages has been specifically structured and defined according to the findings of the research presented in Chapter 6.

Stage 1 of the guidelines has been developed to provide the steps necessary for medical device manufacturers to capture and represent the design decisions that were undertaken during the development stages of a medical device. Stage 2 of the guidelines details the individual steps required for the regulatory authorities to review the design decisions of a medical device that have been represented using design rationale. Stage 3 of the guidelines describes the steps necessary in order to utilise design rationale to diagnose a problem with a medical device that has been recalled from the market.

The three stages of the guidelines all correspond with the activities that were identified in the analysis (Chapter 6) which investigated where in the regulatory approval process for medical devices design rationale could be utilised. These three stages of the guidelines were particularly structured according to the activities identified from the analysis and aimed at the target users who were to undertake those activities, i.e. medical device manufacturers and regulatory authorities.

The structure of the guidelines has been illustrated using a schematic diagram which shows; the medical device activity that each stage of the guidelines is targeted at addressing, the guidance provided at each activity, and who the guidance is intended for. Each stage addresses the necessary actions required from medical device manufacturers and regulatory authorities.

7.5 Chapter Summary

In order to address the gaps identified in existing knowledge from the literature reviewed in Chapter 2 and the aim and fifth objective of the research, a descriptive set of guidelines for utilising design rationale with the regulatory approval of medical devices have been developed and presented in this chapter.

These guidelines provide a generic step-by-step approach for medical device manufacturers and regulatory authorities on how to use design rationale with three key regulatory approval process activities; device development, regulatory approval, and market device (device recall). The guidelines consist of three stages, each of which

targets a key regulatory approval process activity. Each of the three stages is comprised by a number of descriptive steps which uniquely detail the requisite actions necessary from both medical device manufacturers and regulatory authorities in order to utilise design rationale.

The guidelines presented in this chapter are the result from the research that has been systematically conducted and presented throughout the chapters of this thesis. The findings from the research presented in the different chapters have been synthesised in order to form the guidelines, thereby partially fulfilling the aim of the research. Validation of the guidelines is required to fully address the aim of the research.

The following chapter describes the adopted approach taken by the author to validate the guidelines that were presented in this chapter.

CHAPTER 8

VALIDATION

8 Validation

This chapter presents the validation of the research based on the opinions of researchers and experts from a variety of design contexts. The guidelines developed in the previous chapter have been validated to present a comprehensive understanding on the steps required to capture, represent and review the design decisions in the case of medical devices. This chapter addresses the final objective of the research.

The previous chapter (Chapter 7) developed and presented a set of guidelines that were to be followed in order to capture, represent and review the design decisions in the case of medical devices.

The guidelines were targeted at three key medical device activities, consisted of three separate stages, each of which were dedicated to a particular activity, and were comprised of a series of descriptive guidance steps. This chapter presents the approach taken to validate the guidelines that were developed and presented in Chapter 7.

In this chapter, the guidelines that have been developed are validated. The validation of the guidelines has been performed by academics, researchers and medical device experts.

This chapter is presented as follows. First of all, the methodology followed for validating the guidelines is described. This is followed by the presentation and a detailed analysis of the results which have been obtained from the validation process. Additional information obtained during the validation process is presented in conjunction with the analysis of the results. Following this, the results obtained from the validation are discussed. Finally, this chapter is summarised.

The structure of this chapter is illustrated in Figure 8-1.

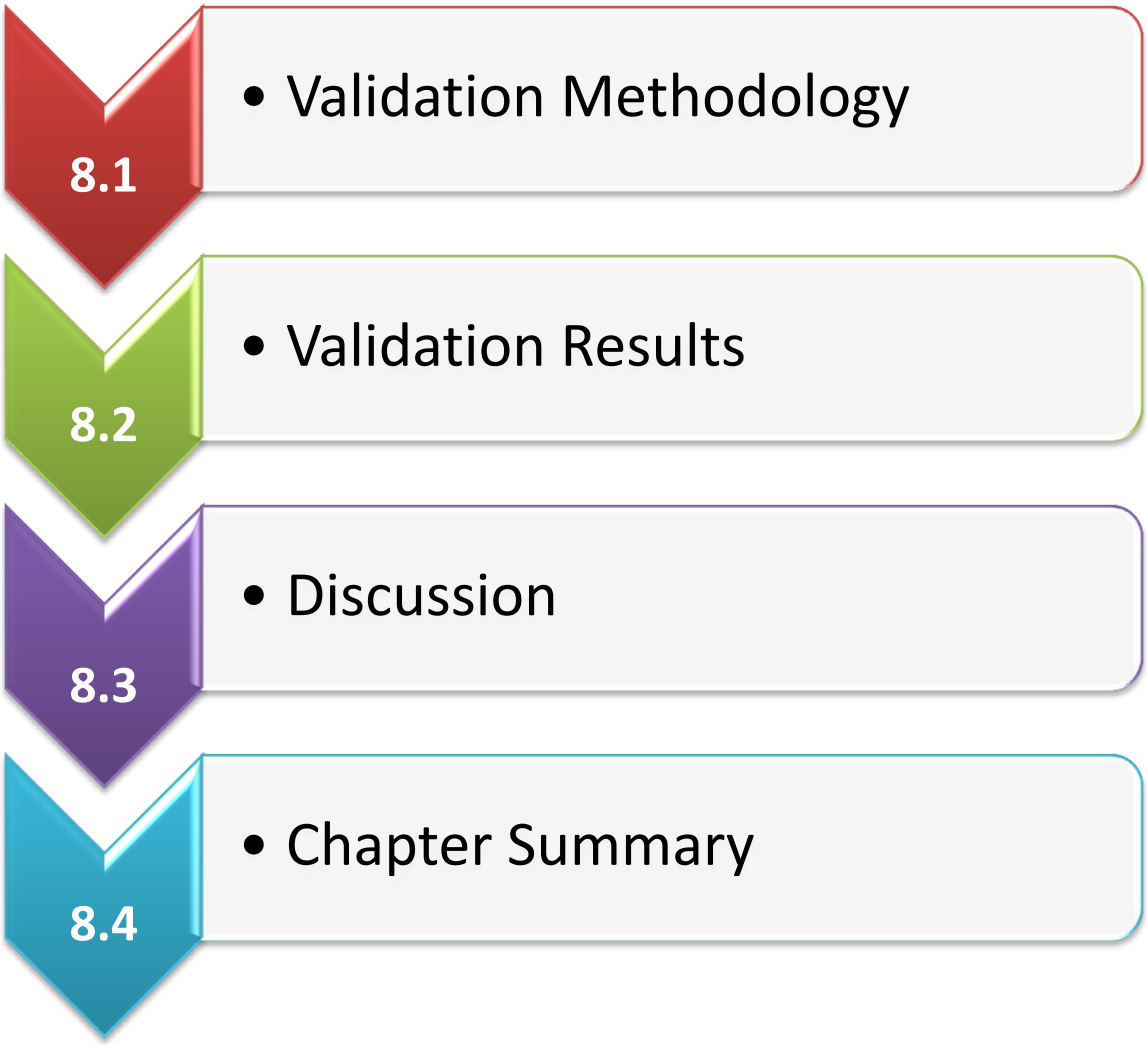

Figure 8-1: Structure of validation chapter

8.1 Validation Methodology

The methodology developed and followed for validating the guidelines is presented in this section. The methodology utilises academics, researchers, and medical device experts to perform the validation of the guidelines. This approach ensures the validity of the guidelines by obtaining the opinions and feedback from the experts and researchers.

Details of the methods followed for the stages in validating the guidelines are presented in the following subsections as follows. Firstly, the method and underlying rationale behind the participant selection to validate the guidelines is explained. This is followed

by a description of how the participants (academics, researchers, and medical device experts) opinions and feedback is to be obtained. Following this, the approach taken to analyse the feedback and opinions from the experts is outlined. This is followed by the utilisation of the guidelines to capture and represent the design decisions of medical devices.

8.1.1 Participant Selection

The initial stage of the approach taken to validate the guidelines required participants to answer the questions in the validation questionnaire. This was performed to ensure that the guidelines could be understood and followed by practitioners. Ten participants were invited to attend a validation workshop which was held on the 21st of September 2012 at Cranfield University, U.K. Further details on the delivery of the questionnaire and completion can be found in section 8.1.2.2.

The participants that were invited to attend the validation workshop were from different schools and departments within Cranfield University. The rationale for this selection is based on the different perspectives and differing core competencies that each of the participants has acquired in the various research and application domains. Also, some of the invited participants have experience in developing medical devices. Participants were invited from the following schools: School of Applied Sciences, School of Engineering, and School of Health.

It is anticipated that the intended users of the guidelines (medical device manufacturers and regulatory authorities) may come from a professional background that has been focussed on applied sciences, engineering and the medical domain. By using participants from divergent backgrounds during the validation process, it is intended that their diverse opinions and feedback would enrich the validation process and provide useful information regarding the guidelines themselves.

By using researchers and academics to validate the guidelines, this provides information regarding future research possibilities or a basis for further investigation. Out of the ten

invited participants, seven attended the workshop. From the seven participants who attended, there was one research fellow and six PhD researchers from different academic backgrounds including; design, computer sciences, engineering, management, physics, chemistry, and biology.

8.1.2 Obtaining Participants Opinions and Feedback

In order to establish whether the proposed guidelines could be used in practice, it was necessary to design an approach to measure the attributes of the guidelines. The attributes of the guidelines were captured and analysed using a validation questionnaire which has been designed and utilised to validate the guidelines with the participants.

The concept of the structured questionnaire to validate the guidelines was selected by the author to formalise the validation process whereby the results obtained could be measured and analysed in an organised and consistent manner, thus eliminating any bias. Details on the design of the questionnaire and the attributes of the guidelines are provided in the following subsection.

8.1.2.1 Questionnaire Design

The questionnaire has been designed to incorporate the questions among the defined sections to reflect the different attributes of the guidelines. The questionnaire has been developed based on previous work published by Younis (2010), Chandraprakaikul (2008) and Platts (1994). The questions have been established to investigate the feedback of the participants at a high-level of abstraction. The intention of the questionnaire design was to give both a detailed analysis of the guidelines and to consider them from the following perspectives:

- Feasibility
- Usability
- Usefulness
- Design Features

Based on the aforementioned perspectives, the questionnaire has been divided into the following sections, each section containing a set of different attributes:

Section A - Feasibility

The first section in the questionnaire addresses the feasibility of the guidelines. This section is intended to gather feedback regarding the practicability of the proposed guidelines. The questions in this section focus on the following attributes:

- Completeness
    - The guidelines consist of relevant steps in order to capture and represent the design decisions of a medical device.
- Consistency
    - The stages and sequences of steps within the guidelines are consistent with one another.
- Applicability
    - The guidelines could be successfully adopted in other similar contexts, i.e. where product development, approval, and post market play a vital role in placing a product onto the market.
- Contingency
    - The guidelines provide the intended users with alternative solutions on how to utilise design rationale with the regulatory approval of medical devices.

Section B - Usability

The second section in the questionnaire has been developed to address the usability of the guidelines. The questions defined in this section focus on the following attributes:

- Time
    - The time required to follow and understand the guidelines is within desirable limits (between 15 minutes to 30 minutes).
- Ease of Use
    - The structure of the guidelines is easy to follow.
- Understanding

    - The goals and intentions of the guidelines are clear and concise.
- Flexibility
    - The guidelines are sufficiently flexible in application.

Section C - Usefulness

The third section of the questionnaire addresses the usefulness of the guidelines. This section intends to understand the effectiveness of the proposed guidelines and whether or not they would be likely to be of use. The questions defined in this section are related to the following attributes:

- Satisfaction
    - The guidelines meet the expectations of utilising design rationale with the regulatory approval of medical devices.
- Success
    - The guidelines were successful in meeting their stated goals and intentions.
- Practicality
    - The guidelines are practical for application.
- Benefit
    - The guidelines could provide essential benefits to medical device practitioners and regulatory authorities.

Section D - Design Features

The fourth section of the validation questionnaire identifies the associative design features of the guidelines. This section of the questionnaire addresses the methodological attributes of the guidelines. The questions defined in this section of the questionnaire address the following eight attributes:

- Strategic Link
    - The guidelines provide an essential link between device development and regulatory approval.
- Key Activities
    - The guidelines successfully target key medical device activities.

- Novel Approach
    - The guidelines provide a novel approach in capturing and representing design decisions, and resolving design issues and/or preventing design issues with a medical device.
- Continuous Improvement
    - The guidelines can be used as part of a continuous improvement programme for medical devices.
- Structure
    - The guidelines are well defined, in a step-by-step approach.
- Documentation
    - The guidelines provide a well-documented set of steps to be used with key medical device activities.
- Participation
    - The intended users of the guidelines are appropriate.
- Deliverables
    - The product/outcome is useful for practitioners.

Section E - Any Other Comments

The validation questionnaire concluded by providing the participants with an additional page to make any comments they felt that were necessary in order to provide feedback in an unstructured way. A further space below each question was made available in the questionnaire for the participants to make any additional comments related to the individual questions.

In order to answer the questions in each of the sections of the validation questionnaire, a standardised scale (Likert scale) for considering each attribute of the developed guidelines was employed. This scale is often used in research that employs questionnaires. It is the most widely used approach to scaling responses in survey research. The standardised scale was used in order to answer all of the twenty questions (4 questions each in sections - A to C, and eight questions in section D). The incorporation of a standardised scale presents a structure with which the participants can select a predefined answer based on the scale, and it also offers the opportunity to assign

numerical values to the responses which can then be used for a complete analysis and cross-comparison of the results. This is described in section 8.1.3. An image of the standardised scale used in the validation questionnaire is illustrated in Figure 8-2.

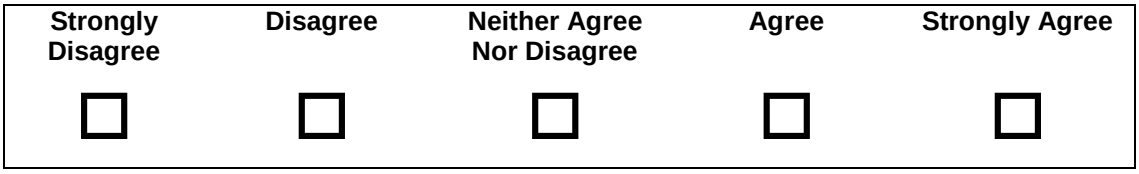

Figure 8-2: Standardised scale

The version of the validation questionnaire that has been used to validate the guidelines with the participants can be found in Appendix D: Validation Questionnaire.

8.1.2.2 Questionnaire Delivery and Completion

The process of validating the guidelines was conducted on the 21st of September 2012 at Cranfield University, U.K. The duration of the validation workshop was one hour. Participants were invited to attend for the whole hour due to the format of the workshop which is presented as follows:

1. Introduction to the research (5mins)
2. Presentation (10mins)
3. Explanation of the guidelines (5mins)
4. Complete validation questionnaire (30mins)
5. Questions and answers (5mins)
6. Discussion and feedback regarding the validation process (5mins)

Details on the format of the workshop consisted of the following. An introduction to the research was presented due to the limited knowledge of the participants regarding both design rationale research and the regulatory approval of medical devices. This included the context of the research and the developed guidelines. This was incorporated into the presentation by providing essential background information. A copy of the validation presentation can be found in Appendix C: Validation Presentation.

An explanation of the guidelines was provided due to the limited time available and limited knowledge of the participants regarding the utilisation of design rationale with the regulatory approval of medical devices. This minimised time used to validate the guidelines and provided focus for the participants on aspects which they were competent to validate.

The participants were then asked to complete the validation questionnaire in the structured format provided by the questionnaire. A separate sheet with the attached guidelines was provided to each of the participants so that they could view the structure of the guidelines and follow them independently within the allotted time frame. A questions and answers session with the participants was arranged within the workshop as to allocate time in order to explain any issues with the validation process itself that required clarification. This was arranged in case the participants did not feel that they could ask questions during the presentation. Finally, a time was allotted for discussion and feedback regarding the specifics of the validation process. Section E on the questionnaire was referred to by the participants in order to provide feedback on the questionnaire, and so that any comments could be addressed at the end of the validation workshop. This part of the workshop captured the feedback of the participants regarding the guidelines and captured any additional improvements to the guidelines which could then be incorporated.

8.1.3 Analysing the Participants Feedback

In order to analyse the responses to the questionnaires from the participants, the questionnaires were gathered upon completion from each of the participants and all of their responses were coded into a spread sheet using Microsoft Excel 2007 edition. The coding of the responses was based on the standardised scale:

- **Strongly Disagree**
- **Disagree**
- **Neither Agree Nor Disagree**
- **Agree**
- **Strongly Agree**

By using the standardised scale, it has been possible to assign numerical values to each individual response in the scale, thereby measuring each of the participant's responses to each of the questions answered. The following list shows the numerical value that has been assigned to represent each of the responses in the scale:

- Strongly Disagree = **-2**
- Disagree = **-1**
- Neither Agree Nor Disagree = **0**
- Agree = **+1**
- Strongly Agree = **+2**

In assigning the numerical values to each of the responses (zero, positive and negative values), this allowed for the comparison of the results for the individual participants, questionnaire sections, and questions, in order to identify the strengths and weaknesses of the guidelines attributes.

Each of the responses from the participants was tabulated into a spread sheet and tables were created for each of the sections (Sections A to D), four in total. These four tables were firstly sorted by the guidelines attributes in each section of the questionnaire, then by the participants (labelled P1 to Pn to preserve the anonymity of the participants), and then by the average values of the responses for each attribute. The actual values given for the responses are also provided in the columns reflecting the response to each question answered in the questionnaire. An example of the table that is to be used to represent the responses is provided in Table 8-1.

Table 8-1: An example of the responses coded for Section A of the questionnaire

Attribute	P1	P2	P3	P4…	Pn	Participant Average
Completeness	2	1	1	2	-	1.5
Consistency	2	2	1	0	-	1.25
Applicability	2	0	1	2	-	1.25
Contingency	2	1	2	1	-	1.5

The data input from the tables (four tables in total) have been used to create radar charts using Microsoft Excel 2007 edition to illustrate the findings from the validation process. These radar charts are then analysed to identify the strengths and weaknesses of the guidelines attributes. A radar chart plots the values of each category along a separate axis that starts in the centre of the chart and ends on the outer ring. Data that is arranged in columns or rows on a worksheet (spread sheet) can then be plotted directly onto the chart. Radar charts compare the aggregate values of multiple data series. Each data series in a chart has a unique colour or pattern and is represented in the chart legend. An example of a radar chart using the data provided in Table 8-1 is illustrated in Figure 8-3.

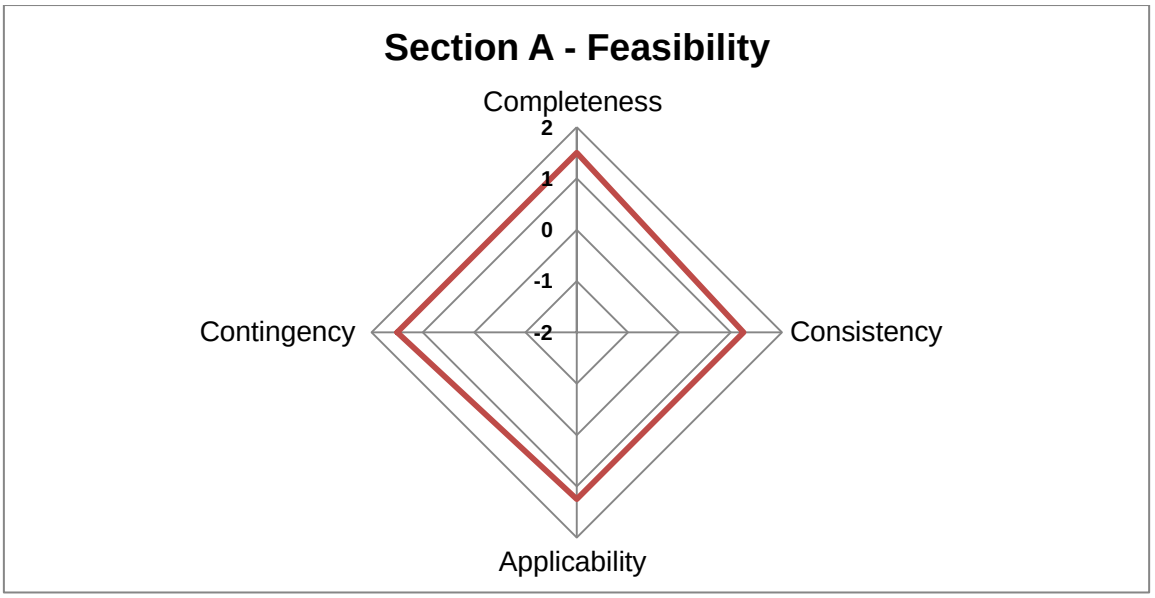

Figure 8-3: An example of a radar chart used for analysing the participants feedback

8.1.4 Utilising the Guidelines to Capture and Represent the Design Decisions of an Infusion Pump

In order to validate the guidelines for use in a medical device industrial setting, a member of the research and development department at a leading international medical device company based in the U.K. was contacted by email and asked to participate in validating the guidelines by using them in order to; capture and represent the design decisions of a medical device, diagnose a well-documented problem with an infusion pump, and design a solution. The validation participant has over sixteen years of

experience as a principal research and development engineer developing medical devices such as airways assisted products, diagnostic and monitoring equipment and therapeutic devices. Due to confidentiality, the principal engineer omitted certain aspects of the guidelines, however followed them to diagnose an issue regarding the battery of the infusion pump and designed a possible solution. Decisions were firstly captured and represented on paper by the principal engineer according to the chosen design rationale methodology. These were illustrated by the researcher using the designVUE tool. Illustrations of the decisions were shown to the principal engineer who verified them by checking the semantics of the decisions and corresponding arguments.

8.2 Validation Results

Results that have been obtained from the validation process as presented in this section. The validation results follow the order of the sections defined in the questionnaire and are presented as follows. Firstly, the results regarding the feasibility of the guidelines are presented. This is followed by the results for usability, usefulness, and design features. Following this, the average results for four of the sections in the questionnaire (A – Feasibility | B – Usability | C – Usefulness | D – Design Features) are analysed. Finally, the comments and feedback that were noted by the participants on the questionnaire are summarised.

8.2.1 Feasibility

The results obtained from the validation process regarding the feasibility of the guidelines, according to the defined scale and numerical values, is presented in Table 8-2 and represented by the radar chart illustrated in Figure 8-4.

Table 8-2: Section A – Feasibility results

Attribute Name	P1	P2	P3	P4	P5	P6	P7	Attribute Average
Completeness	2	1	1	2	1	2	2	2
Consistency	2	2	1	2	2	2	2	2
Applicability	1	1	2	0	2	2	1	1
Contingency	1	0	1	1	2	2	2	1

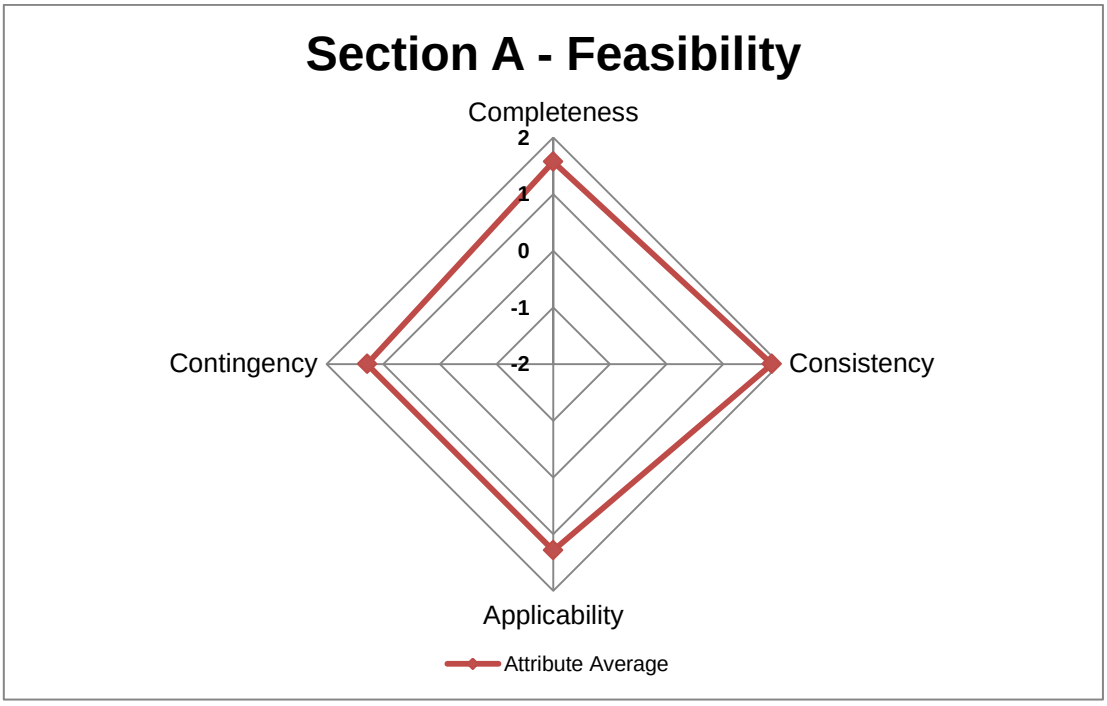

Figure 8-4: Radar chart showing the average results for feasibility

From the results obtained and shown in Table 8-2 and Figure 8-4, the experts and researchers considered 'completeness' and 'consistency' to be the strongest attributes of the feasibility of the guidelines. By analysing the results further for these two attributes, it is noticed that the consistency of the guidelines ranks higher than completeness. The attributes 'applicability' and 'contingency' were equally ranked behind 'completeness'.

8.2.2 Usability

Results that have been obtained regarding the usability of the guidelines are presented in Table 8-3 and Figure 8-5. Both Table 8-3 and Figure 8-5 show that the experts and researchers considered the attribute 'understanding' to be the most favourable attribute.

Table 8-3: Section B – Usability results

Attribute Name	P1	P2	P3	P4	P5	P6	P7	Attribute Average
Time	-1	1	2	2	0	1	1	1
Ease of Use	1	0	1	2	1	1	2	1
Understanding	2	1	2	1	2	2	2	2
Flexibility	0	0	2	0	0	1	1	1

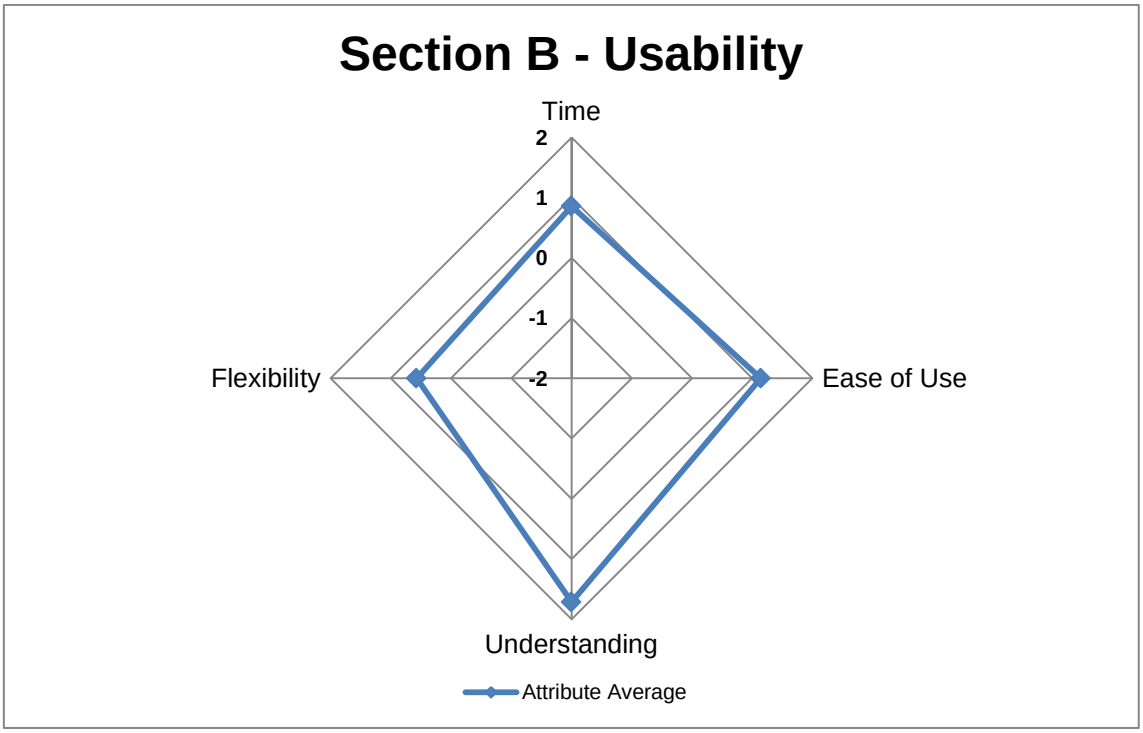

Figure 8-5: Radar chart showing the average results for usability

As it is listed in Table 8-3 and illustrated in Figure 8-5, the attribute 'understanding' was followed by 'ease of use'. This indicates that the experts and researchers considered the ease of use of the guidelines to be favourable behind understanding. This was thirdly followed by the 'time' required to understand the guidelines. The attribute that was ranked the lowest by the experts and researchers was 'flexibility'.

8.2.3 Usefulness

Results regarding the usefulness of the guidelines are presented in Table 8-4 and illustrated by the radar chart in Figure 8-6.

Table 8-4: Section C – Usefulness results

Attribute Name	P1	P2	P3	P4	P5	P6	P7	Attribute Average
Satisfaction	2	2	1	2	1	2	0	1
Success	1	1	1	2	2	2	2	2
Practicality	1	1	2	2	1	1	2	1
Benefit	2	2	2	2	1	1	1	2

As shown in Table 8-4 and Figure 8-6, the experts and researchers considered the attributes ‘success’ and ‘benefit’ to be the highest and of equal importance regarding the usefulness of the guidelines. They also considered the attributes ‘satisfaction’ and ‘practicality’ to be equally important but not as favourable when compared to the attributes ‘success’ and ‘benefit’.

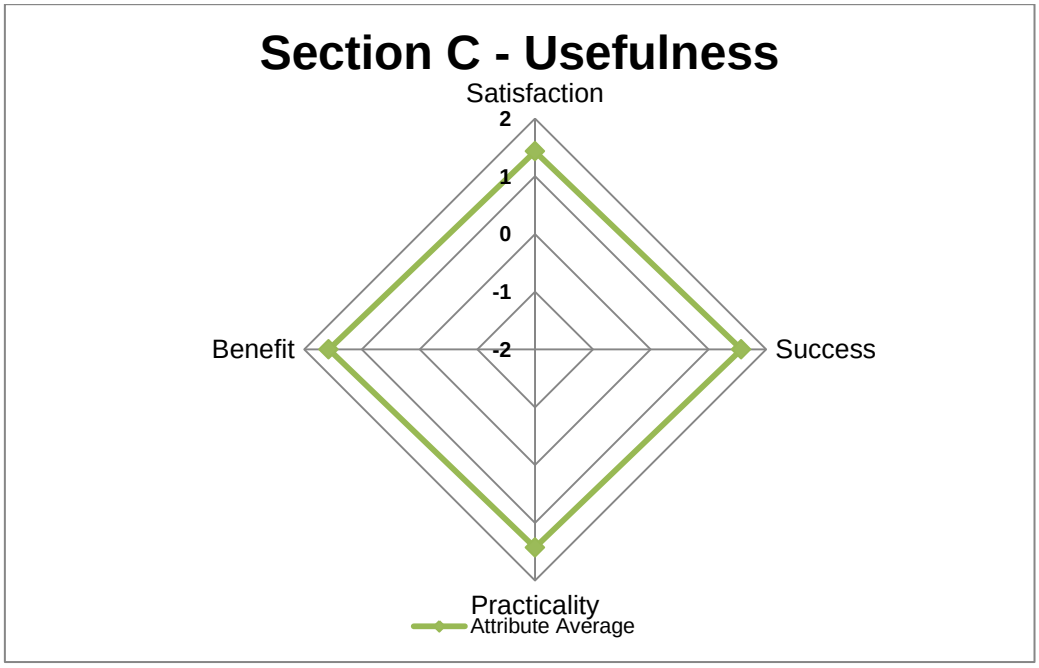

Figure 8-6: Radar chart showing the average results for usefulness

8.2.4 Design Features

Results for the evaluation of the design features and corresponding attributes as assessed by the experts and researchers is presented in Table 8-5 and shown in Figure 8-7.

Table 8-5: Section D – Design features results

Attribute Name	P1	P2	P3	P4	P5	P6	P7	Attribute Average
Strategic Link	2	1	1	2	2	2	2	2
Key Activities	1	1	2	2	2	0	2	1
Novel Approach	0	0	2	1	1	1	1	1
Continuous Improvement	2	1	2	2	2	2	2	2

Structure	2	1	1	2	2	2	2	2
Documentation	2	2	2	2	2	1	2	2
Participation	2	1	2	2	2	1	2	2
Deliverables	2	1	2	2	1	2	1	2

The radar chart (Figure 8-7) and the results from the assessment presented in Table 8-5 highlight that the experts and researchers favourably evaluated the attributes of the guidelines design features. This is clearly shown in the radar chart and indicated by the high ranking attribute averages as shown in Table 8-5. Out of the eight attributes that comprise the design features of the guidelines, six of the attributes have been ranked with an attribute average of 2. This numerical value signifies that the experts and researchers highly favoured most of the attributes which comprise the design features of the guidelines. The attributes for design features were ranked by the experts and researchers as follows. The attributes ‘continuous improvement’ and ‘documentation’ were equally ranked the highest and considered to be most favourable. This was followed by the attributes ‘strategic link’, ‘structure’, and ‘participation’ which were also equally ranked. The ranking of the attributes that followed were; ‘deliverables’, ‘key activities’, and finally, ‘novel approach’.

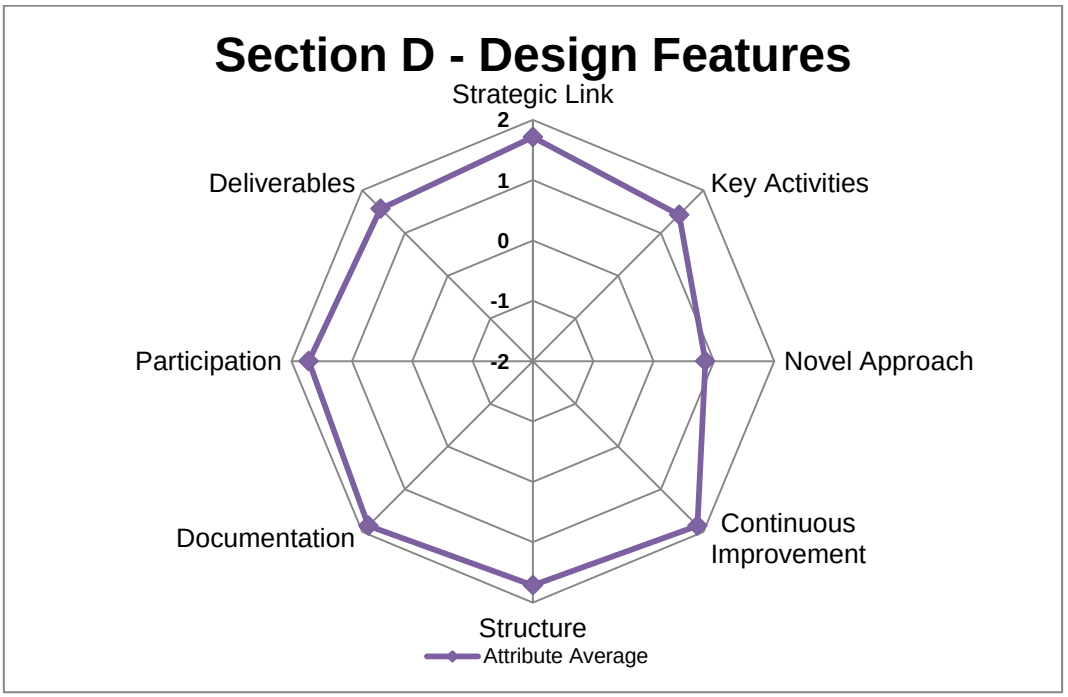

Figure 8-7: Radar chart showing the average results for design features

8.2.5 Final Ranking for Sections A, B, C and D

The average results for each of the responses from the experts and researchers were calculated and combined to provide an overall average for each of the comprising sections of the questionnaire. These results are provided in Table 8-6 and Figure 8-8.

Table 8-6: Average results for sections A to D

All Sections	P1	P2	P3	P4	P5	P6	P7	Section Average
Section A - Feasibility	2	1	1	1	2	2	2	2
Section B - Usability	1	1	2	1	1	1	2	1
Section C - Usefulness	2	2	2	2	1	2	1	2
Section D - Design Features	2	1	2	2	2	1	2	2

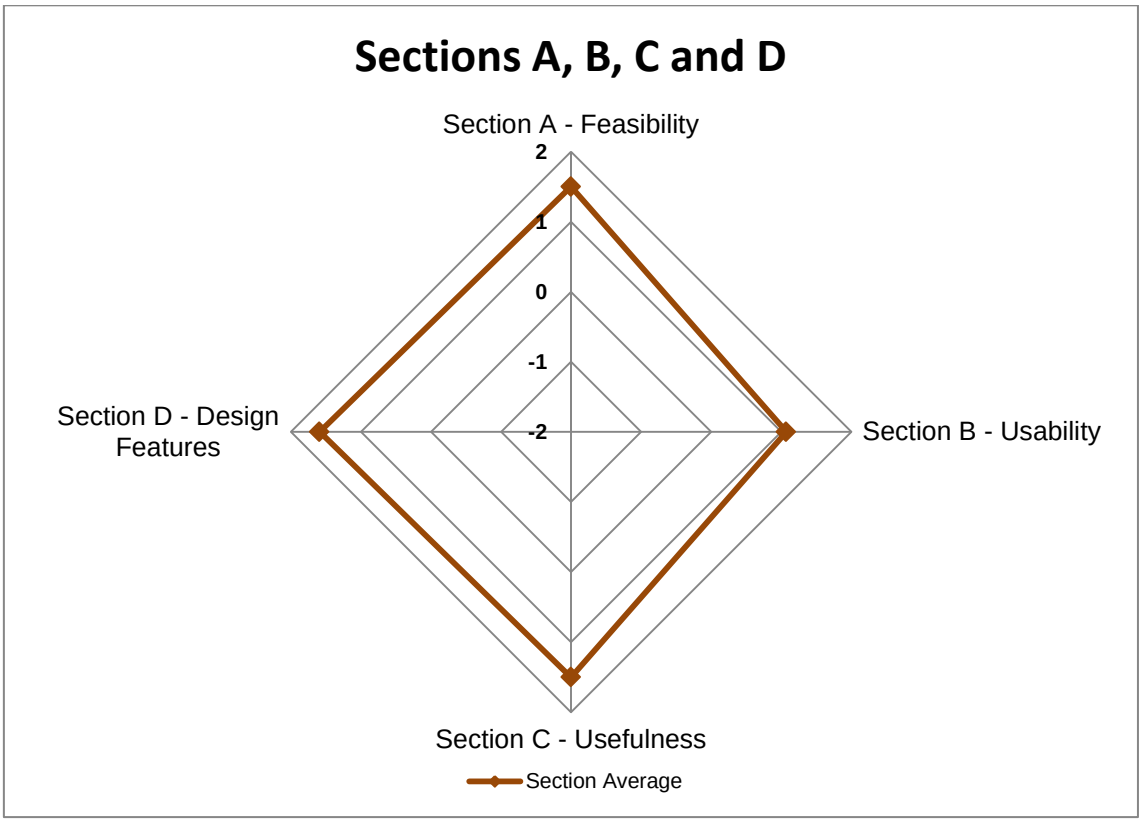

Figure 8-8: Radar chart showing the average results for sections A to D

From the radar chart (Figure 8-8) and the ranking of the coded responses (Table 8-6), the following three sections of the questionnaire (perspectives of the guidelines) were

ranked and considered of equal importance by the experts and researchers: feasibility (Section A), usefulness (Section C), and design features (Section D).

The results from the validation process indicate that the usability of the guidelines was ranked lower by the experts and researchers as compared to the feasibility, usefulness, and design features of the guidelines.

8.2.6 Participants Comments and Feedback

In addition to the results obtained from the questionnaire and presented in the tables and radar charts in the previous five subsections (sections 8.2.1 to 8.2.5), the comments and feedback that were provided by the experts and researchers at the end of the validation questionnaire (Section E) have been detailed in this subsection as follows.

- **Participant No. 1 (P1):**
  - *The guidelines are useful as a Kaizen method which is important in product development.*
  - *The guidelines can also be considered to be a knowledge management tool, which is also important in lean product development.*
  - *The guidelines encourage people to capture, store and share product development knowledge, which are key activities in product development.*

- **Participant No. 3 (P3):**
  - *All questions arising in my mind were answered in each of the steps, no vital steps were missing.*
  - *Guidelines are truly generic, easily applicable and adoptable for other similar products.*
  - *Guidelines are easily understandable for new or inexperienced users.*

- *Schematic presentation of the guidelines is clearly understandable.*
- *Since the high-level of steps have been explained without describing specifics, these steps are flexible in terms of use.*
- *The guidelines are also applicable to other similar products.*
- *The three stage approach in the guidelines appears to be novel.*
- *The novel guidelines will help designers / practitioners to improve their products.*

- **Participant No. 6 (P6):**
  - *I think that the guidelines are generic.*

8.2.7 Utilising the Guidelines to Capture the Design Decisions of a Medical Device

The principal engineer at a leading medical device company in the U.K. utilised the guidelines to capture the design decisions of a medical device. Decisions were captured in order to diagnose a documented problem (chapter 2) with an infusion pump and to design a solution. This is detailed in sections 8.2.7.2 and 8.2.7.3.

The engineer was shown several design rationale representation frameworks, as described in chapter 2, and their underlying principles were explained. The principal engineer selected the IBIS-based methodology used by the current DRed tool (Bracewell *et al.,* 2009).

This selection was based on the relevance of the DRed methodology to engineering design and that engineering design methods are widely used during the design and development of medical devices.

8.2.7.1 Capturing and Representing the Design Decisions of an Infusion Pump

The documented problem was shown to the principal engineer who then followed the DRed methodology to diagnose the problem with the infusion pump and mapped the decisions onto a sheet of A4 plain paper according to the DRed elements (Figure 8-9). On a different sheet of paper, the engineer then documented his decisions on designing a possible solution to resolve the problem.

On completion of capturing the design decisions from the principal engineer, the decisions for both the diagnosis and solution design were then illustrated using the designVUE software tool by the researcher.

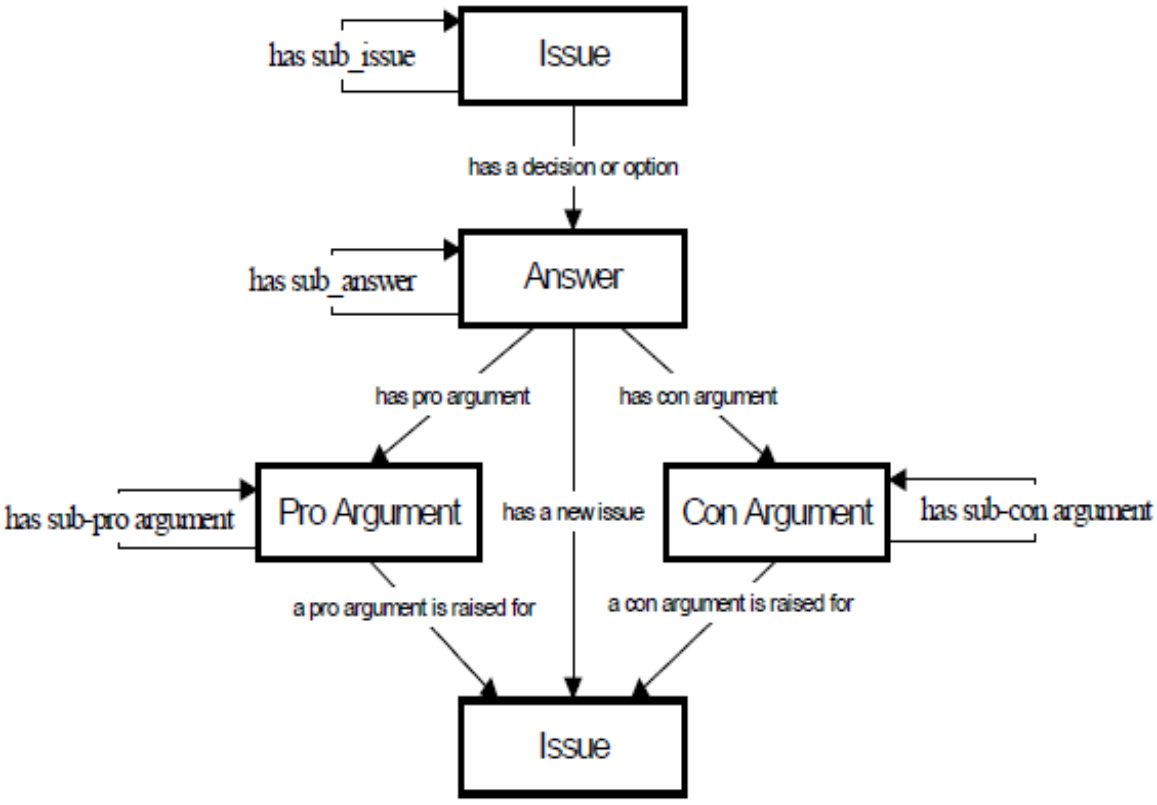

Figure 8-9: DRed elements (Kim *et al.*, 2007)

Figure 8-10 shows a screenshot of the IBIS nodes used in designVUE as arranged according to the DRed elements illustrated in Figure 8-9.

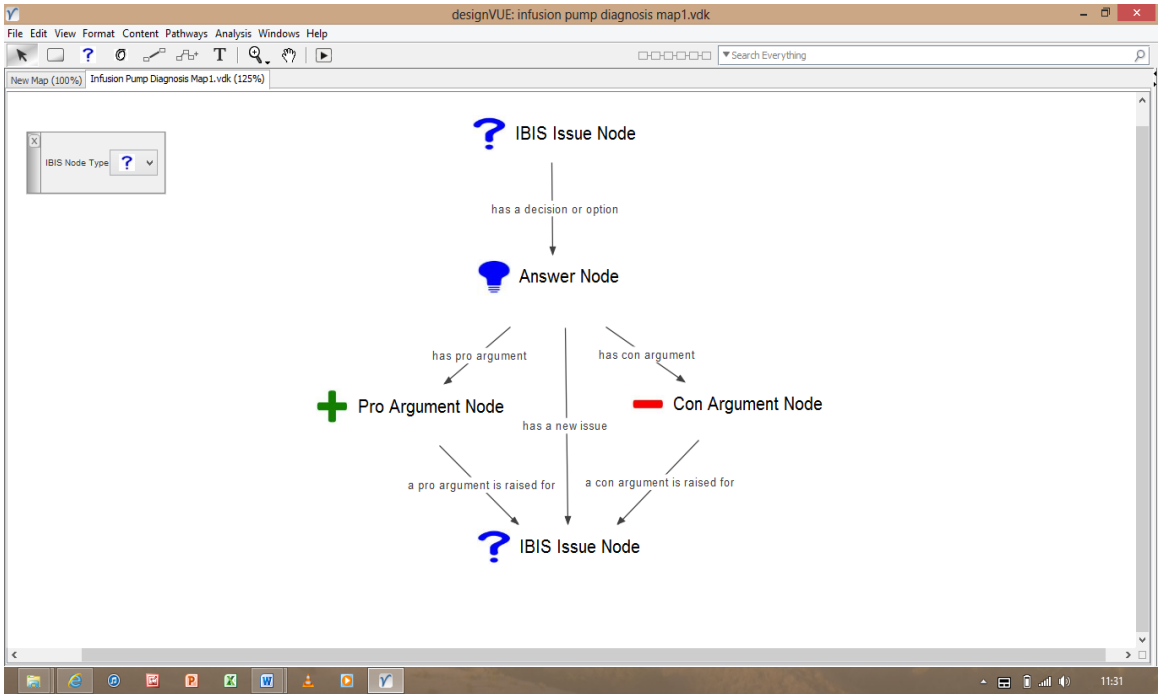

Figure 8-10: IBIS node types in designVUE arranged according to the elements defined by the DRed methodology and tool (Kim *et al*., 2007)

The designVUE software tool is an open source tool and was downloaded from the internet (http://www3.imperial.ac.uk/designengineering/tools/designvue). Its functionality includes support for IBIS argumentation and bi-directional hyperlinking between designVUE files. This tool was selected by the researcher to illustrate the design decisions based on its availability and ability to support IBIS-based argumentation structures. As shown in Figure 8-10, the different IBIS nodes are illustrated as follows: question mark – issue node; light bulb – answer; plus symbol – pro argument; and minus symbol – con argument.

8.2.7.2 Diagnosing a Problem

The principal engineer was asked to diagnose the following design issue identified with the battery of an infusion pump (details provided in chapter 2):

- **Battery failures:**
    - A design issue causes over-heating of the battery and leads to premature battery failure. See Figure 8-11.

Figure 8-11: Image showing sealed lead-acid battery damage [23]

In order to diagnose the issue with the battery, firstly, the top-level issue was defined by the principal engineer according to the selected design rationale methodology (Kim *et al.*, 2007) – '*What is causing the overheating of the infusion pump battery*?' The possible answers were then listed and linked to the top-level issue and their corresponding arguments (pro and con) were presented. The representation of the design decisions taken by the principal engineer to resolve the top-level issue is illustrated using the designVUE tool in Figure 8-12.

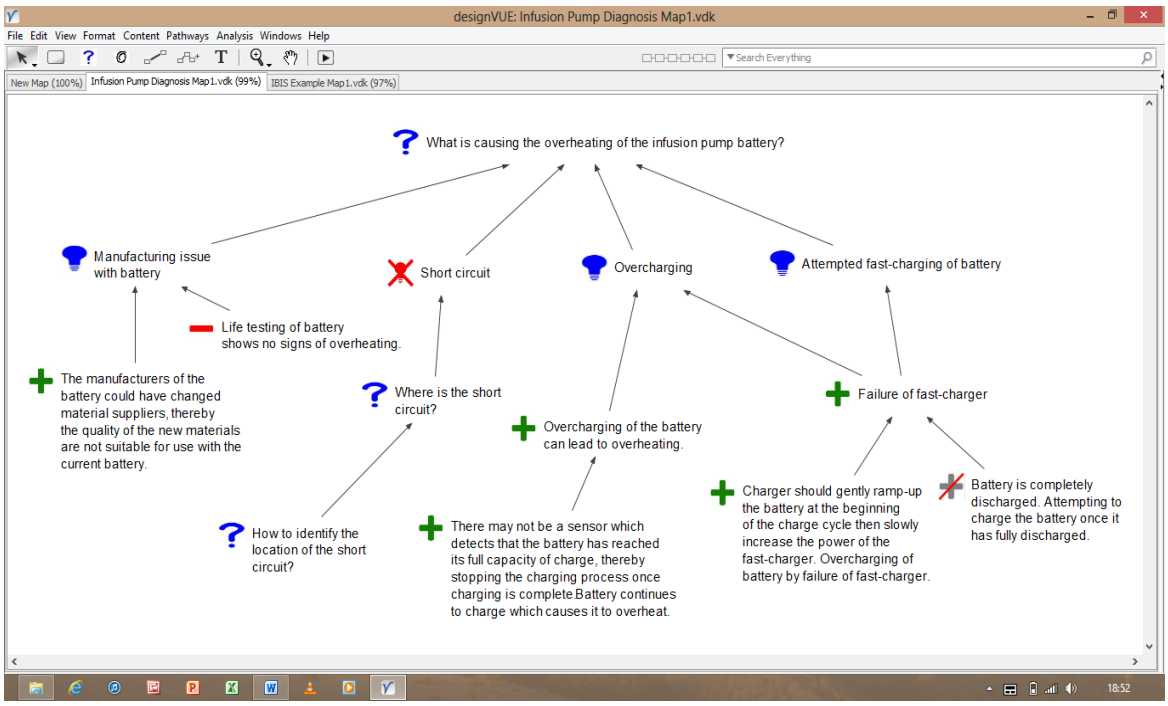

Figure 8-12: Representing the design decisions concerning the diagnosis of battery related issues with the infusion pump

8.2.7.3 Designing a Solution

In order to design a solution to resolve the overheating issue with the infusion pump battery, the principal engineer defined the following top-level issue: '*How to stop the overheating of the infusion pump battery*?' The possible solutions (answers) were listed along with their corresponding arguments and further sub-questions were also raised. The design decisions for designing a solution as captured by the principal engineer are illustrated using the designVUE tool in Figure 8-13.

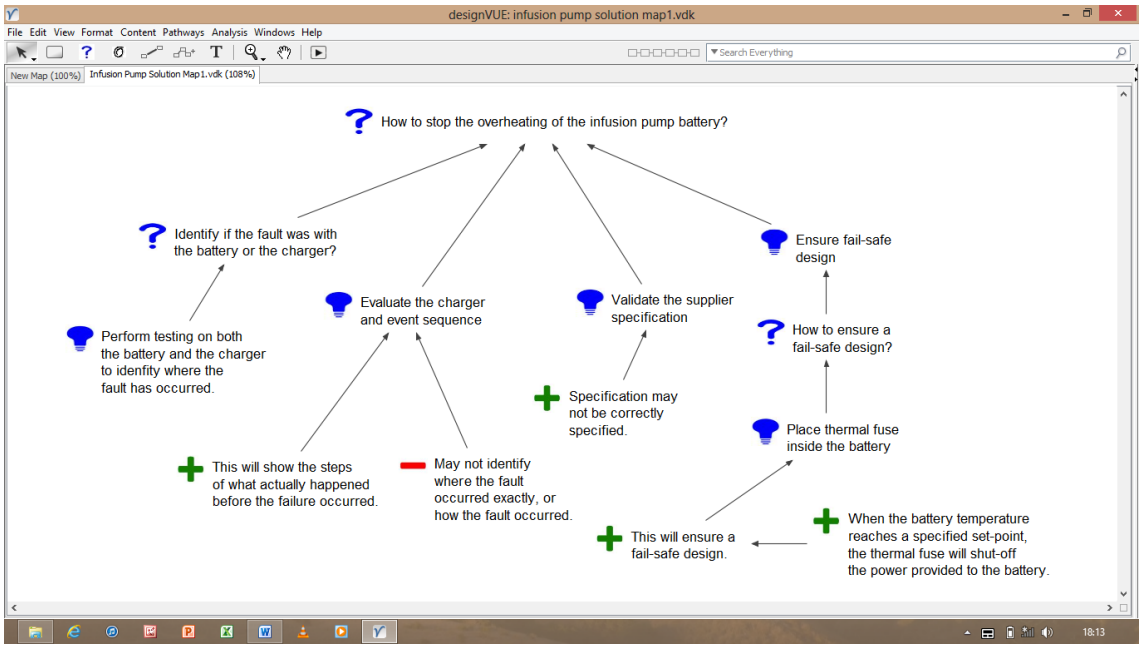

Figure 8-13: Representing the design decisions of possible solutions to resolve the battery related issues with the infusion pump

8.3 Discussion

This section discusses both the quantitative and qualitative results obtained from validation process.

The experts and researchers who were invited to the validation workshop in order to perform the validation of the guidelines provided important feedback regarding the guidelines from the following four perspectives: feasibility, usability, usefulness, and design features. These perspectives were structured as part of the validation

questionnaire that was used to obtain responses to twenty questions from the experts and researchers, each of these questions highlighting a different attribute of the guidelines and linked to the individual sections of the questionnaire.

Comments were also provided by three of the seven participants who attended the validation workshop. These comments were noted and found to be representative of the guidelines that have been developed. For the remaining four participants that did not make any further comments regarding the guidelines on the questionnaires, the informal discussion and feedback session at the end of the validation workshop was used to obtain their opinions. From this informal discussion, all of the seven participants found the guidelines to be feasible and useful. This was reflected in the quantitative results that were represented by the radar charts and corresponding ranking of the attributes in the respective tables of results.

In comparison, the quantitative results obtained for the feasibility and usefulness of the guidelines showed that the experts and researchers did not consider the guidelines to be as usable as much as they are feasible and useful. The highest ranked attribute of the usability of the guidelines was the understanding that the guidelines provided, i.e. the goals and intentions of the guidelines are clear and concise. The attribute ‘understanding’ was ranked higher in comparison to the other three attributes (time, ease of use, and flexibility) that comprised the usability of the guidelines.

Out of the four attributes comprising the usability of the guidelines, the lowest ranked attribute as shown in the results was – flexibility. A possible reason for this is that the validation participants were validating the logic and rationale underlying the guidelines development rather than in actual application. The attribute ‘flexibility’ is aimed at evaluating if the guidelines are sufficiently flexible in application. The term application was understood by the participants to mean – in actual application when developing and regulating the approval of medical devices. This was raised during the discussion and feedback session by the participants at the end of the validation workshop. After this informal discussion, it was suggested to the author by the participants that greater clarification was required regarding this particular attribute that was being measured

(flexibility). In contrast, one of the participants (P3) considered the guidelines to be flexible in terms of use and noted that since the generic steps have been explained without describing specifics, these steps are flexible in terms of use.

An interesting point that was noticed from the results obtained for the design features of the guidelines was the low ranking given by the participants for the attributes 'key activities' and 'novel approach'. A possible explanation regarding this is that the participants were not familiar with the areas of research concerning design rationale and the regulatory approval of medical devices. Therefore, they were unaware of the novelty of the guidelines that have been developed by the author due which target the key activities. However, the author did make it clear during the presentation that the guidelines were targeted at three key activities of the regulatory approval processes for medical devices, and the guidelines themselves were structured in three stages based on the three key activities that they intended to address. Conversely, one of the participants (P3) did comment that the three stages underlying the structure of the guidelines appeared to be novel. It was further commented by this particular participant (P3) that the novel guidelines could help designers and practitioners to improve their products.

The outcome from the validation process reported in this chapter has verified that the guidelines are indeed feasible, usable, and useful and comprise of a unique set of design features. Examples of design decisions for an infusion pump have been captured from a medical device expert, working in a leading medical device company in the U.K, and represented using an open source rationale capture computational support tool. As a result, this signifies that the guidelines can be used by medical device practitioners in industry to diagnose a problem and to design a solution in the case of a medical device. This chapter is summarised in the following section.

8.4 Chapter Summary

This chapter has presented the results from the final stage of the research that has been systematically followed by the author, the validation of the guidelines. The validation of the guidelines presented in this chapter has been performed by a number of experts and

researchers who have assessed the guidelines from the following four perspectives: feasibility, usability, usefulness, and design features.

Core attributes of the four guidelines perspectives were defined by the author and a methodology to assess these attributes was established. A structured questionnaire consisting of twenty questions was designed by the author and used as an essential part of the validation process to obtain the experts and researchers opinions and feedback regarding the attributes of the guidelines. Seven out of the ten invited experts and researchers attended a validation workshop and completed the validation questionnaires, thereby providing the vital feedback regarding the feasibility, usability, usefulness, and design features of the guidelines. Additional comments and feedback provided by the experts and researchers were also detailed. Results obtained from the validation process have highlighted that the guidelines are equally strong from the following three perspectives; feasibility, usefulness and design features. However, the results also showed that the usability of the guidelines was not ranked as highly by the experts and researchers.

The guidelines have been used by a principal engineer from a leading medical device company based in the U.K. to capture the design decisions for an infusion pump. Guidelines were followed in order to diagnose a known problem with the battery of an infusion pump and to design a solution to resolve the problem. The design decisions were captured by the medical device expert using a design rationale representation framework. These decisions and their underlying arguments were illustrated using the designVUE open source computational support tool dedicated for rationale capture. This signifies that the guidelines can be used in an industrial context to capture and represent the design decisions in the case of medical devices.

This chapter has fulfilled the final objective of this research, to validate the guidelines. The following chapter of this thesis provides a discussion on the different stages of the research, and presents the main contributions to knowledge made by this research.

CHAPTER 9

DISCUSSION AND CONCLUSIONS

9 Discussion and Conclusions

This chapter provides a comprehensive understanding surrounding the process of capturing and representing the design decisions in the case of medical devices. The author's reflection regarding the research process is provided, the main contributions to knowledge are outlined, and recommendations for future research are proposed.

Conclusions to the thesis are provided in this chapter with a discussion of the findings that have emerged throughout this research investigation. This chapter consolidates the findings of the research and directly addresses the primary research question that has been guiding this research.

Section 9.1 describes how the primary research question has been answered. Section 9.2 highlights how the aim and objectives of the research have been addressed and fulfilled. Section 9.3 outlines the key contributions to existing knowledge made by this research. Section 9.4 provides the authors own reflection on the research investigation which details the strengths and limitations of the research. Section 9.5 presents the recommendations for future research and further advancement based on the findings that have emerged. Section 9.6 concludes with a final summary of the research presented in this thesis.

9.1 Addressing the Primary Research Question

The primary research question that was defined in Chapter 1 was:

Can Design Rationale be used with the regulatory approval of medical devices?

This was addressed in the following two stages. The first stage of the research, detailed in Chapters 4, 5 and 6, undertook multiple case studies which identified, compared and analysed design rationale and the regulatory approval processes for medical devices, in

particular, how design rationale methods and tools could be utilised with the medical device domain. A flexible methodology was undertaken consisting of:

- a comparison of the state-of-the-art in design rationale research with the state-of-the-art in medical device design,
- a comparative analysis of the U.S. and EU regulatory approval processes for medical devices, and
- an analysis of the possibilities for utilising design rationale to capture and represent the design decisions in the case of medical devices.

This resulted in a multitude of qualitative data which was systematically synthesised to form the guidelines that were presented in Chapter 7. The second stage of the research, detailed in Chapters 7 and 8, developed and validated a set of descriptive guidelines. The researcher organised and undertook a validation workshop with 7 participants. All of the participants were from an academic background. The data obtained from the validation process was then analysed. The analysis revealed that the guidelines were feasible, usable, and useful and consisted of novel design features. The result of this was a set of guidelines that have been validated by academic experts and researchers. Further validation was performed with a research and development professional from a leading medical device company based in the U.K. This highlighted that the guidelines could be used in an industrial environment in order to capture and represent the design decisions of medical devices.

Finally, the research investigation has therefore addressed and answered the primary research question and has provided validated results to support this. In summary, design rationale can be used with the regulatory approval of medical devices.

9.2 Addressing the Research Aim and Objectives

This section now details the aim and objectives on which the research was based. Evidence is provided of how the research investigation has addressed each objective, and subsequently, fulfilled the aim of the research. The following six research objectives have been addressed:

Obj. 1. Understand the state-of-the-art in design rationale research and medical device design.

Evi. 1 This research objective was met by conducting a comprehensive review of current and relevant literature related to the area of design rationale research and medical device design (Chapter 2). The review presented and discussed the state-of-the-art design rationale research and identified the current capabilities it has to offer, and identified the state-of-the-art in medical device design. Synthesis of the literature resulted in identifying thirteen capabilities of design rationale, each capability representing design rationale's ability to perform a specific action. These capabilities were presented in Table 2-7. These capabilities were addressed in detail, compared to the capabilities of the best practices in medical device design, and were utilised to form the basis of the guidelines.

Obj. 2. Compare the state-of-the-art in design rationale research with the current state-of-the-art in medical device design.

Evi. 2 This research objective was met by identifying the state-of-the-art in design rationale methods and tools and comparing these with the current state-of-the-art in medical device design (Chapter 4). Results from the comparison presented several offerings for the possible utilisation of design rationale with the medical device domain. The strengths of design rationale as compared to the existing best practices in medical device design were also highlighted. Fulfilment of this objective formed the basis for the need of a systematic research approach in order to further investigate how design rationale could be utilised with the medical device domain.

Obj. 3. Identify the individual activities that constitute the U.S. and EU regulatory approval processes for medical devices.

Evi. 3 This research objective was met by developing, comparing and analysing a set of descriptive process models which uniquely illustrated the individual activities that constitute the U.S. and EU regulatory approval processes for

medical devices (Chapter 5). Data was identified, collected, analysed, and process models were developed using the IDEFØ process modelling tool. The modelling tool constituents were used as an initial basis for comparison. The comparison identified the differences and similarities between the U.S. and EU processes. The process models illustrated; the regulatory approval processes as a sequence of activities with an input and output connecting the individual activities, mechanisms to indicate the physical resources required at each activity, and the factors controlling the successful outcome of each activity.

Obj. 4. Analyse the possibilities of utilising design rationale with the U.S and EU regulatory approval process activities.

Evi. 4 This research objective was met by utilising the design rationale capabilities that were identified in Chapter 2 and independently mapping these with the individual process activities that constitute that U.S. and EU regulatory approval processes that were defined in Chapter 5. The analysis (Chapter 6) identified a set of possibilities for utilising the current capabilities that comprise design rationale with three regulatory approval processes activities for both the U.S. and EU processes. The analysis also suggested the possible benefits offered to both medical device manufacturers and regulatory authorities. As a result of the analysis, three key medical device regulatory approval activities were identified where design rationale methods and tools could be utilised.

Obj. 5. Develop a set of descriptive guidelines.

Evi. 5 This research objective was met through synthesising the key findings from stage one of the research (Chapters 4, 5, and 6). In stage two of the research, a novel set of descriptive guidelines were presented (Chapter 7) and validated (Chapter 8). It is intended that the guidelines be used in conjunction with existing working practices. The guidelines are structured into three stages, each stage targeting one of the three key regulatory approval process activities that were identified from the analysis in Chapter 6. Each of the stages

respectively describes; the generic practice of capturing and representing the design decisions of a medical device, the factors that need to be considered in order to review the design decisions of a medical device, and the steps necessary in order to diagnose a problem with a medical device that has been recalled and to design a solution in order to resolve the problem.

Obj. 6. Validate the proposed guidelines.

Evi. 6 This research objective was met by organising and conducting a validation workshop with experts and researchers from academia who were invited to participate in the process of validating the guidelines (Chapter 8). A brief presentation on the research presented in this thesis was given to the participants by the author. This presentation highlighted how the guidelines have been developed, described the intended aim and objectives of the guidelines and introduced the guidelines themselves. The process required to validate the guidelines was explained. Participants were asked to complete a structured questionnaire consisting of twenty questions which specifically addressed the four different perspectives of the guidelines, namely; feasibility, usability, usefulness, and design features. The participants were additionally asked to provide their feedback at the end of the questionnaire. This method was successful in validating the guidelines and verifying the kernel of the research investigation. A research and development professional from the medical device industry validated the use of the guidelines in an industrial context by using the guidelines to diagnose a problem with an infusion pump and to design a solution. Design decisions were captured and represented using an open source rationale capture tool.

The aim of the research was is to develop a set of guidelines which detail the steps required to capture and represent the design decisions in the case of a medical device. This aim has been addressed by the fulfilment of the six objectives of the research.

9.3 Contribution to Knowledge

The contribution to knowledge made by this research is twofold as follows; firstly, through the implementation of this research investigation, and secondly, through the findings of the research that have been generated throughout the research itself. Implementation of the research investigation allowed the author to create a study which focussed on amalgamating two diverse areas of research and application. This amalgamation resulted in the realisation of a novel contribution to knowledge. As a result, the findings that have been generated throughout the research are also considered to be a contribution to existing knowledge. Since a similar study which focuses on utilising design rationale with medical devices has not been identified prior to commencing this research investigation or during its completion, a significant contribution to knowledge has been indicated.

The main contributions to knowledge are summarised as follows:

- Showed that design rationale has additional capabilities compared to the existing best practices in medical device design
- Showed the current processes required for regulating the approval of medical devices in the U.S. and EU as a set of descriptive activities
- Showed how design rationale could be utilised with key medical device regulatory approval activities
- Showed the sequential steps necessary to capture and represent the design decisions in the case of medical devices

The guidelines proposed in this thesis provide guidance in order to communicate design decisions in the case of medical devices. Currently, the guidelines provide generic steps dedicated for medical device professionals to follow in order to capture and represent the design decisions undertaken during the development and regulatory approval of a medical device.

The contribution of the guidelines is divided into three separate stages which consist of a series of generic guidance steps each detailing the necessary actions required to utilise design rationale. The guidelines describe the actions that are required by medical device

manufacturers and regulatory authorities during the process of developing a medical device, reviewing a device application, and diagnosing a problem and designing a solution for a device that has been recalled.

The descriptive guidelines directly address the gaps in existing knowledge where, currently, there is a lack of information which; details the utilisation of design rationale methods and tools with medical devices, addresses its feasibility for use with the regulatory approval of medical devices, explains how design rationale could be utilised with the development of medical devices for regulatory approval and the benefits it could provide, and defines the individual steps required for medical device manufacturers and regulatory authorities to capture, represent and review design decisions.

The design, production and presentation of the research investigation presented in this thesis has significantly added to and built upon existing research. Furthermore, the research has contributed to knowledge and understanding within the area of design rationale research and medical device regulatory approval.

9.4 Reflecting Upon the Research

In this section, the author's reflections upon the limitations that were encountered during the research are discussed including how these challenges were addressed. Specific consideration is paid to the research methodology, the resultant data that was collected, and the findings of the research. The suitability of the multiple case studies is also considered. Strengths and weaknesses of the methodology followed by research were previously discussed in Chapter 3 (see section 3.6). The main limitations of the research were encountered during the following phases:

- Comparing the state-of-the-art in design rationale with the state-of-the-art in medical device design.
    - This phase of the research aimed to compare design rationale with the existing best practices available in the literature concerning medical device design. In order to make a direct comparison between design rationale and medical device

design, one document was identified which described the use of assurance case practices for medical devices. Due to the limited availability of documentation, the assurance case practice was the only available documentation that was used in the comparison. However, this seminal document has received much coverage in the form of being referred to by researchers and the regulatory approval authority for medical devices in the U.S. (FDA).

- Identifying the regulatory approval processes for medical devices.
  - Details regarding the U.S. and EU regulatory approval processes for medical devices were captured from the websites and documentation published by the U.S. and EU regulatory authorities. There was a lack of process models available in the wider literature which illustrated both the U.S. and EU practices for regulating the approval of medical devices as a set of process models labelling each unique activity. This limitation was addressed by the author by developing a set of descriptive models which represented the individual activities that constitute both the U.S. and EU medical device regulatory approval processes.
  - As a consequence of developing the process models, another limitation encountered was that these models have not been directly validated by medical device manufacturers or the U.S. and EU regulatory authorities. To address this issue, the author has submitted an article to a peer-review scientific journal (Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine) in order to validate the findings from this research activity.
- Validating the guidelines.
  - The main limitations surrounding the validation of the guidelines were the lack of available medical device experts and practitioners including members of organisations which govern the regulatory approval of medical device in the U.S. and EU. Due to the time constraints of the research itself, the author validated the theoretical framework of the guidelines with experts and researchers from academia. However, one medical device expert from industry was contacted and the guidelines were validated using the infusion pump as a

case study. By using the guidelines, the medical device expert was able to capture and represent the design decisions for an infusion pump which were then illustrated using an open source rationale capture tool. Another limitation was the overall number of participants that attended the validation workshop. However, their contribution to the validation process has proved effective and useful, and shows that the developed guidelines are feasible, usable, and useful. One of the invited participants had previous experience in developing medical devices but was not familiar with regulatory approval. The participant's unfamiliarity with the regulatory approval processes for medical devices also provided some limitations during the validation process.

9.5 Recommendations for Future Research

This research investigation has concluded that there is a need for further research within the area of design rationale and additionally the utilisation of methods and computational support tools with the development and the regulatory approval of medical devices in general.

The research provided its target audience with a set of guidelines that have been developed to provide support in capturing and representing the design decisions of medical devices. The research does not claim, however, that these guidelines are fully complete. As a result, further research is required to evaluate these guidelines in application, to liaise with medical device manufacturers and regulatory authorities to develop the existing framework of the guidelines into a more comprehensive set of detailed steps using real-life medical devices that are currently in development as examples. Additionally, the findings of the research, the guidelines, provide a set of generic steps for device manufacturers and regulatory authorities but they are not necessarily fully complete. Research needs to investigate whether the guidelines, presented within this thesis, can be used in practice or if there is further additional development or modification required in order for the guidelines to be adopted by device manufacturers and regulatory authorities in everyday practice.

Findings of the research indicate that design rationale, even after more than forty years of research contribution, still needs to address a wider audience in order for design rationale tools to be used and understood by personnel other than designers. Future research needs to address how the methods and tools can be more successfully integrated within a product development and/or regulatory approval process and how personnel other than designers can benefit from using and implementing a design rationale practice. Currently, there are no dedicated design rationale methods and computational support tools that have been extended or specifically developed for application in the medical device domain. This identifies a considerable gap in research and a significant opportunity for future research that needs to be addressed by both the design rationale research and medical device communities. Future research should involve the collaboration of researchers and practitioners in both domains to develop tools that are customised and bespoke for use in the medical device domain.

9.6 Conclusions and Final Thesis Summary

This research investigation intended to enhance existing knowledge and understanding and generate new knowledge surrounding the utilisation of design rationale with the regulatory approval of medical devices. This was achieved by developing and proposing a novel set of guidelines that are to be used by medical device manufacturers and regulatory authorities in order to capture and represent design decisions in the case of a medical device. The guidelines consist of three stages, each of which targets a key regulatory approval process activity for medical devices. Each individual stage of the guidelines presents the steps necessary in order to; capture and represent the design decisions of a medical device during device development, review the design decisions of a medical device, and diagnose a problem and design a solution for a device that has been recalled from the market. The findings of the research, in particular the guidelines that have been developed based on the emergent research findings, provide medical device manufacturers and medical device regulatory authorities with support and guidance concerning the integrative steps necessary to capture and represent the design decisions of medical devices.

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APPENDICES

Appendix A: List of Compiled Design Rationale Capabilities

Actions	Descriptions	Reference	Outcomes	Extracted Verb	Capability Names	Capability Sub-Category Names	Capability Identifier
To answer design questions.	Design rationale can answer questions about why a given design takes the form that it does.	(Haynes *et al*., 2008)	Questions concerning a particular design are answered.	Answer	Answer	Design Questions	A
To solve design problems.	Design rationale is a methodology for problem solving and decision making in a design context.	(Li *et al*., 2002)	Available method for problem solving in a design context.	Solve	Answer	Design Problems	A
To capture design knowledge.	Design rationale is a method of capturing the knowledge and reasoning that justify the resulting design.	(Tang *et al*., 2006)	Design knowledge and reasoning captured.	Capture	Capture	Design Knowledge	B
To capture designers decisions.	Design rationale captures the reasons why designers make the design decisions that they do, how they moved through a design space to identify questions and the answers to solutions to those questions, and the criteria they used to	(Haynes *et al*., 2008)	Designer's decisions and reasoning are captured.	Capture	Capture	Designers Decisions	B

	determine that a particular solution will work, or will work better than other possible alternatives.						
To express the design relationships.	Design rationale is an expression of the relationships between a designed artefact, its purpose, the designer's conceptualisation, and the contextual constraints on realising the purpose.	(Moran and Carroll, 1996)	Design relationships are expressed.	Express	Communicate	Design Relationships	C
To describe the design space.	Design rationale is a description of the design space.	(MacLean *et al*., 1989)	Description of the design space is provided.	Describe	Communicate	Design Space	C
To transmit information.	The intent of design rationale is to transmit information from a designer working at one time and in one context to another designer working in another time and context.	(Atwood and Horner, 2007)	Information transmitted from one designer to another.	Transmit	Communicate	Information	C
To note logical reasoning.	Design rationale is a notation for the logical reasons for a designed artefact.	(Moran and Carroll, 1996)	Logical reasoning is noted.	Note	Communicate	Logical Reasoning	C
To design an artefact with	Design rationale is a method of designing an	(Moran and Carroll, 1996)	Reasoning behind the	Design	Design	Artefact	D

explicit reasoning.	artefact whereby the reasons for it are made explicit.		design is made explicit.				
To determine the reasoning behind a design.	Design rationale is the reasoning that goes into determining the design of the artefact.	(Dutoit *et al*., 2006)	Reasoning underlying a design is determined.	Determine	Determine	Reasoning	E
To document the design decisions.	Design rationale documents more than the results of each decision: it documents what the decisions were, what alternatives were considered and rejected, and what arguments were used in making the alternative selections.	(Burge and Brown, 2008)	Design decisions are documented.	Document	Document	Design Decisions	F
To list the design decisions and reasoning.	Design rationale is the explicit listing of decisions made during a design process and the reasons why those decisions were made.	(Jarczyk *et al*., 1992)	Design decisions are explicitly listed.	List	Document	Design Decisions	F
To record the design history.	Design rationale is a historical record of the reasons for the choice of an artefact.	(Yakemovic and Conklin, 1990)	Historical evidence of the reasoning is provided.	Record	Document	Design History	F
To document the design history.	Design rationale is a documentation of: (a) the reasons for the design of	(Moran and Carroll, 1996)	Historical evidence of the design process	Document	Document	Design History	F

	an artefact, (b) the stages or steps of the design process, and (c) the history of the design and its context.		is provided.				
To document the decision-making processes.	Design rationale can serve as a memory aid for those who have participated in the decision-making and the other is to inform those who did not participate in the decision-making process but are affected by the decisions.	(Burge *et al*., 2008)	Decision-making processes are documented.	Document	Document	Decision-Making Processes	F
To document the design reasoning.	Design rationale framework explicitly documents the reasoning and argumentation occurring in design.	(MacLean *et al*., 1991)	Design reasoning is documented.	Document	Document	Design Reasoning	F
To record logical reasoning.	Design rationale presents the logical reasons given to justify a designed artefact.	(Moran and Carroll, 1996)	Logical reasoning of a designed artefact is recorded.	Record	Document	Logical Reasoning	F
To explain the reasoning behind the designed artefact.	Design rationale is an explanation of why the designed artefact (or some feature of an artefact) is the way it is.	(Moran and Carroll, 1996)	Explanation of the designed artefact is provided.	Explain	Explain	Design	G

To explain the reasoning behind the design.	Design rationale is an explanation of how and why an artefact, or some portion of it, is designed the way it is.	(Gruber and Russell, 1996)	Explanation of the designed artefact is provided.	Explain	Explain	Reasoning	G
To justify the argument behind the design decisions made.	Design rationale can include not only the reasons behind a design decision but also the justification for it, the other alternatives considered, the trade-offs evaluated, and the argumentation that led to the decision.	(Lee, 1997)	Justification of the design decisions is provided.	Justify	Justify	Argument	H
To provide historical evidence.	Design rationale provides a history of the design process as well as capturing the intent behind the decisions made.	(Burge and Bracewell, 2008)	Historical evidence of the design process is provided.	Provide	Provide	Historical Evidence	I
To represent the design reasoning.	Design rationale is a representation of the reasoning behind the design of an artefact.	(Shum, 1996)	Reasoning underlying the designed artefact is represented.	Represent	Represent	Design Reasoning	J
To illustrate rationale behind the artefact.	Design rationale is a set of psychological claims embodied by an artefact.	(Carroll and Rosson, 1990)	Rationale is embodied within the artefact.	Illustrate	Represent	Rationale	J

To represent the reasoning of design solutions.	Design rationale is an approach to design which emphasises working with explicit representations not only of possible design solutions, but also of the reasons and processes behind them.	(McKerlie and MacLean, 1994)	Representation of the design solutions.	Represent	Represent	Reasoning	J
To expose the reasoning underlying an artefact.	Design rationale helps to expose the underlying propositions and mechanics of a given theoretical position by exposing the otherwise invisible reasoning that unifies a theoretical construct with a constructed object.	(Haynes *et al*., 2008)	Rationale for a constructed artefact is exposed.	Expose	Represent	Reasoning	J
To structure designers decisions.	A design rationale system intends to let designers think and discuss design within a certain knowledge framework.	(Regli *et al*., 2000)	Designer's decisions structured to a given framework.	Structure	Structure	Designers Decisions	K
To structure designers decisions.	Design rationale is a type of argumentation that is structured according to a given schema.	(Dutoit *et al*., 2006)	Designer's decisions structured to a given schema.	Structure	Structure	Designers Decisions	K
To assist designers in	Design rationale could help designers follow the	(Lee, 1997)	Structured decision-making	Assist	Support	Designers	L

decision-making.	issues and alternatives being explored including their evaluations, which in turn clarified the overall structure of the reasoning process and supported decision making.		process.				
To support designers.	One of the goals of design rationale systems is to support designers by providing a means to record and communicate the argumentation and reasoning behind the design process.	(Atwood and Horner, 2007)	Reasoning and argumentation communication support system is established.	Support	Support	Designers	L
To teach others about design.	Design rationale is a helpful aid for teaching students or inexperienced designers; because it provides an explanation for why particular design components or features were chosen.	(Moran and Carroll, 1996)	Explanation of the designed artefact is provided.	Teach	Teach	Design	M

Appendix B: Tabulation of Activities and Their Controls, Mechanisms and Outputs for the U.S. and EU Processes

Activity No.	U.S. Process Activity Name	U.S. Process Controls	U.S. Process Mechanisms	U.S. Process Outputs
A1	Define Device	Device Definition	FDA Website; Device Manufacturer	Defined Medical Device
A2	Classify Device	Device Classification Criteria; Regulatory Controls	Device Manufacturer; CDRH Classification Database	Classified Device: Class I; Classified Devices: Classes II and III
A3	Select Marketing Process	Device Classification Criteria; Regulatory Controls; Marketing Clearance Requirements	FDA Website; Device Manufacturer	Premarket Notification 510(k) Requirements and Premarket Approval Application (PMA) Requirements
A4	Prepare Marketing Application	Marketing Clearance Requirements; Quality System Regulation (QSR)	Device Manufacturer; Clinical Trials; Clinical Performance Data; Quality Management System (QMS)	Device Data and Documentation
A5	Submit Marketing Application	Application Submission Requirements	FDA Website; Device Manufacturer	Device Marketing Application
A6	Review Device Application	Premarket Approval Application (PMA) Regulations; Premarket Notification 510(k) Regulations	FDA Personnel	Device Approvable Letter
A7	Register Device Details	Premarket Requirements; Marketing Clearance Requirements	FDA Website; Device Manufacturer	Medical Device Registered with the FDA
A8	Market Device	Marketing Clearance Requirements; Quality System Regulation (QSR) Postmarket Requirements Medical Device Reporting Regulations (MDR)	Device Manufacturer; FDA Personnel	Medical Device Registered and Approved for Intended Use in the U.S.

Activity No.	EU Process Activity Name	EU Process Controls	EU Process Mechanisms	EU Process Outputs
A1	Classify Device	Medical Device Directive (MDD)	Device Manufacturer; EU CA Website	Classified Device: Class I (ns/nm); Classified Devices: Classes I (s/mf), IIa, IIb and III
A2	Implement QMS	Medical Device Directive (MDD); ISO Standard 13485:2003	Device Manufacturer	QMS Compliance
A3	Prepare Technical Documentation	Medical Device Directive (MDD); Risk Management Requirements	Device Manufacturer; Clinical Data	Technical File or Design Dossier
A4	Appoint EU NB	EU Location	Device Manufacturer; EU CA Website	Appointed EU REP for Classified Device: Class I (ns/nm); Appointed EU REP for Classified Devices: Classes I (s/mf), IIa, IIb and III
A5	Audit QMS and Documentation	Medical Device Directive (MDD)	EU Notified Body	CE Certificate for Class I Devices (s/mf); CE Certificate for Class IIa, IIb and III Devices
A6	Register Device Details	Medical Device Directive (MDD)	Device Manufacturer; EU CA	Registered All Class I Medical Devices
A7	Market Device	Medical Device Directive (MDD); CE Mark; Postmarket Surveillance (PMS); Declaration of Conformity	Device Manufacturer; EU NB	Medical Device Certified and Approved for Intended Purpose in the EU

Appendix C: Validation Presentation

Design Rationale for the Regulatory Approval of Medical Devices

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Validation

Jeevan Sagoo

Supervisors:
Prof. Ashutosh Tiwari and Dr. Jeffrey Alcock

21st September 2012

EPSRC Engineering and Physical Sciences Research Council

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Presentation Structure

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- Introduction to the research (5mins)
- Presentation (10mins)
- Explanation of the guidelines (5mins)
- Complete validation questionnaire (30mins)
- Questions and answers (5mins)
- Discussion and feedback regarding the validation process (5mins)

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Introduction to the Research

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- This research investigation is set within the context of:
  - A crossover project between the Innovative Manufacturing Research Centre (IMRC) funded research into product-service systems, and
  - The Cranfield University research on the manufacturing of a microfluidic demonstrator as part of the 3D Mintegration Grand Challenge project.
- The aim of the project is to:
  - Develop a set of methodologies to facilitate the design of product-service systems in which three-dimensional micro-integrated devices (μIDs) form the physical core of the system.

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Introduction to the Research

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- Product-service systems (PSS) is described to be:
  - An integrated product and service offering that delivers value in use (Baines et al., 2007).
- μIDs are a combination of mixed technologies characterized by multi-disciplinary factors.
- An example is a:
  - Microfluidic circuit (manipulation of fluid at the micro scale) which will take a sample of the mother's blood and analyze it for chromosomal abnormalities. This microfluidic circuit would be embedded within a medical device that performs the actual diagnosis.

This research considers the contribution of design rationale as an aid to the service delivery for medical devices.

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Background to the Research Investigation

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- Design rationale captures:
  - The reasons why designers make the design decisions that they do, how they move through a design space to identify questions and the answers to solutions to those questions, and the criteria they use to determine that a particular solution will work, or will work better than other possible alternatives (Haynes et al., 2008).
- Essentially, design rationale is:
  - A methodology directed towards problem solving and decision making in a design context which relies on understanding human cognitive processes and understanding the variety of design domains (Li et al., 2002).

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Background to the Research Investigation

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- Currently, there is no available evidence in the published literature that reports on the application of design rationale methods and with the regulatory approval of medical devices.
- Utilising design rationale with medical devices is challenging as **it is currently uncertain as to what steps the device manufacturers and regulatory authorities should follow in order to utilize design rationale with the regulatory approval processes for medical devices**.
- This research is therefore **necessary** to provide enhanced knowledge and understanding of the incorporative and methodical process required to implement methods that capture and represent the design decisions of medical devices.

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Research Focus

- At the beginning of the research, however, it was discovered that there were, among others, four significant gaps in knowledge. There was no literature available which addressed:
  1. The utilization of design rationale methods and tools with medical devices,
  2. The feasibility of design rationale for use with the regulatory approval of medical devices,
  3. How design rationale could be utilized with the regulatory approval of medical devices and the benefits it could provide, and
  4. The steps required for medical device manufacturers and regulatory authorities to utilize design rationale with the regulatory approval of medical devices.

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Research Question, Aim and Objectives

- Primary Research Question:
  - Can Design Rationale be used with the regulatory approval of medical devices?
- Research Aim:
  - The aim of this research is to develop guidelines for utilizing design rationale with the regulatory approval of medical devices.
- Research Objectives:
  1. To understand the state-of-the-art in design rationale research.
  2. To identify the individual activities that constitute the U.S. and EU regulatory approval processes for medical devices.
  3. To analyze the possibilities of utilizing design rationale with the U.S and EU regulatory approval process activities.
  4. To develop a set of guidelines.
  5. To validate the proposed guidelines using multiple methods.

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Key Findings from the Literature Review

- The review of literature has indicated, among others, four significant gaps in existing knowledge that this research investigation is dedicated to addressing:
  1. The utilization of design rationale methods and tools with medical devices,
  2. The feasibility of design rationale for use with the regulatory approval of medical devices,
  3. How design rationale could be utilized with the development of medical devices for regulatory approval and the benefits it could provide, and
  4. The steps required for medical device manufacturers and regulatory authorities to utilize design rationale with the regulatory approval of medical devices.

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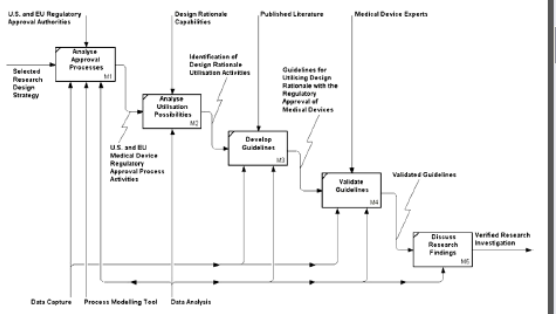
Research Methodology



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Regulatory Approval of Medical Devices

- Medical devices are used for diagnosis, screening, monitoring, or the treating of patients suffering from disease, injury, or disability.
- The number and variety of medical devices is vast and incorporates most healthcare products other than medicines.
- Uniquely, medical devices are products that require rigorous regulation before they can be sold in the U.S. or countries that are member states of the EU.
- Identified the individual activities that constitute the U.S. and EU regulatory approval processes for medical devices.

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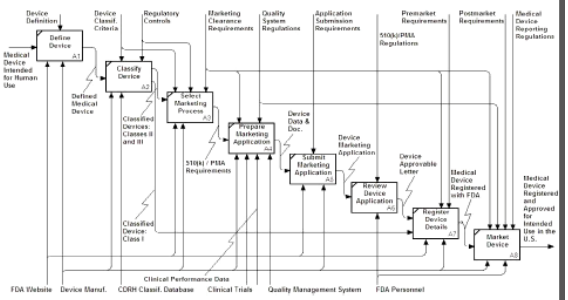
Regulatory Approval of Medical Devices



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Utilising Design Rationale with the Regulatory Approval of Medical Devices

- Analyzed the possibilities of utilizing design rationale with the different activities that constitute both the U.S. and EU regulatory approval processes for medical devices.
- Aimed to identify the relevant U.S. and EU regulatory approval process activities where design rationale could be utilized and the benefits it could provide to medical device manufacturers and regulatory authorities.
- Identified that design rationale could be utilised at three key activities in both U.S. and EU approval processes.

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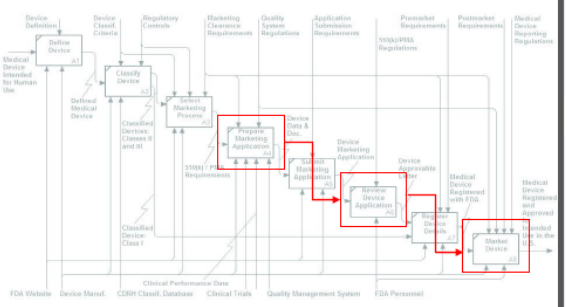
U.S. Regulatory Approval Process



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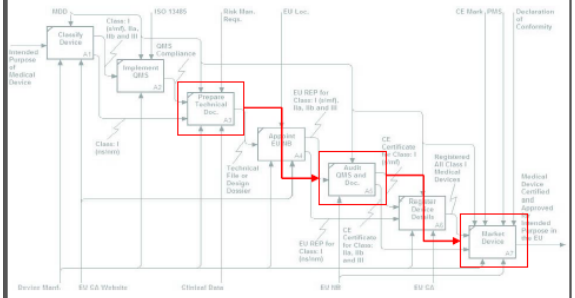
EU Regulatory Approval Process



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Guidelines for Utilising Design Rationale with the Regulatory Approval of Medical Devices

- Aim was to develop a set of guidelines that can be used by medical device manufacturers and regulatory authorities to capture, represent, and review the design decisions in the case of a medical device.
- The focus of the guidelines developed is placed on three key activities that constitute the application of design rationale with the regulatory approval of medical devices.

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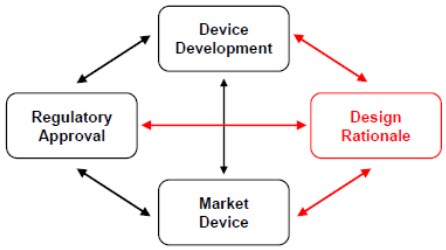
Guidelines for Utilising Design Rationale with the Regulatory Approval of Medical Devices



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Guidelines for Utilising Design Rationale with the Regulatory Approval of Medical Devices

- Aim of the Guidelines :
  - The aim of the guidelines is to provide guidance in support of utilizing design rationale with the regulatory approval of medical devices in order to communicate design decisions in the case of a medical device.
- Guidelines Objectives:
  1. Provide a step-by-step approach on how to utilize design rationale to capture and represent the design decisions of a medical device.
  2. Describe the factors that need to be considered when reviewing the design decisions of a medical device.
  3. Explain the steps necessary in order to utilize design rationale to resolve and/or prevent a design issue with a medical device.

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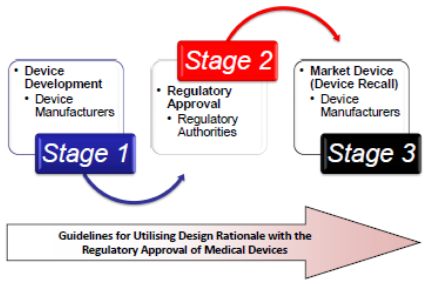

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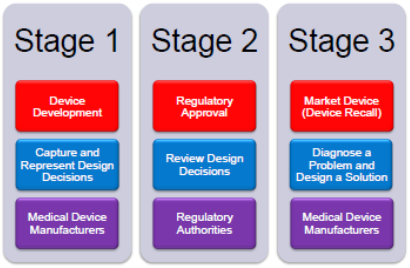

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- The generic practice of capturing and representing the design decisions of a medical device is explained step-by-step in Stage 1 of the guidelines.
  - 16 steps.
- The steps specified in Stage 2 of the guidelines give details on the actions required in order to review the design decisions of a medical device.
  - 5 steps.
- Stage 3 of the guidelines details the steps necessary in order to utilize design rationale to diagnose a problem with a medical device that has been recalled from either the U.S. or EU markets.
  - 22 steps.

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Validation of the Guidelines

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- To validate the guidelines the have been developed for utilising design rationale with the regulatory approval of medical devices.
- To obtain feedback and opinions from participants regarding the developed guidelines.
- Structured questionnaire developed to obtain feedback.

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Validation Questionnaire

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- Structured into five sections that address:
  1. Feasibility
  2. Usability
  3. Usefulness
  4. Design Features
  5. Any other comments
- Total of 20 questions.
- A standardized scale is adopted in order to respond to all of the twenty questions (4 questions each in sections A to C, and eight questions in section D).
- Complete all four sections.

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Validation Questionnaire

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- For each question, select the appropriate response according to the following scale:
  - **Strongly Disagree**
  - **Disagree**
  - **Neither Agree Nor Disagree**
  - **Agree**
  - **Strongly Agree**
- Add any comments in the space provided that you feel are necessary

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Appendix D: Validation Questionnaire

Guidelines for Utilising Design Rationale with the Regulatory Approval of Medical Devices

Validation Questionnaire

The purpose of this validation questionnaire is to capture the opinions of academics/researchers on the guidelines that have been developed for utilising design rationale with the regulatory approval of medical devices. This process of capturing the opinions forms an integral part of the validation process. Results from the validation process are to be analysed and presented in the final thesis.

Complete sections A to D of this validation questionnaire. Please feel free to make additional comments as required, supplementary space is provided below each of the questions.

Name: .....
Organisation: .....
Job Title: .....

PhD: Design Rationale for the Regulatory Approval of Medical Devices
Researcher: Jeevan Sagoo
Supervisors: Professor A. Tiwari and Dr. J. Alcock

Section A. Feasibility

1. **(Completeness) The guidelines consist of relevant steps in order to capture and represent the design decisions of a medical device.**

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
☐	☐	☐	☐	☐

Comments: .....

2. **(Consistency) The stages and sequences of steps within the guidelines flow sequentially without missing any vital steps in between.**

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
☐	☐	☐	☐	☐

Comments: .....

3. **(Applicability) The guidelines could be successfully adopted in other similar contexts, i.e. where product development, approval, and post market play a vital role in placing a product onto the market.**

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
☐	☐	☐	☐	☐

Comments: .....

4. **(Contingency) The guidelines provide the intended users with solutions on how to utilise design rationale with the regulatory approval of medical devices.**

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
☐	☐	☐	☐	☐

Comments: .....

Section B. Usability

5. (Time) The time required to follow and understand the guidelines is within desirable limits (between 15 minutes to 30 minutes).

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
☐	☐	☐	☐	☐

Comments: .....

6. (Ease of Use) The structure of the guidelines is easy to follow.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
☐	☐	☐	☐	☐

Comments: .....

7. (Understanding) The goals and intentions of the guidelines are clear and concise.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
☐	☐	☐	☐	☐

Comments: .....

8. (Flexibility) The guidelines are sufficiently flexible in application.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
☐	☐	☐	☐	☐

Comments: .....

Section C. Usefulness

9. (Satisfaction) The guidelines meet the expectations of utilising design rationale with the regulatory approval of medical devices.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
☐	☐	☐	☐	☐

Comments: .....

10. (Success) The guidelines were successful in meeting the goal and intended purpose.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
☐	☐	☐	☐	☐

Comments: .....

11. (Practicality) The guidelines are practical for application.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
☐	☐	☐	☐	☐

Comments: .....

12. (Benefit) The guidelines could provide essential benefits to medical device practitioners and regulatory authorities.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
☐	☐	☐	☐	☐

Comments: .....

Section D. Design Features

13. (Strategic Link) The guidelines provide an essential link between device development and regulatory approval.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
☐	☐	☐	☐	☐

Comments: .....

14. (Key Activities) The guidelines successfully target key medical device activities.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
☐	☐	☐	☐	☐

Comments: .....

15. (Novel Approach) The guidelines provide a novel approach to capturing and representing design decisions, and resolving design issues and/or preventing design issues with a medical device.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
☐	☐	☐	☐	☐

Comments: .....

16. (Continuous Improvement) The guidelines can be used as part of a continuous improvement programme for medical devices.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
☐	☐	☐	☐	☐

Comments: .....

17. (Structure) The guidelines are well defined, in a step-by-step approach.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
☐	☐	☐	☐	☐

Comments: .....

18. (Documentation) The guidelines provide a well-documented set of steps to be used with key medical device activities.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
☐	☐	☐	☐	☐

Comments: .....

19. (Participation) The intended users of the guidelines are appropriate.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
☐	☐	☐	☐	☐

Comments: .....

20. (Deliverables) The product/outcome is useful for practitioners.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
☐	☐	☐	☐	☐

Comments: .....

Section E. Any Other Comments

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