HALMSTAD UNIVERSITY

TAPRAh15 Industrial Management & Business Administration 60 HP

MASTER THESIS

New Product Development in a Medical Device Context

Managing Projects of different Novelty

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Thesis in Industrial Management & Business Administration

Halmstad 2016-06-18

Abstract

Healthcare is a topic that matters since it aims to ensure better well-being for people. An important and essential part of health care is medical devices since it has the potential to increase the quality of life for people with a health problem. Among the suppliers of innovation, the medical device industry is a dynamic field providing thousands of products to the market every year with the aim to enhance people's lives. However, there are many actors that influences the medical device development such as regulations that ensures that medical devices follow a specific procedure during development, at the same time buyers and end-users need to be integrated throughout the medical device design, this results in challenges during medical device development.

This thesis focuses on new product development (NPD) and investigates how projects are managed in a medical device context. Furthermore, the thesis elaborates projects of different novelty and the influence from the characteristic of complexity. This is done with a single-case study of a case company that develop and market medical devices. The empirical findings shows that the main challenges are in the area of clinical studies and product development, furthermore, managing NPD projects in a medical device context deals with specialized knowledge that is dispersed among a group of actors which can influence the development of the medical device no matter the novelty. It was found that the difference between the studied projects was minor in terms of complexity. Though, it was noticed that the project of radical novelty had more interaction with the end-user, which can relate to uncertainty in the function of the product, as a consequence from being completely new product. As a result from the findings, the implication is that the projects can not be treated and managed similarly as a result from uncertainty, thus, it depends on the integration of actors, consequently, influencing time of development and resources.

This thesis contributes to the community of companies operating in a medical device context where there is minor focus on complexity in projects, it was found that it might be beneficial to make distinctions in complexity characteristics when identifying challenges and addressing NPD projects in a medical device context.

Keywords: Medical Device, Project Management, Novelty, New Product Development, Complexity

Acknowledgements

We would like to thank the case company for giving us the opportunity to study them for the purpose of conducting business research in the field of medical devices. We would like to thank the managers for giving up their valuable time letting us interview them.

A special thanks to our supervisor Rögnvaldur Saemundsson for always having time to help us and all the valuable inputs throughout the thesis. The knowledge he possesses and his experience in the field of study has been immensely helpful and important for the thesis

We would like to the seminar group together with the supervisors Maya Hoveskog and Mike Danilovic for their helpful comments and inputs.

The authors, 2016

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1. Introduction

The first chapter treats the research topic and aims to give insight to the background of medical devices. The chapter highlights the importance of healthcare and more specifically, the medical devices and the management of new product development (NPD). The relevance is emphasized in the section background and problem discussion and leads to the purpose and research questions.

1.1. Background and Problem Discussion

Medical devices have the potential to ensure better health and increase the quality of life for people with a health problem (Maresova, Penhaker, Selamat & Kuca, 2015). Currently, the mission of the healthcare industry is to focus on generating solutions and innovative products to assist and benefit the population, at the same time, provide patients with the care they require. The healthcare industry is organized around capabilities to drive innovation, protect intellectual property rights, manufacture high quality assets and commercialize them while complying with a convoluted set of regulations and guidelines (Morgon, 2015; Lawrence, 2010). However, healthcare is associated with high costs, for example, in poor countries and emerging economies the problem is affordability, and the cost must be suitable for the nation (Lawrence, 2010). Since healthcare matters, The United Nations launched a development agenda with goals to transform the world including many targets dedicated to health improvements in order to ensure healthy lives and promote well-being at all ages. (United Nations, 2016) Furthermore, Horizon 2020 is an innovation programme initiated by the European Commission which aims to drive economic growth, create jobs by coupling research and innovation in order to tackle societal challenges which includes health and well-being. The aim is also to remove barriers to innovation and strive towards greater collaboration between sectors to ensure faster development of projects and to achieve faster results. (European Commission, 2015)

The healthcare industry has wide knowledge of its science base, but failing to use available knowledge has been shown to be costly and harmful in terms of overuse of unhelpful care, underuse of effective care and errors in execution (Berwick, 2003). Healthcare need innovations in all aspects from clinical methods that involves patients, to pharmaceuticals and medical devices as well as the organization and financing of services related to healthcare, thus the industry has to deal with data, diagnosis and relationship between institutions (Singh & Lillrank, 2015; Hone, 2008; Laurell, 2015). One of the main challenges is *public health systems* involving emerging needs and overcoming health inequalities. The second is *balance between financial sustainability and patients' needs* and the third relates to *competitiveness and innovation* involving challenges in research and development, emerging technologies and regulations. (European Commission, 2016) An important part of the healthcare industry is medical device technology, which had its origin at the first half of the 19th century and the research has been taking off during the last 50 years. This resulted in medical devices becoming an important and essential part of healthcare in the pursuit of diagnosing and treating people with medical conditions. (WHO, 2010) The medical device technology has evolved in recent years and among the suppliers of innovation, the medical device industry is one of the most dynamic fields providing thousands of new products to the market every year with the aim to enhance people's lives (Kirisits & Redekop, 2013). Currently, the focus for medical device producers is in flexibility, to launch products and break new markets quickly (Amplexor, 2015). The largest medical device market is in the US with a market size expected to reach USD133 billion by 2016

(SelectUSA, 2016) while the European market is the second largest valued at €58 billion (Cunningham, Dolan, Kelly & Young, 2015). The US medical device industry has approximately 6500 small and medium-sized enterprises while Europe has 25000 (SelectUSA, 2016; European Commission, 2016). In order to enable fast development of medical devices, there is a need for cooperation and exchange of ideas between medical and engineering communities, that means speed of innovation and communication between communities is important in the interest of bringing new products to the market (Bergsland, Elle & Fosse, 2014).

Companies that operate in the medical device industry need to consider a group of actors that can influence the development of a medical device. These are, healthcare providers, payers, regulators, patients and medical technology suppliers (Laurell, 2015). Throughout the thesis, these are the actors considered in the medical device context. Companies operating in a medical device context face a number of challenges when it comes to development of medical devices. These include for example: decisions that are not made efficiently during projects, inability to drive fast development since it is important with time-to-market and resource commitment for projects (Pomager, 2013, December 3). Another example is when the medical device reaches the user, the biggest risk for errors are often: manufacturer-related errors or device-use errors (Mattox, 2012). Either the manufacturers have not developed the product to the standard needed and required, or the user of the medical device does not fully understand the purpose and consequently can influence the safety of the patient. Thus, it is important during the stages of development to meet the standards of buyers as well as end-users (Medina, 2015).

On a project management level there are many factors that need to be addressed during the development of medical devices. Thus, it is of extremely importance for managers to understand the context in order to pursue new product development (NPD) projects in a company. A concern for medical device companies is the regulatory controls that ensure that medical devices must follow a specific procedure during the development process. A company must also show that the device is harmless and have a formal procedure for the intended use of the medical device. Additionally, clinical tasks needs to be addressed, which consists of activities that involves patients in order to ensure safety and effectiveness of products classified as medical devices (Abdel-aleem, 2009). Thus, the handling of clinical studies and regulations considering the medical device can result in difficulties during the development. (Bergsland et al., 2014; WHO, 2003; van Merode, Adang & Paulus, 2002).

Furthermore, NPD projects can be of different *novelty,* which can either be of the incremental or the radical type (Tidd & Bessant, 2013). A company can either *exploit* existing products to enable incremental innovation or at the same time *explore* new emerging opportunities to achieve innovation of the radical type (Andriopoulos & Lewis, 2009; Benner & Tushman, 2003). Thus, the balance between exploration and exploitation is a generic challenge for companies. In the medical device context, there are multiple stakeholders involved, which influences the activities of exploration and exploitation within a company. Consequently, NPD projects of different novelty can have variations in activities and these can be dependable, thus, the complexity in the project needs to be considered (Yugue & Antonio Cesar, 2013, p. 5). Previous literature on NPD for medical devices has focused more on factors that influence the success of projecs rather than the novelty and complexity in projects (Russel & Tippet, 2008). Managing NPD projects with the aim to develop medical devices is therefore challenging since the projects can be of different novelty, at the same time regulations and the context can influence the development process. This

thesis focuses on NPD projects and the challenges managers are faced with in a medical device context.

1.2. Purpose and Research Question

The aim with this thesis is to identify the challenges that occur when managing NPD projects in a medical device context, since there are different stakeholders that influence the NPD. Companies normally manage NPD projects at the same to balance the activities of exploration and exploitation, hence projects of different novelty. Thus, the novelty as well as the stakeholders, which mean the actors, influence projects. The research questions in this thesis are:

1. How are new product development (NPD) projects managed in medical device companies and what are the main challenges?

2. How does project management, and the associated challenges, differ across projects of different novelty?

It is believed that by identifying the challenges that occur when managing projects of different novelty, and the implications of managing these at the same time, it can lead to greater insight to the difficulties managers are faced with. Thus, the purpose of this thesis is to gain insight to the challenges managers are encountered with and what challenges need to be addressed when conducting NPD projects in a medical device context.

1.3. Structure of the Thesis

This thesis is divided into five chapters, where Chapter 1 describes the background and aims with the thesis. Chapter 2 presents the theoretical framework used for the thesis. Chapter 3 treats the case selection and methodology. In Chapter 4 the empirical findings are presented. An analysis and discussion is presented in Chapter 5. The thesis ends with a conclusion in Chapter 6 together with suggestions for future work.

2. Theoretical Framework

This chapter describes the theory found and used in this thesis in order to understand the area and analyse the gathered empirical data. The framework consists of concepts and fields this thesis focus on: a definition of medical devices, actors in a medical device context, regulations in the European Union, New Product Development, Novelty of products, complexity in NPD projects and Managing NPD for medical devices. The theory was acquired from books and scientific articles.

2.1. Medical Devices: Definition

The European Union (EU) and the US Food and Drug Administration (FDA) define a medical device as:

"*any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings with 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 of a physiological process.*

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." (Ogrodnik, 2013, p. 5-6)

2.2. Actors in a Medical Device Context

When a company operates in a medical device context there are actors that can influence how projects and activities are managed. The medical device context can be illustrated as a broad network with different perspectives and expectations on the medical devices, this is illustrated as the different areas in figure 1. The actors with different roles influencing the networked healthcare are the five groups illustrated in figure 1, these are: *regulators, patients, providers, medical technology suppliers and payers* (Laurell, 2015). This thesis focuses on medical devices where the main areas are *patients,* which are end-users with medical conditions that need treatment with a medical device. They can influence with their input on how the medical device should be designed since they are the end-user. The *payers* are the hospitals where they have healthcare *providers,* which are doctors and nurses, they in turn can also influence the development of a medical device since they have the expert knowledge required. *Regulators* have directives and laws in which the companies developing medical devices has to follow. The role of the *supplier* is in the development process of a medical device where they provide the hardware and software required.

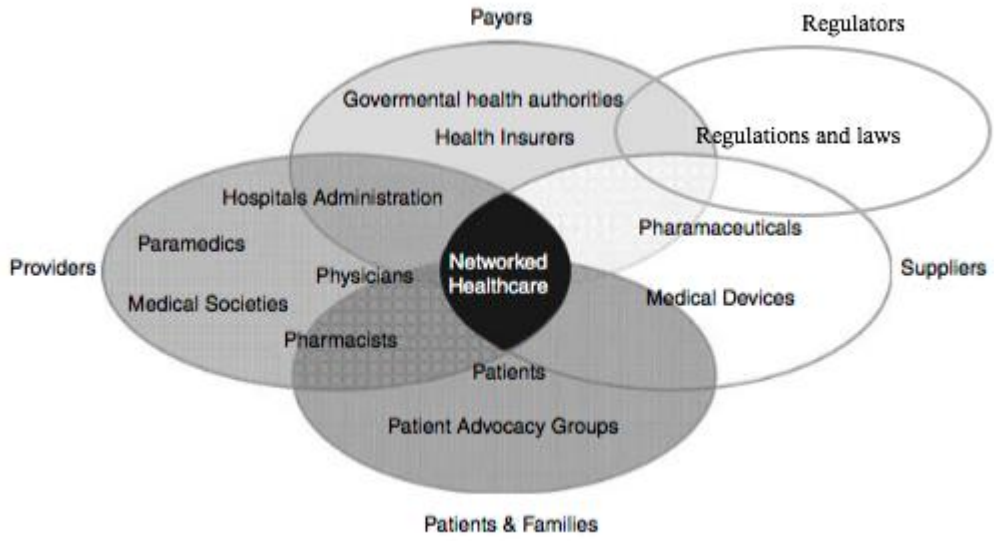

Figure 1. Networked healthcare. Adapted from Laurell (2015) and Sobrio and Keller (2007).

During the development of a product classified as a medical device the actors should be integrated (Sobrio & Keller, 2007). Furthermore, Sobrio and Keller (2007) mentions that there are approaches on how and why the network should be integrated during the innovation process, the external stakeholders needs to be involved because they provide knowledge and experience regarding the intended product and help the company make correct decisions during the development process. If a company manage to involve the stakeholders and achieve a knowledge-based community, which could consist of *patients*, *payers* and *providers*, they can then objectively from their perspective provide feedback during the innovation process on the product's characteristics, in order to make decisions that will benefit the end product. These actors with their roles are important to consider for companies developing medical devices since they influence the development process and have the specialized knowledge required. With this in mind, the underlying aim for a medical device company is to identify customer needs and develop solutions to meet the requirements from the customer. Thus, the project teams that develop medical device products needs to know who the stakeholders are. The voices of the different stakeholders needs to be heard in order to have guidelines regarding medical device design, to integrate appropriate departments and to have efficient communication (de Ana, Umstead, Phillips & Conner, 2013).

2.3. Regulations in the European Union

Medical devices has the intent to contribute to enhancing quality and effectiveness of healthcare, this approach was initiated in 1985. Currently, the European legal framework of medical devices is enclosed by three essential directives, these are: directive 90/385/EEC relating to active implantable medical devices, directive 93/42/EEC on medical devices, directive 98/79/EC to in vitro diagnostics and directive 2007/47/EC amending the two first mentioned directives as well as reinforcing the evaluation of clinical medical devices. These separate directives cover the entire population of medical devices. (Fouretier & Bertram, 2014; Sastri, 2014; European Commission, 1990, 1993, 2007)

1. The Active Implantable Medical Devices Directive (AIMD) - 90/385/EEC

2. The Medical Device Directive (MD) - 93/42/EEC

3. The In Vitro Diagnostic Directive (IVDD) Directive - 98/79/EC

Medical devices in the EU are classified into three categories from low to high risk, class 1 is associated with *low risk*, class 2a & class 2b with *low*- to *high-moderate risk* and class 3 with *high risk* (note that the US classifies low-moderate risk and moderate-high risk into a single class 2). It should also be mentioned that China, Japan, Australia and Singapore have similar classifications but with different notations. The risk level depends on the duration of the medical device's contact with the body, degree of invasiveness, whether the device is implantable or active (Ramakrishna, Tian, Wang, Liao & Teo, 2015).

Generally, national healthcare policies and regulations act differently in various countries with different levels of hierarchy that ranges from *act*, to *regulations* and *guidance/documents/standard*. For the EU, the highest level is the directives as discussed previously. According to the EU, the goals in the medical sector is to develop a shared understanding of healthcare goals, overcoming health inequalities and finding balance between patients needs and financial sustainability (European Commission, 2016).

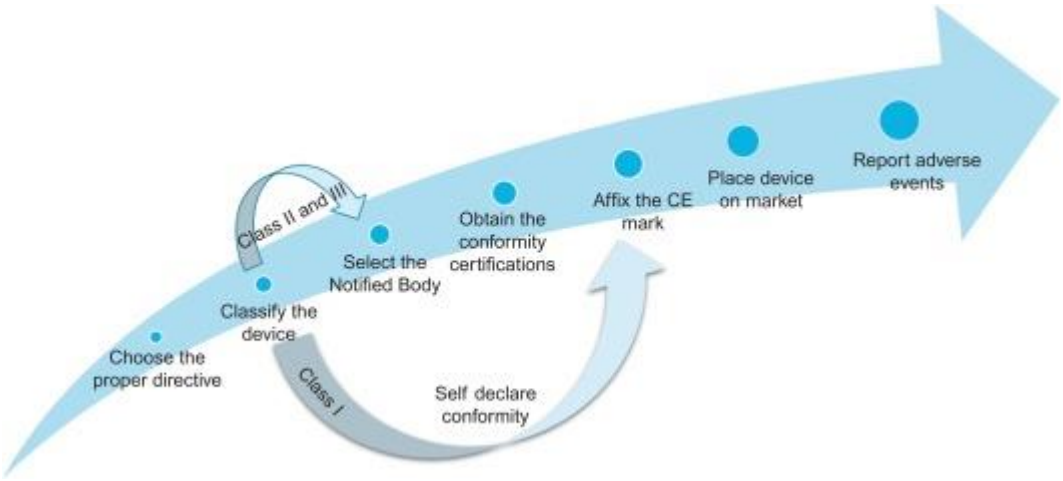

Figure 2. Route towards complying with the regulatory requirements in the EU (Ramakrishna et al., 2015).

Figure 2 illustrates the route a medical device company has to follow in order to comply with regulatory requirements to market and sell their products in Europe. The different steps are shown in the figure. (Ramakrishna et al., 2015)

Class 1 devices only require a self-declaration conformity of the essential requirements to a national authority. This can be done by the manufacturer in order to receive an CE certificate. Devices of class 2a, 2b and 3 has involvement of a notified body and require a combination of clinical and non-clinical data being evaluated (Ramakrishna et al., 2015).

Practically, each manufacturer of medical devices must establish and maintain a *quality system* that meets the requirements intended for the specific device (Kimmelman, 2008). The standard is set and authorized by a third party organization within the EU called "*Notified Body*" and assess whether the manufacturers products fulfils the requirements set by the directives (CTE, 2006). If the products complies with the essential requirements, it is marked with a CE certificate (European Conformity) and can be marketed and sold throughout Europe (Kimmelman, 2008).

This thesis focuses on the regulations from the EU, but it should also be mentioned that the FDA and the barriers to medical device innovation regarding financial resources, research costs and regulatory processes influences the processes for companies that operate in a medical device context (Sastry, 2014).

2.4. New Product Development

Innovation can be seen as the process of growing ideas into practical use (Tidd & Bessant, 2013). A process view of innovation can be seen as "*a process of turning opportunity into new ideas and putting these into widely used practice*" (Tidd & Bessant, 2013, p. 19) thus, innovation can be seen as the process of turning ideas into reality and capturing value from them. Innovations are achieved through projects, which can be defined as "*a temporary endeavor undertaken to create, a unique product, service or result* (Archibald & Archibald, 2015, p.3). This thesis focuses on innovation in terms of new product development (NPD) where the process can be seen as a product development process and be defined as "*a collection of related activities targeted to convert a new idea, concept, or market opportunity, into a marketed product*" (Karniel & Reich, 2011, p. 20)

NPD is essential for organizations to achieve growth and survival (Cooper, 1996). Therefore, projects and activities related to NPD are important to consider in order to have successful products (Millson & Wilemon, 1998). When it comes to NPD practices, there are two paradigms. The first is: *Process concurrency*, which can be illustrated as the degree to which different organizational functions simultaneously conduct project work (parallel development). The second is: *Team integration*, which can be illustrated as multi-functional teams or cross-functional teams, which are self-managing project groups with representatives from a company's relevant departments. These practices, together with the characteristics of the projects will influence NPD performance such as product performance, development speed, design time, improved market share and profitability (Ahmad, Mallick & Schroeder, 2013). *A system*, or *technical product* that is composed of different parts or a *project* consisting of a number of steps, has the characteristics of dependencies between the parts that makes up the system. Practically, these dependencies make the handling of the system or the technical product difficult (Lindemann, Maurer & Braun, 2009).

2.4.1. Novelty of Products

Changes that are fundamental to a technological trajectory and organizational competencies can be seen as *radical innovation*, while smaller changes in the technological trajectory are denoted *incremental innovations*. For these two types of innovations the degree of novelty differs depending on how they change a technological trajectory (Benner & Tushman, 2003; Tidd & Bessant, 2013). In terms of innovation, companies that achieve both *exploitation* and *exploration* are more likely to be successful. Organizations that are good at *exploiting* existing products to enable incremental innovations but at the same time *explore* new emerging opportunities to

achieve innovations of the radical type are more likely to be successful (Andriopoulos & Lewis, 2009). Having these two types of activities of *exploration* and *exploitation*, studies have shown that management of these activities are not always easy (Benner & Tushman, 2003). Normally, development projects have the range from improvements to existing products, through to "new to world" products that are considered radical. The important factor for a practicing manager is how close projects are to their previous skills and experience, thus what is novel for one company might not be for another company. That can determine if it is new to market, new to the firm or new to the world. Thus, managers can use different approaches when conducting projects depending on the novelty of the product. (Tidd & Bodley, 2002, p. 128-129)

2.4.2. Complexity in New Product Development Projects

NPD projects are affected by two key characteristics, which are *uncertainty* and *complexity*. It is argued that *uncertainty* and *complexity* negatively affects the performance of NPD projects and makes the projects difficult to manage (Ahmad et al., 2013). Complexity theory has it roots from Simon (as cited in Simon & Cilliers, 2005) where the view of complexity is a structure that needs to be hierarchically organized (Simon & Cilliers, 2005). As for *complexity*, it is understood and defined differently depending on fields and industries. But historically, there are two main scientific approaches, which are *descriptive complexity* and *perceived complexity* when approaching project complexity and complexity management. *Descriptive complexity* is something that is an intrinsic part of a system and could be measured, either if it is a technical complexity that is related to the product or organizational complexity. *Perceived complexity* is a type of complexity, which is observed and understood by the perceiver (Vidal & Marle, 2008).

The literature suggest that project complexity can be characterized into three important characteristics which encompasses; *The variety of the system* and *interdependencies within the project system,* which means that the elements in the system depends on each other and influences the others. *Context-dependence,* since the implications of the context on the project needs to be considered. Note that *the size of the project system* might be a condition and a driver for project complexity (Vidal & Marle, 2008).

A NPD project involves a sequence of activities or subtasks and the *complexity* is determined by the mentioned characteristics of complexity and how dependent the activities are of each other (Vidal & Marle, 2008; Ahmad et al., 2013). The *uncertainty* of a project is the level of ambiguity in the activities and the relationship between them in the beginning of the project (Ahmad et al., 2013). Depending on how complex and how uncertain the project is, information processing is influenced as well as the outcome of the project. These two characteristics define the difficulty level of an NPD project. Note that the literature has many definitions of project complexity, but with previous explanations in mind: "*Project complexity can be seen to relate to the novelty of the product, to its development process and performance objectives; and to its technological interdependence and difficulty*" (Yugue & Antonio Cesar, 2013, p. 5), thus, complexity can be seen is a managerial challenge.

Companies need to comply with diverse demands that satisfy customer requirements and preferences in order to produce successful products, thus companies inevitably needs to deal with complex projects (Marti, 2007; Cookes, Crawford, Patton, Stevens, Williams & Terry, 2011). The design process of product portfolios need to address both *external complexity* which concerns market needs and the actors influencing the product, as well as *internal complexity*

which concerns variety in products, internal activities and consequently affects the complexity within the company. Products must be designed to cope with implications of both types of complexities in order to achieve profits and assure long-term survival (Marti, 2007). Since the process and projects are complex, the work must be divided in order to be integrated later on.

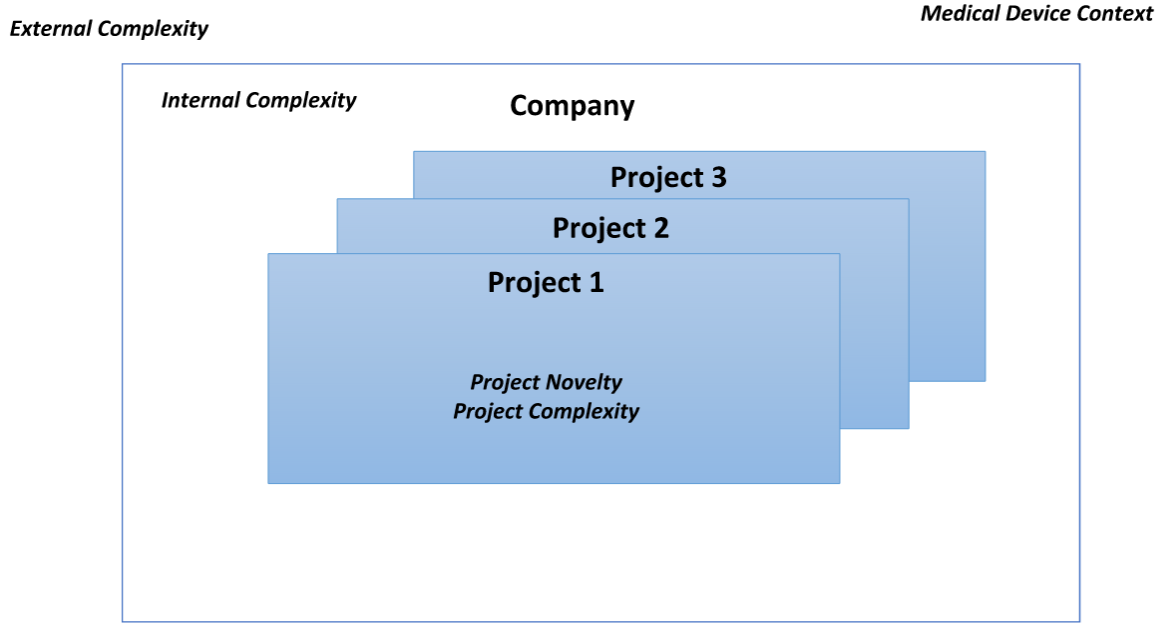

Figure 3. Illustration of the complexity in projects.

Figure 3 is an illustration of projects where the project characteristic can be of different novelty. Generally, the project complexity is determined by the characteristics discussed in previous paragraphs, thus, complexity is a challenge that needs to be managed, that means both *internal complexity* and *external complexity* (Marti, 2007). As a result from the medical device context, managing NPD projects that relates to the development of medical devices is a challenge since the actors needs to be considered as well as regulations.

2.5. Managing New Product Development for Medical Devices

Managing the NPD projects in the medical device industry is a difficult task since it requires the development of knowledge and the knowledge is distributed among many different actors in the context of medical devices (van Merode et al., 2002; Laurell, 2015). Knowledge management has two sides, one focuses on the sharing of knowledge and can be tied with organizational learning. The second focuses on the making and development of knowledge and connects knowledge management with innovation management (McElroy, 2003). Since the knowledge often is distributed by many actors, companies that acquire and distribute knowledge needs to consider and manage interorganizational relations. Therefore, cooperation and exchange of ideas between engineering and medical communities should be established when developing medical devices. (Russell & Tippet, 2008; Hagedorn, Grosse & Krishnamurty, 2015) This can be related to *external complexity* that needs to be managed (Marti, 2007).

The source of new techniques and devices can be seen to originate from users where user innovation in techniques can trigger product use and product innovation (Hinsch, Stockstrom, & Lüthje, 2014). There is a large variety of technologies applied in medical devices (Lotz, 1993),

thus making medical device product groups vary, which can influence the development pattern. (van Merode et al., 2002) The technical aspects of the function of a medical device needs to be concerned as well as management of people and other resources in a medical device context, thus the interface between users and producers of medical devices can determine whether the complexity in projects is reduced or not, this can be related to *external complexity* (van Merode et al., 2002; Laurell, 2015; Marti, 2007).

A manager's responsibility is to use implementation processes provided by the organization in order to enable department personnel to work towards the goals of the organization. At the same time, the need to plan, organize, lead and control activities as well as establish good communication line with departments is essential in order to have effective project management. This task in not easy in a medical device context with all of the actors previously discussed as well as the influence from complexity (Bronzino, 1992). Depending on the type of medical device, for example implantable or diagnostic, the application on humans might be difficult and not always possible. Thus, managing information regarding the device for intended use, its functions and the methods are important to consider when developing medical devices. Therefore issues concerning regulations needs to be managed in order to achieve approval to market a specific product. The activities related to managing regulations can be seen as *internal complexity* since it involves handling of documents and activities related to for example CE certificates and risk work (Ramakrishna et al., 2015; Marti, 2007) Furthermore, clinical deliverables must be managed which involves for example: development of protocols, qualifications and approvals. (Abdel-aleem, 2009; Russell & Tippet, 2008; Bergsland et al., 2014) These clinical deliverables include studies in terms of efficacy i.e. explanatory trials in order to determine results under ideal circumstances, or effectiveness trials which means the extent of beneficial effect under conditions representing real world clinical settings. (Gartlehner, Hansen & Nissman, 2006; Ross, Blount, Ritchie, Hodshon & Krumholz, 2015) For example, the clinical protocol should contain the details of patients and how they are recruited, approval for the study operating procedures and activities related to data processing and development of the final clinical report. This is done by clinical experts and not the company. (Abdel-aleem, 2009)

A field study made by Millson and Wilemon (1998) investigated NPD in the medical device industry and found that organizational integration was associated with market success. Furthermore, the authors found that NPD proficiency from launch to post-launch of a product was related to organizational integration with suppliers. Thus, it is of importance to manage suppliers when operating in a medical context. Multiple case studies in the electro medical device industry by van Merode et al. (2002) found that the cooperation between a device company and clinicians, as well as the user-manufacturer integration can lead to success, consequently it is important to manage activities related to clinical studies as well as end-users.

3. Methodology

This chapter describes the choices regarding the methodology in the study. The qualitative research design is described where the research approach is a single-case study design. The case-company selection is described as well as the development of the interview guide. Time horizons, research ethics and trustworthiness is described.

3.1. Research Approach

It is important to understand the implications of business research and why business research should be done. It is also necessary to be aware of and reflect on concepts such as *inductive* or *deductive* approach. (Bryman & Bell, 2015) *Epistemological* considerations treat acceptable knowledge within a discipline and *Ontological* considerations treat whether the social world is outside the social actors or if the people involved in the process constructs it in both the research questions and research process (Bryman & Bell, 2015). With an epistemological perspective, this study aims to understand rather than explain the medical device context, which influences how the research is conducted, thus having an *interpretivist* view (Bryman & Bell, 2015). With ontological considerations in mind, this study has a constructive approach since philosophy concerns the nature of social units, and by having questions of why, and the social phenomena can be understood and the system can change by internal and external forces which is the case for the medical device context with all the factors influencing. The aim with this thesis is understanding and this can be done with a single case study. This study does not have a *deductive* approach since it does not involve hypotheses where data is collected in relation to the concepts that make up the hypotheses (Bryman & and Bell, 2015, p. 11). With an *inductive* approach, it is more related to drawing generalizable inferences out of observations (Bryman & Bell, 2015, p. 13). This thesis aims to understand a company that develops medical devices and try to figure out how projects of different novelty are managed, consequently, it can be seen as trying to figure out connections through observation, thus the approach can be seen to lean towards the *inductive* type (Bryman & Bell, 2015).

3.2. Qualitative Research Design

The major focus is to investigate how projects of different novelty are managed and the associated challenges in a medical device context. Employing a qualitative research design to a single case study provide a framework for the collection and analysis of data since the aim is to understand behaviour and the meaning of that behaviour in a specific social context. (Bryman & Bell, 2015). We found this approach suitable since we study the medical device context in order to find connections and the behaviour of different managers in projects i.e. social phenomena and the interconnections (Bryman & Bell, 2015). The main steps employed in the thesis were:

1. *General research questions* - we read about the topic of new product development for medical devices in order to understand the research area and found that the context in which medical device companies operate can be challenging since there are many factors influencing how medical devices are developed and consequently, how projects are managed.

2. *Selecting relevant site(s) and subjects* - the criteria we had was that the company had to operate in a medical device context and develop products classified as medical devices. The subjects for interviews should be managers working with product development

projects involving the development of the medical devices.

3. *Collection of relevant data* - data was collected through in-depth semi-structured interviews with managers in order to have a rich and detailed description of the development of the projects in order to obtain relevant data. The interviews were recorded.

4. *Interpretation of data* - data was transcribed and the different projects were addressed as themes, where quotes were used as primary data in order to understand what has happened during the projects.

5. *Conceptual and theoretical work* - the data was presented as empirical findings where quotes were taken from different managers in order to present a rich and detailed description of the themes, which were related to managing projects of different novelty and the implications. The analysis combined chosen theory with the empirical findings to discuss challenges new product development projects and the implications.

6. *Writing up findings/conclusions* - the analysed data and discussion provided findings and conclusions that are presented.

3.3. Research Strategy

A single case study design is based on detailed and intensive analysis of a single case, which in this thesis is a company (Bryman & Bell, 2015). The study is on individuals in a real life context, in this case, managers at company that operates in a medical device context (Eisenhardt, 1989: Bryman & Bell, 2015). On the project management level, the medical device company either runs incremental improvements to existing products through projects, or completely new projects to new products, which can be of radical nature. With the strategy to study the management of the new product development projects, it is possible to identify the challenges that arise when managing projects in a company that produces medical devices. The in-depth interviews focuses on how the managers manage and deal with projects of different novelty that focuses on incremental improvements as well as new projects of more radical nature. The data from the in-depth interview is expected to provide insight to the challenges associated with the management of medical devices, the difference in novelty between projects as well as their implications. By having this research strategy it enables more in-depth understanding of how projects are managed in order to answer the research questions.

Data collection in the single case study was from semi-structured in-depth interviews, since it refers to a context in which the interviewer has a series of questions that are in general form of an interview schedule but is able to vary the sequence of questions (Bryman & Bell, 2015). In depth-semistructured interviews was held with a Development & Quality assurance manager, a Risk & Software manager and a Product & Marketing manager. The data used in the thesis were primary data and no secondary data was used.

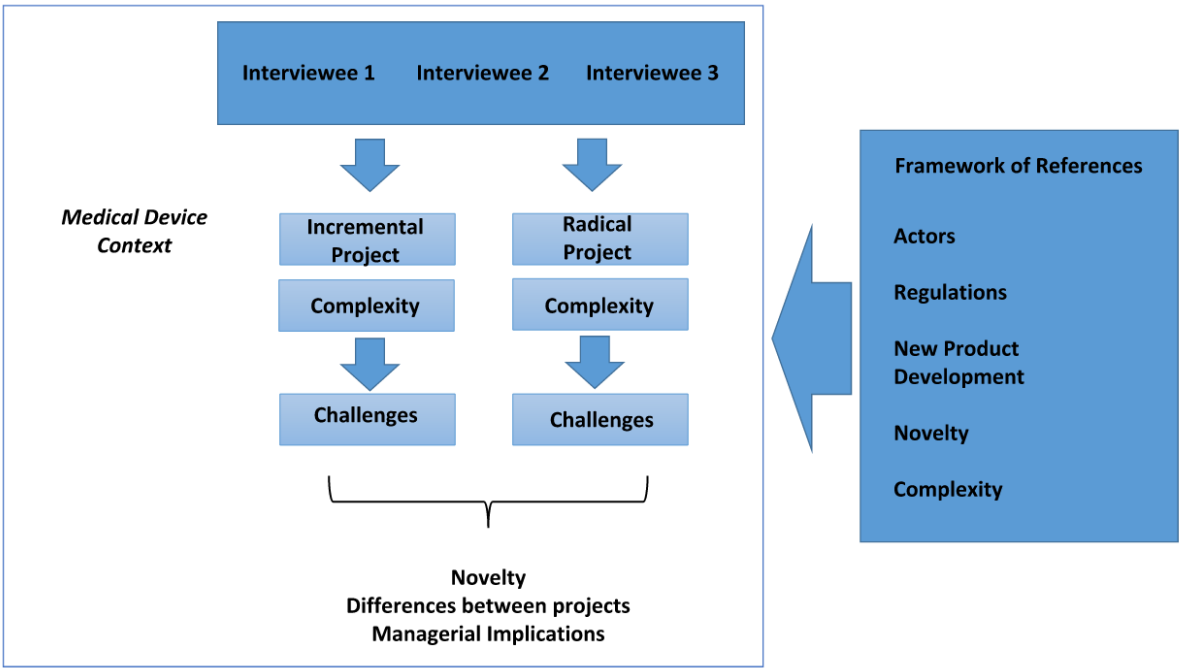

Figure 4. Research strategy.

In order to answer the three research questions, the research strategy was first to understand the medical device context, new product development (NPD), novelty of the projects and the complexity in the projects. This has been elaborated in the theoretical framework with the sections about the *Medical Devices definition, Actors in a Medical Device context, Regulations in the European Union, NPD and Managing NPD for Medical Devices*. By studying a project of incremental novelty in order to understand how the project has been managed as well as the challenges associated, it is suggested that that the NPD and managerial implications can be understood for the project. Furthermore, by studying the management of a project of radical novelty as well as the challenges associated, it is suggested that a deeper understanding is gained regarding the type of NPD project and the managerial implications.

Analysing and comparing the two projects of different novelty and the associated challenges, it is suggested that insight project management will be provided, which enables deeper understanding over the challenges the management of NPD projects are faced with in the medical device context.

3.3.1. Case Company Selection

This study focuses on the medical device industry and a company that operates in the context. Due to the short time of the thesis and the willingness of companies to participate, the number of qualitative interviews was restricted. Reducing the amount of data by considering selected data is common in business research (Bryman & Bell, 2015). Before selecting the case company, selection criteria needed to be defined (Eisenhardt, 1989), where the criterion was that the company must develop medical devices and conduct NPD projects of different novelty. Note that the criterion of the case company selection also results in a limitation for the thesis, thus, the research is limited specifically for similar companies operating in a medical device context.

The case company selected is a small subsidiary company located in Sweden that develops and markets medical device products in medical cooling and their vision is to be a leading actor in the

cooling area of medical devices. The company has a board of directors and in 2010 they were founded as a subsidiary with license to develop the parent company's device and has been conducting and marketing their own devices ever since then. They develop and markets cooling devices for treatment of stroke, cardiac arrest and oral mucositis. Furthermore, the company has collaboration with universities and hospitals with focus on development and application of temperature measurements. Data is anonymized in the thesis since the case company wanted confidentiality.

3.3.2. Choice of Respondents

The choice of respondents was managers with different missions. Because the study deals with the management of projects, the respondents were considered suitable since they were likely to possess knowledge and provide with the information needed to answer the research questions. Furthermore, the respondents were asked the same questions about the same themes, which should give a clear and rich overview over the development and what has happened during the projects. The interviewees were approached by email and telephone with introduction of the research topic and potential outcome i.e. why the interviews should participate in the study (Bryman & Bell, 2015). The interviews were scheduled in March and April 2016.

Interviewee 1 is an experienced professional who has been working with management and software development. He has vast experience in product development and has skills with regards to planning, specifications, user interfaces, testing, quality assurance, documentation and interaction with customers and team members. He has previously worked at over 10 different companies before starting at the parent company and later moved over to the subsidiary that was founded 2010, but became a subsidiary 2014. He has also been working with quality systems for a long period of time and is now working with the development of different projects and products and the associated software. Interviewee 1 was interviewed in person 2016-03-10.

Interviewee 2 has worked at two different companies before moving over to parent company, later he and the CEO founded the subsidiary. He has previously worked at various projects at the parent company but is today a product manager and marketing manager at the subsidiary. His main responsibilities is the link between the company and clinics as well as with questions regarding marketing. Interviewee 2 was interviewed in person 2016-03-10.

Interviewee 3 has during his career held several senior roles within NPD and sustaining engineering of medical devices. He has been working in both small and large companies, he has a great understanding and insight to the business challenges that are beyond product development. He has previously worked at the parent company and partly in the subsidiary before moving over in 2014. He is a project manager and also a development manager and quality assurance manager in the company. Interviewee 3 was interviewed 2016-03-16 over telephone.

Table 1. Information about the respondents, their experience, and role in the thesis.

	Role in the Company	Experience	Role in the Thesis (*Referred to as*)
Interviewee 1	Risk Manager & Software Manager	Mechanical Engineer Product Development Marketing Software Management Senior Project Management Account Management Regional Management	Risk Manager
Interviewee 2	Product Manager & Marketing Manager	Chemical Engineer Service Engineering Sales Management Product Management Sales Director	Product Manager
Interviewee 3	Development & Quality Assurance Manager	Energy Engineer Development Engineering Project Leading PLEM Senior Project Management	Project Manager

3.3.3. Development of the Interview Guide

The theoretical framework acted as a guide when structuring the interview guide. The focus area of the interview guide is on themes which were: *General Questions, Theme 1 - Incremental project, Theme 2 - Radical project and theme 3 - Managing projects at the same time (Managerial Implications).* The type of questions were of open nature, where the respondents are asked questions they can reply however they wish (Bryman & Bell, 2015). Further the questions were of the type: "informant factual questions" where they are in the position of informants, "Personal factual questions" where the questions are about behaviour, which can rely on the respondents memories, "factual questions about others", which asks for personal information about others, team performance in conjunction with the productivity of team members, "questions about belief" where they are asked if certain matters are true or false, "questions about knowledge" to test the respondents knowledge in the area. (Bryman & Bell, 2015) By having this type of semi-structured interview guide with these type of questions, we argue that an in-depth understanding of how the projects have been managed can be gained.

3.4. Time Horizons

A large amount of time during the thesis were spent on finding companies that operated in a medical device context in order to participate as a case company for the study. The thesis was a short-time study and the case company is a small company that develops medical devices.

This study was not a longitudinal study since this type of research is over a long period of time, where qualitative interviewing is conducted more than one occasion. This type of research relates to different time periods. (Bryman & Bell, 2015, p. 68) With a cross-sectional research design, the typical form is qualitative interviews or focus groups at a single point in time. The single case

study in the thesis was more a cross-sectional study where the managers at the case company were interviewed at a single point in time (Bryman & Bell, 2015, p. 68).

3.5. Techniques and Procedures

The interviews were held in Swedish, recorded and transcribed before they were translated into English. During the transcription the focus was on transcribing exactly what has been said and during the translation the words were carefully chosen. The transcription of each interview took approximately 3-4 hours. Even though the interviews were held in Swedish and translated into English, it is argued that this did not affect the interview data since the concepts discussed could be understood.

Quotes from the transcribed data from the different managers were used to understand how the projects have been developed and managed, his is presented in the empirical findings. Data analysis started with using the quotations from the managers to understand what has happened during the projects. While treating the data, three themes were held separately: *incremental project*, *radical project* and *Managing projects at the same time (Managerial Implications)*. The concepts from the theoretical framework was used to understand the actors and influence from complexity in the themes, Bryman and Bell (2015, p. 585) refers this to understanding and elaborating the data so it is representing real-word phenomena i.e. what has happened during the projects. The analysis and elaboration of the data resulted in findings, which are relationships between the themes held in the thesis, in this case differences in novelty and the associated challenges. Furthermore, the steps and considerations in treating the data was followed which was, *to transcribe as soon as possible, reading through the set of transcripts and field notes, reviewing the notes to see further connection as well as keeping the data in perspective* (Bryman & Bell, 2015, p. 595).

3.6. Research Ethics

When it comes to business research ethics, the issues that arises concerning ethical matters needs to be addressed when collecting and analyzing data. Relations with researchers and participants where the main areas can relate to: *harm to participants*, *informed consent*, *invasion of privacy* and *deception*. (Bryman & Bell, 2015)

When conducting the qualitative in-depth semi-structured interviews, the managers gave up their valuable time and they were provided a credible rationale for the research they were asked to participate in. They were provided with a special thanks for participating in the interview and at the same time provided with the information about the importance of the study, in this case identifying the challenges during the projects in order to address these when managing projects.

The identification of both the interviewer and the interviewee was made clear and that the participation was voluntary. Reassurance of the confidentiality of the information provided and that the responded will not be identified or identifiable in any way. Data was anonymized since the company is providing sensitive information and wanted confidentiality. (Bryman & Bell, 2015)

3.7. Trustworthiness

Trustworthiness are made up of four criteria which are important when assessing the quality of qualitative research (Bryman & Bell, 2015, p. 400). These are *credibility*, *transferability*, *dependability* and *confirmability*.

Credibility means that "*the findings entails both ensuring that research is carried out according to the canons of good practice and submitting research findings to the members of the social world who were studies for confirmation that the investigator has correctly understood that social world*" (Bryman & Bell, 2015, p. 401). This can be referred to as respondent validation. In this thesis, we provided the managers with an account of our findings, which mean that they will be provided feedback of our findings. This was important since we wanted to ensure that there was good correspondence between our findings and the perspectives and experiences of the research participants, in this case, the managers.

Transferability deals with that "*qualitative findings tend to be orientated to the contextual uniqueness and significance of the aspect of the social world being studied*" (Bryman & Bell, 2015, p. 402). In this thesis, the context is medical devices and the actors influencing the NPD process, thus the context is specific for small companies developing medical devices. The findings should for the specific context in which the case company operates in, and as Bryman and Bell (2015, p. 402) describes it, we are encouraged to produce rich accounts of the details of a culture, that means a thick description of the case company in order to have possible transferability of the findings. A suggestion from Yin (2009) is that if case studies are performed in a correct manner, the findings can be generalized to similar companies in similar context. However this study was made on a small company operating in a medical device context, the findings can be applicable to companies of similar size producing similar products.

Dependability means "*establish merit of research in terms of this criterion of trustworthiness, researchers should adopt and 'auditing' approach. This entails ensuring that complete records are kept of all phases of the research process"* (Bryman & Bell, 2015, p. 403), which entails that the activities should be documented and accessible, in order to be able to audit. Furthermore, it is sometimes difficult to establish what researchers did and how they arrived at the study's conclusions, thus there can be a lack of transparency (Bryman & Bell, 2015, p. 409). In this thesis, we kept documentation throughout the research process. First of all, a group diary was kept where important internet links and what we did throughout the thesis was documented. Document with contacts with different companies were kept as well as the selection of the case company, e-mails to the case company, the interview guide together with recordings and transcriptions.

Confirmability deals with "*recognizing that complete objectivity is impossible in business research*" (Bryman & Bell, 2015, p. 403), that means that we could have shown to have acted in good faith and let personal values or theoretical inclinations to influence the way the research was carried out, hence the findings. However, the quality of the interviews depends on the respondent so the answers can be subjective according to Bryman and Bell (2015). With this in mind, in terms of replicability, the interview guide was designed for others to replicate it (Bryman & Bell, 2015). Even though three interviews were held with three different managers working with the same projects, the quality of the data should be challenged due to the subjectivity, but it is argued that the subjective results aims to understand the action of the company in order to provide data to answer the research questions.

4. Empirical Findings

This chapter presents the empirical data collected in this study. The empirical data is acquired from interviews with managers from the case company is presented. The empirical findings are divided into three themes, these are: incremental project, radical project and managing projects at the same time.

4.1. Interviews with Case Company

Figure 5. Illustrates the three themes held in the interviews. The empirical findings are presented separately in the chapter.

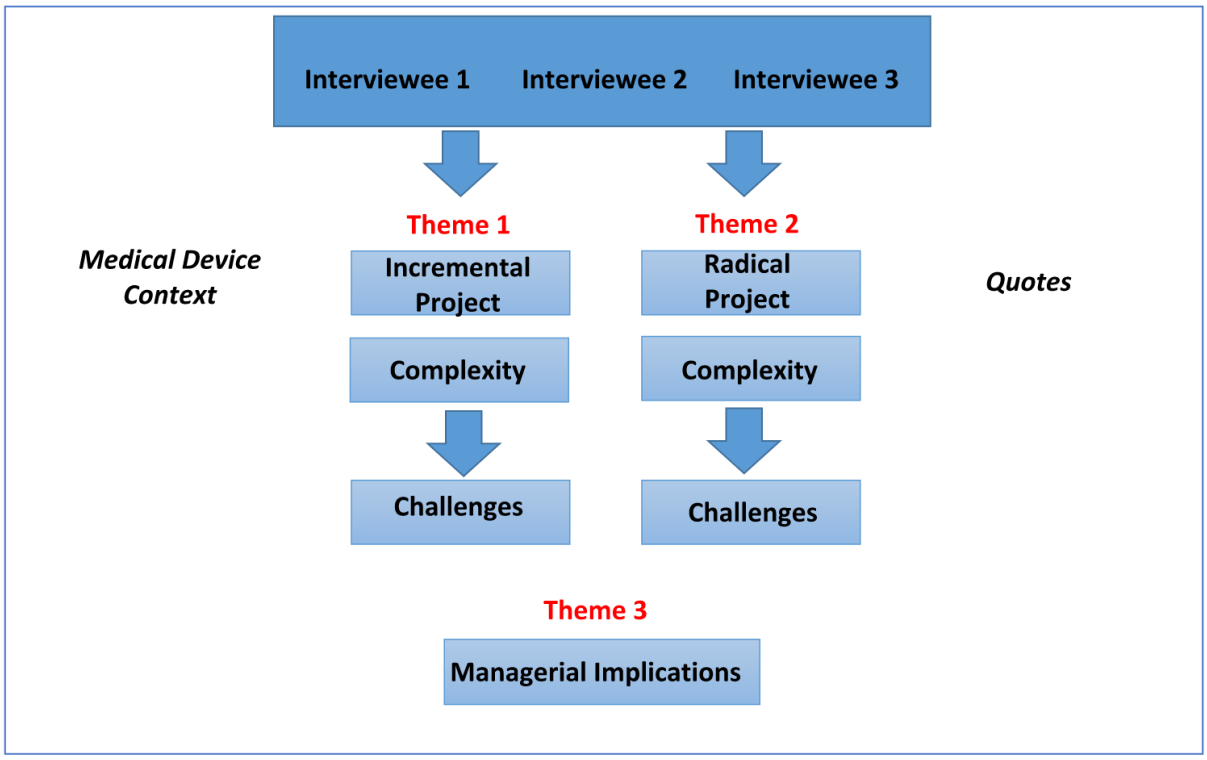

Figure 5. Themes held in the in-depth semi-structured interviews.

4.2. Theme 1 - Incremental Project

This theme is about an incremental project that has been conducted in the case company. It is about a cooling device that can treat patients with stroke. There is a hypothesis behind the treatment of stroke patients with brain cooling, the hypothesis is that the brain can handle oxygen deficiency significantly better at cooling down and thus take less damage. For stroke patients, traditional hypothermia treatment causes a number of side effects such as infections and increased bleeding risks. By instead cooling the patient's head, it is a more efficient process than cooling the whole body. By lowering the temperature in the brain, studies have shown that stroke is alleviated by lowering the temperature of the brain and at the same time, the risk of brain damage is reduced (Case Company, 2016).

4.2.1. Project Start-up

According to the product manager who came from the parent company, the project started with him running into a neurologist that was a manager at a medical faculty and the idea with cooling the brain emerged. "*Anyhow, we had money to do something so the CEO of the parent company*

and me started the subsidiary". The neurologist wondered if the brain could be cooled to a certain temperature so in order to treat patients with stroke and heart diseases and the project started. "*The CEO got the idea that we could do something, and we played with the idea*". They started to develop an old system that was developed during the 90s from the parent company and modified into a working medical device. "*We took an old system, played around with it, made it cool the brain, the neck and at the same time changed some features in order to make a proof of concept*". Drawings and blueprints for the device was made and it resulted in testing of blood flow and at the same time tests were made with spectroscopic methods since it was difficult to test healthy volunteers for temperature measurements in the brain. These tests were made in Scotland. "*Scotland is one of three Universities that can cool the brain, they are very good and made a study for us, essentially the whole company is built on that study*".

4.2.2. People and Actors involved

Involved in the project was the product manager, the CEO and then came the project manager together with the risk manager that made the physical medical device. "*It was me from the beginning, together with the CEO, then came the project manager, so it is him and the risk manager that developed the product from scratch. Me and the CEO uses the parent company's device for testing*". The development of the product was aided by a Danish person that had been developing an old system. "*We brought in a Danish "doer" that had been developing a very old system for the parent company during the 90s*". According to the product manager, the marketing activities were important but medical competence was also needed. "*The medical competence is needed to evaluate clinical studies, from the beginning it was a literature study where we had collaboration with hospitals doctors to test for voluntary participants and patients"*.

The company has many suppliers since the product is quite complex and consist of many parts. These had to be managed during the project and they provided feedback on component parts for the medical device. *"The suppliers had a few solutions, they have really high competence. We did drawings, we own all the development and documentation. The suppliers just do what we tell them. But we have taken components that they suggest, that are better than what we thought from the beginning"*. Furthermore, most activities related to the suppliers are on them, the company mostly focuses on the right article number. *"They make all purchases, it's on them, but there we have an expert on pumps, heat exchangers and those things. From the beginning we had put in a too large pump. Out with that and in with a smaller, so we have changed things like that during the project"*. As a result from being a small company, collaboration with suppliers were very important. *"Yes we collaborate with many, we are a small company so very much of our strategy is to work with suppliers and we have different collaborations" - Risk Manager*

Apart from the suppliers, there were also a numerous amount of consultants involved. According to the project manager all suppliers contribute with competence but at a certain cost, ideally he wants that the competence provided should be free so one strategy was to aim for the development budget that the suppliers have. *"You have to sell the idea that, if you invest capital on certain developments for us there is potential for you (the suppliers) to produce much of the devices in the future and make a huge profit, why would we take all the risk?"*. Other consultants were also part of the project that dealt with the mechanical constructions and they in turn, had sub-suppliers for the constructional parts. Industrial designers also have a part in the development of cooling plates as well as insulation and they in turn collaborate with the suppliers dealing with mechanical parts. *"We also take in specialist competence regarding materials and quality, this*

project spans across every wide areas, both technical and other questions regarding quality and regulatory issues. Of course, we have collaboration with clinics and doctors".

The buyers, which were hospitals provided with feedback. Clinical managers, cardiologist and other partners were also part of the project when it come to the medical part. *"We have been interviewing nurses and doctors in south of Sweden, Ireland, Germany. Received information from them, it is important when developing a product. It is easy that we build an engineering product, flashing lights and fancy displays with a lot of effects and things, but not all nurses want that, they might just want an on/off switch"*. The product is going to change a lot since it will be out for a year, and then the software is going to be changed as a consequence from the feedback from buyers and other actors such as users. *"They are very thorough with operation, usability and they get furious if you give them a complex product. They want simple and easy to use. We have talked with not just doctors and the functionality, but also cooling-groups, nurses and operators. The plates, how they should be, how it should be packaged. It is very important to make them happy. Then they will use it more"*. Also the inputs from clinical studies and doctors had an influence on the development of the product under the project. *"One of the best ideas we had, came over a cup of coffee at a conference where we talked about something completely different. Doctors think that they know everything, but it was simple thermodynamics and very easy to implement"*. The interviewees says that more or less all of the people and actors involved have been provided with ideas and suggestions to the product, to certain extents.

4.2.3. Project progress and Activities

The medical device was built with no influence from regulations in the beginning since the aim was to have a "proof of concept" and this was a study before entering the project. The prototype was tested and then about 1-2 million SEK was spent to build the medical device. *"We felt that this could work, we have been thinking straight, we had enough cooling power, the pumps work, it looks sustainable and could be used for healthcare".* This type of device has many components and the strategy from the managers in the beginning was to develop the product into a working device. Activities related to pre-studies were carried out very early in the beginning, and experiments were carried out before the real product development started. *"I cannot say that our first product was a full functional product, but at least we knew what the system should look like. We had worked with all the important key components in the beginning and thereafter we needed to fine tune the system, with different methods, then came the development of the software"*. In the beginning, there was not much documentation, but after doing the risk analyses it was important to manage documents properly. *"One device, 15 binders, and the notified body looks through all of them"*. After that the design issues were addressed.

The specifications on the medical device were further developed and a first version of the physical prototype medical device was finished 2015. The work progressed with a fast approval of a quality system in order to obtain CE certificate of the devices. *"It went really fast, very much of it relies on that me and the project manager has been working with technological and quality systems before, we knew what needed to be done, and it's extremely fast for us, since many other companies might have to spend two to three times longer in order to get to that point".* The quality system was developed and maintained by the risk manager and the project manager, but then it became difficult to maintain the quality system with the projects going on parallel so a new quality assurance manager was hired.

When it comes to activities in the development of the medical device for cooling of the brain, there were many activities. According to the product manager, the most important activity is the marketing activities as a result from the huge costs in developing the product. "*The most important activity? The market.. Otherwise we would never have started it, there is money to gain. It cost a lot to develop a new product*". This type of medical device also needed medical competence since the focus must also be on the patient and the risks as the risk manager states. *"You need medical competence, because risk analysis is what we base our development and the development methods on so that we can focus on the main risk for the patient"*. The most important activity for the project manager was the meetings with all the managers since he has been working a as project manager for many years and in large companies. According to him it is important for them to have face-to-face contact all the time and there must be trust in the project team. Even though they sometimes work very far from each other it is important for them to meet all the time. *"I have been working as a project manager for many years at a large company. Everything goes very slowly there, the product development takes 8-12 years to complete. I think the most important activity is for us to meet all the time and have effective, short meetings where we make decisions"*.

Another significant and major activity is concerning the software because the medical device needed to be functional, reliable, have features and be operational by users. "*It has to be a mix, this product already has an established market, so there is competition, we have large competitors, Japanese and a few in Americ*a". Furthermore, activities related to software development and studying competitors was quite time consuming for the managers since conducting the studies and projects related to the medical device was complex. "*We spent a lot of time on the competitors, what are they doing? The most important thing is to provide something unique. It is a lot of machinery and integrated. It doesn't exist so much data, you cannot drive the projects the same way as more established companie*s". Having the software resulted in the medical device being classified as a 2b which is moderate to high risk.

There were activities related to interviewing doctors because it was important to have their view of the product development during the project. Since they have close relation to patients and can provide feedback. "*The risk manager and project manager had to come up with clever solutions, you have to be responsive. We had to interview many doctors, what do you want that can cool? What do you lack? And they responded: This should be very good, but we don't want this. So we took the input and did something with it*" - *Product Manager*. The risk manager agrees that many of the requirements came from the doctors: *"We have been talking with the hospital personnel a number of times and they have many point of views on how the system should be designed, many of their requirements are on the list of the product, you can mention sound level, usability which they emphasize very much"*.

The end-users i.e. patients did not have any inputs in this project since their only wish at this stage is to become healthy again. Even though chromatomy can be made on the brain, it is their least concern, they want to become healthy, explains the product manager. "*There were no inputs from the patients, when we started to scout with doctors regarding comfortability, they said: screw it, you are going to save their brain"*.

Activities related to suppliers and their inputs had an influence during the project. *"The people we have worked with have been very fascinated by the product and what is to be achieved, and*

they have provided with own ideas and asked challenging questions, our industry designers, programmers and mechanical constructors".

When it comes to activities related to regulations the focus was on writing up a quality system that the risk manager and project manager was responsible for. This activity was very central in medical device development according to the risk manager. There musts be a quality system and it needed be followed, that system is specified and moves further into all the development. *"We need to have a quality policy and a quality manual that gives a comprehensive overview on how the quality is maintained in the company. We also have Standard Operating Procedures that describes the different areas in the different standards, there must be routines such as how to handle complaints from customers, how to develop software, testing of electronics, there are all possible requirements there, how to maintain improvements on the quality system"*

The clinical activities resulted in the creation of the company. "*We wanted clinical evidence and that's what we got".* The product ended up fulfilling the requirements and is unique. The question: Did the project end up as expected? Was asked to the product manager. *"I don't think so, both yes and no. It is a business model you perhaps get a thumbs up on, and it's unique in its part, both yes and no*". The project resulted in a confirmation that a person could be cooled down. Depending on which country it is there are different indications on how much and how long a person can be cooled down. This can have influence over what temperature a patient can be cooled down to. According to the risk manager, the project resulted in a medical device that was safe. But all NPD projects always require more time but the strategy was successful. *"The end result was a medical device that was safe, our improvement projects aims to make it more commercially attractive, I would have dared to cool down myself or a family member, but then there are many other details that needs to be considered"*. Furthermore the aim with the project was to obtain a safe and efficient product and being approved by the notified body rather than getting out to the market. *"The big aim was to be approved by the notified body so it ended as we hoped for, we are as astonished as you are".* According to the project manager, projects never end up as planned from the beginning, but if goals and visions are not set you don't get anywhere. *"We reached our bosses expectations and perhaps some additional, a bit less in other areas. There are many, many other things in this, right price for example, we have to be able to make some money".*

4.2.4. Challenges during the Project

Challenges with the project was discussed during the interview and according to the product manager, there are always bottlenecks even though the managers worked efficiently. Some of these were clinical studies and healthy volunteers. *"Well, we should have done more, bottlenecks are always clinical studies and healthy volunteers".* Other issues were regarding the testing of the devices in order to gain more data. *"Testing of devices, perhaps we should have done more of that in order to obtain data, but it is very expensive, if you are small then the focus in on finishing a product and then stick to it. But you would have gained more by doing more studies and get feedback and tweak it up afterwards"*. According to the project manager there must be clinical evidence in order to be CE certificated but there are different ways to obtain clinical evidence. They mostly used healthy volunteers since the product they are developing already has an established market. *"We use temperature studies, so we use what others have tried in order to move forward faster".*

The workload was high but the focus was very narrow so according to the risk manager, not much was changed during the project. *"We didn't have much time and was very focused. Of course there were changes before and after, but we were very concentrated and had a narrow focus on this project"*. The risk manager felt that not everything went as smooth as expected. The project manager felt there were many things to handle and the most important thing was to prioritize, address and delegate the issues to the right areas. *"It's like handling 50-100 problems all the time. Then it's important to prioritize them and see which ones that are most important to solve first".* One example he gives is that if you have 100 problems, the engineers can solve 70 of them, but then there is still 30 left. The project manager delegates 20 of them to the hired consultant and they report to their project leader, and together they might solve 80 of the problems, 20 goes to the project manager where he can solve 18 of the, and the rest 2 problems needs inputs from the CEO to solve. *"Is it an engineering problem? If you delegate them upwards all the time it comes to my level, and then it comes to me to solve them and I must guess and things don't end up so well. You sort the problems to the right place"*.

A major issue was related to quality system and regulations. The project manager explained that depending on what approach you have to regulations the outcome can vary and can have tremendous consequences on operation and cost. *"The regulations are made in a way that it should fit all companies, but not all regulations are appropriate to all companies. Then you have to interpret them in a smart way. If you are not familiar with regulations then a project can cost everything from 100 million Swedish crowns to billions"*. For him it was important to focus on the safety of the patient, if the quality system is not handled properly a patient might get hurt. *"80% of these quality systems adds value to the company and the rest of 20 % does not. It's about finding and adjusting so that you only do as much required to the not so important areas and a really good job on the important areas where the importance lies in the patient"*. It was a difficult task but the project manager had been working with questions regarding quality systems and regulations for 15 years in his previous company. After a while and somewhat 40-50 audits with FDA he learned and was familiar with the important things to address when it came to regulations.

According to the product manager: "*General problems are that regulations influence the process, but we have done our homework. We have made some kind of Swedish record. From nothing in May 2014 to a quality system 13485 for medical devices and an CE certificate in less than a year, the risk, software and product managers are extremely good at that, otherwise it doesn't work"*. During an old project in a previous company that the manager worked in, the quality system costed 24 million crowns but this case company made it on 750 thousand crowns. "*An example is that the quality system on a large company differs from a smaller company. Here closeby, a company has spent 40 million on their product and quality system, but still they have nothing. They have been operating for 12 years, they have a difficult product and they have done a lot*". The work was constantly monitored by the notified body since the quality system was developed during the development of the project. After writing a quality system that follows the regulations that are adapted to the size of the company, the quality system must be followed. There are external rules, laws, directives and standards that needs to be followed and if these are not followed, you have to show that you have something similar which is often is much tougher. "*We follow the standard 14971 which is the standard for risk, and it's a very good standard to have, it is relatively easy to implement in a company, the first step is to show that you follow the standard and show that you have done all the risk work that needs to be done*". Choosing a tough notified

body is not as easy as it seems but they require much work and have high standard according to the risk manager. *"They have high standards, they have been monitoring us a few times before we have been audited"*. The company have to have a quality system, a quality policy with a quality manual that describes the way quality management works in the company. Standard operating procedures must be included that describes the different areas in which the standards are, and there must also be routines for everything the standards require. *"We need to have Standard Operating Procedures that describes how to handle complaints from customers, how to develop software, how to test electronics, and how to improve and maintain the quality system"*. The risk manager continues to explain that even though you make it easy for yourself by writing down the requirements, you still have to follow them to every point. Furthermore, the essential requirements need to be fulfilled. The project manager agrees. "*It is different with different types of products, some are difficult to test on healthy volunteers, there is a certain point to what you are willing to test a volunteer for. It's a different viewpoint, our is more a commercial one, some clinics that are interested in our system require us to have some type of quality assurance"*.

The project resulted in a class 2b medical device and is among the moderate to high risk classification of devices. If the software is not functional a patient can be harmed. When it comes to the temperature interval nobody knows exactly the optimal temperature for hypothermia "*It is very difficult, they are constantly fighting with it, many go with 32 degrees Celsius, but nobody knows. It's the charm with Hypothermia. There are more complications the lower you go. The risk analysis is very tricky if you lower the temperature too much. It is smart to put it to 33 degrees Celsius*". The link between the market and the clinics was held by the product manager where he found doctors to assist with the development of the project. *"The product manager is the link between the clinics and the market. And the development, he is very brave and goes out with our product, and then unexpected things happen, the alarm goes, hot water is leaking"*.

The project manager reflects back on the project and says that since the device itself consists of 300-400 pieces and many tests were conducted both internally and externally, one of the main challenges was the cooling pads. Since it had to fit patients of different age, size, shapes etc. and that took a lot of time. *"If I were to do the project all over again, I would have focused on the surfaces on the device that touched the head. I would have been thorough to focus on that early. Now it was last step in the project".*

One of the challenges during the project according to the risk manager was the time. The managers have a lot to do. "*When i was senior manager at another company I was responsible for the really large projects, then I spent 38 hours on meetings, to listen to people that were angry because they did not receive the right information or something that did not contribute to the project. I perhaps had 2 hours during the evening I could actually do what I was hired to do. A larger company couldn't produce this type of product on six months because it would have taken 6 months to discuss who should be the project manager*". Furthermore, he states that in the company they fight over who has the least amount of titles since they have a lot to do. The project manager says that the most important issue in the beginning was to find the right project team and the financial resources in order to pull the project off. *"In the beginning of a project you don't know what has happened after a year. You can look back at the project planning and see that you were quite detailed during the beginning. 8-10 months after and the things at the end is a game of guessing. That's the challenge"*.

4.3. Theme 2 - Radical Project

This theme is about an ongoing project that is conducted in the case company. It is about a cooling device that aims to cool the mouth. More specifically, a product that could cool the mouth of patients to prevent oral mucositis, which is inflammatory condition that affects a large proportion of patients treated with chemotherapy or radiotherapy for cancer. Almost every patient that undergoes bone marrow transplantation receives this type of unwanted side effect of the treatment. These treatments targets fast growing cells in the mouth, which results in wounds in the mouth as a result from the cells dying. By cooling the mouth, it can prevent the occurrence of oral mucositis. The medical need for this treatment is very high. (Case company, 2016).

4.3.1. Project Start-up

This project with aim to find a product that can prevent oral mucositis by cooling the mouth was initiated by a partner to the company as the product manager explains. *"A partner asked if we could find a product they could sell, then we thought, hmm perhaps we can do a product ourselves. Because nothing existed, there was only pharmaceuticals and the market was very expensive"*. After conducting a marketing research in order to identify problems and the size of the market in order to elaborate the business potential, one of Sweden's top researchers in the area of the mouth disease was interviewed and later on joined the team and the project started. *"We did market analysis in order to identify the problems and contacted the researcher that we are hiring now"*.

4.3.2. People and Actors involved

Involved in the project are all the managers, risk, product and project manager. They handle the market, partners, clinics, device development, documents and certificates. Apart from them dentists are also involved. *"We checked with dentists that are experts in the oral cavity and he provided us with a PhD student, so we sponsored him at the hospital to help us develop the mouth-device".* Additionally, a professor in odontology is involved together with a PhD student. The university and institutions deal with the literature and clinical studies since it is something that the company cannot deal with, they need help from the hospitals, explains the project manager. *"They deal with the literature because we can't, they have to deal with the healthy volunteers with studies in vitro. In the mouth cavity and those things, very much of those things are dealt with in the project"*. The inputs and feedback from the hospitals have influenced the development of the project states the product manager. *"The product has been modified in over a year, it goes back and forth to find the optimal solution. With all the help from the competence from the university hospitals"*.

A company that deals with the design questions are part of the project as well as a company in Germany that produces the cooling device used in the medical device. Much of the work is done by consulting firms and suppliers, the company have requirements that for the device that needs to be fulfilled. Then it is up to for example the suppliers to maintain the requirements. The many suppliers can also have feedback on the development of the project. *"It is a long list if we were to count all of the suppliers, we have industry designers as well as suppliers from China for example" - Risk Manager*

The buyers i.e. the hospitals can also influence the development of the project and as the project manager explains, much of the feedback is from the doctors and healthy volunteers. *"We have been trying on dental students and they have perfect teeth so it is a bit different for them*

compared to the older people". This type of cooling device for the mouth operates in temperature intervals and these are associated with risks, under 28 degrees Celsius excessively cooled, 28-32 degrees Celsius is moderate and above 35 degrees Celsius is normal body temperature. The project manager explains that operating in too low temperatures generates more danger than advantages. *"It can be adjusted to temperature between 32-28 degrees Celsius. So you can change depending on what the doctor finds suitable"*.

Another actor that is in the project (as well as previous project) are the so called notified bodies which is an entity to assess whether a product that is placed to the market meets certain requirements. The company has a good relationship with the notified body they have chosen. *"When it comes to notified bodies, we can take easier ones than the ones we have chosen. It doesn't matter what system it is, it doesn't affect the quality of the end product. We have chosen a notified body in Germany since they can make audits for FDA, and it is a tough quality stamp so then it makes it easier to assess the regulations in other countries. If you have a relationship with the notified body, then you know what they require and it is easier to understand their way of thinking"*. The company has a quality system of ISO 13485 and it applies to the products developed in the company, but it is just a quality system that gives the permission to be CE certificated, the company has both of these certificates to develop the medical device. If the products go outside the scope, the application for other certificates needs to be made according to the risk manager.

4.3.3. Project progress and Activities

It turned out very difficult to develop this type of new oral product says the product manager. *"It was very, very difficult to develop this type of product, mainly because cooling box is bad because anyone can develop that, you don't have to be smart. But developing a product that is going to be inside the mouth was harder than we expected"*. Activities involving the patient are important in this type of studies and project since it has to fit a large number of varying patients. The project manager agrees and also states that the cooling device is easy to develop because they know what they want, it is more of an issue regarding the design and the surfaces that will touch the inside of the mouth. *"The last project was about the cooling pads and the surfaces, this project is about having it in the mouth. It has been the most difficult thing, to develop the device intended for use in the mouth"*.

But at the same time, according to the product manager, things are progressing and testing of the prototypes on healthy volunteers are awaiting. Afterwards, clinical studies will be made. *"It has to fit many patients, they are sore in the oral mucosa so you have to have a soft material, you need to be able to have it in the mouth, for several hours. It is very hard, and there has been many prototypes that we have dismissed"*. This device must feel comfortable to have in the mouth since the patient that are treated usually have nausea during the treatment, adding a device in the mouth might be uncomfortable.

Since the quality system for the company is established and they have a CE certificate makes it easier to follow the regulations says the product manager. The device is classified as a type 2a which is low to moderate risk. "*This device doesn't have a software, so it goes much faster*". When it comes to classification of the device, there is a formal procedure that needs to be followed and is according to the project manager not so difficult to do, but takes a lot of time.

Being a small company, the work is more effective in the sense that there are less meetings and more time can be spent on the development of the medical device. *"It takes a lot of time with many departments, too much meetings, meetings about meetings, and too much inputs"*. The drawback is the limited budget the company has to operate with, larger companies can deal with many paths and have more healthy volunteers and not worry about the cost. The workload was also high during this project. *"The project manager must have spent 14 hours per day, seven days a week working. We should have had someone dealing with questions regarding quality in the beginning so the project manager can deal with the issues be find important. He is good in dealing with quality, but not everybody is"*. The project manager agrees with previous statements. *"The biggest challenge is the time, my boss wanted it finished yesterday. I think we could have been better there"*.

4.3.4. Challenges during the Project

When asking the product manager for challenges during the project the answer is clinical studies i.e studies that involve human beings. *"It depends, we receive new prototypes now, if they are good, the only challenge is the clinical studies. To get the studies finished as fast as possible. It costs a lot"*. Depending on the type of product that is tested, the time and cost for clinical studies can vary as the product manager describes. *"This is a new indication, no competitors, you want to be fast. Then you have to build a solid clinical evidence. It takes time, it is the biggest challenge"*. The project manager says that so far the studies have been made on healthy volunteers and then studies will be made on more of them, but if clinical studies were to be made it cost more. Healthy volunteers are cheap, but it needs to be approved ethical. *"It might be difficult back and forth, and if you cannot get ethical approval, it has to go through the review board and then it becomes more expensive"*.

Apart from that, the essential requirements need to be maintained, the product manager was not aware of them. *"Very good question, I don't know, it's the project manager that does this, we give them an Scandinavian Risk Solution as well as provide the required Medical Laboratory Science, then it's up to the suppliers to handle the requirements"*.

Even though the project is progressing with a few months lagging behind there are the issues with clinical studies which according to the managers are time consuming and costly. The product manager explains: *"This study is progressing slowly, there has been clinical studies for other products, so we expect the same feedback and then we want clinical evidence"*. At the same time, during the progression of the project there are a number of suggestions for improvements from external actors that constantly influences the layout of the project. *"During the clinical studies, a number of suggestions for improvement will emerge, the device cannot have a display, it cannot have this and that, and then we change it and then we make a large launching of the product".* The customers, which are the hospital has a lot of influence on how the product should look like. *"We have inputs from the customers. There are always those who want everything in a product, people that want it to be super easy. You have to find a balance so that it doesn't become too costly. Certain standards of stability needs to be held. It is very difficult, you can make a super cheap product and you can make an advanced product for those who want it. It is tough to find a suitable product that everyone likes. It is tough"*. An issue that the project manager addresses is the comparison between the healthy volunteers which are in the age span between 20-25 while the patients are in the age span of 40-50. *"If you think about it, the older people have another*

dental hygiene, because if you are 20-25 then you don't have so many holes and shooting pains. But when you are 50-60 you have smoked and hooked and have another type of dental hygiene".

The people that are going to use this product is going to have it in the mouth which is not so comfortable at all times. The product manager is optimistic about the final result. *"The mouth-device must be tolerable. It is difficult, difficult, difficult. If we can handle the part then we know that every piece will fall together. 100% of the data we have is good data. A simple product, tolerable is what we want".* At present, the only treatment for the patients is chemotherapy, the patients have strong nausea, but apart from that they have to want to use the product. The device itself must be in the mouth, for a long period of time at depending on treatment. "*The nurse must like the product, the patient must like the product. If it is tough to have in the mouth, they don't want it"*. At this time, only pharmaceuticals exists for the treatment of this disease, and they only alleviate.

When asking the project manager for the challenges, the response is mainly about the production. How to deal with issues regarding production and issues resulting from suppliers. *"We work very much with the other medical device (the system in the incremental project) and at the same time I am needed in this project. I find it the most challenging thing. I want to focus 100 percent on the mouth device now"*. He states that; "*When 80 % of the project is done, there is 80 % left. You think you have reached the goal but it is never that way. It is a lot of small issues at the end to make it work well. In the production, I found that: how should we do this? How should we do that? Even though you think the product is finished, there are always new things emerging. A supplier that cannot handle things correctly and has wrong measures, and it's so much going on with the other project and I don't have so much time"*. He continues, *"It is very difficult to make everyone happy. If you can make 70 % happy, 25 percent quite happy and 5 % perhaps happy in the future, you should be happy"*. This was not easy, it was very difficult.

There are many markets for this product that the company is not used to operate in. These are the middle-east, central Asia, Africa and the third world countries. The aim is to make a cheap product that can be implemented in the different countries. The managers are positive to the outcome of the project, especially the project manager: *"I believe much in the project, nothing exists today, only medicines that you can take when you have received the cold sore. If we succeed with the project then we remove the problem completely, no such product exist today"*

4.4. Theme 3 - Managing Projects at the same time

When the product manager is asked how projects are chosen the answer is through networking and if there is a potential market for it. *"Many ideas pop up through networks, you discuss what is available, what actually works, and at the end if you start, is there a market?"*. Even though it was discussed that other products related to children and products related to dental care could have been investigated, the market was too small and there was not much to gain. Also much of the ideas have been from outside of the company, from someone who is interested and from that new things can emerge. *"If you have someone that is really interested, then you only use spare time, it becomes cost-efficient and fast"*. The product manager further continues with discussing that it is much about tasting an idea, his boss and the project manager is out to investigate if there is interest in projects, because the doctors must have interest otherwise it is difficult to make something happen. *"It is much business, resources, networks, my role is to examine the possibilities of patents and after we have looked at that, the board of directors take a look at it"*.

If there is not a solid patent protection it is difficult to choose a project. *"The board of directors makes the decisions, we cannot start anything without their permission"*.

Companies normally manage projects at the same time and it was the same with the case company. The product manager says: *"At the moment, I am working with three parallel projects, and it is quite tough. Even though the cycles of the projects are clear, there is always a waiting game for certain projects and some are suffered. You deal with the radical project, where the other is awaiting and press on"*. Another important discussion was about the significance of certain projects, the first project the company conducted vital to succeed and needed much focus. "*Our first project was vital, otherwise the other projects would have been finished now if we had pressed on*". So the focus is different depending on the novelty and significance of the project. The managers agrees that since the time was limited, the focus needed to be narrow in order to make progress since the company is small. *"Since we didn't have so much time, we said that we only do this and don't care about the other things, we were very focused. But at a delimited focus, we didn't change so much" Risk Manager*.

The company tries to keep the projects alive which means that the product is constantly being improved depending on feedback and implementation of the information received from customers. *"We do something, and then we update and improve it. After one year then we receive tremendous feedback from customers. Then we scale it down to if it is doable or not, how much effort and testing is needed and how expensive it is going to be"*. The project manager is also working with 3 projects parallel and he reflects over how it is to manage projects at the same time. *"It depends on how you look at it, when I was working at my old company we had small projects concerning products that had been on the market for 10 years, then complaints come in and you had to improve, then I dealt with 100 projects per year"*. When he is asked how it is to manage 3 projects at the same time the answer is that it is very fun but takes a lot of time, sometimes it can be too much.

Managing projects can also relate to managing improvements to existing products. The product that is soon to be marketed is expected to receive feedback regarding adjustments which in turn also affects how the suppliers will be managed explains the project manager. *"The product we ship to the marked will be open for modifications and then we will do a cost efficiency. Since we are a medical device company, the suppliers cannot make any changes without our permission. Of course they can come up with ideas, but then we need to make decision on what needs to be done. That's why I am very thorough with the changes without our permission"*. Which means that, this was a bottleneck in the sense that every decision regarding changes must go through the project manager.

Practically, the work in the company is parallel where each of the managers have their field of responsibilities. The risk manager focuses on software and risks etc.. Managing the projects involving software tended to be complex which made the product difficult to improve says the product manager. *"We have removed the software from the ongoing project, only a on/off switch and hardware with some electronics such as alarm and diodes for notifications, but those are hidden"*. Having little software and much hardware makes operation easier and if there is need for service, the device can be opened and be repaired. *"You have to deal with both the usability for the doctors and nurses, and at the same time the requirements from the patients"*. The project manager also has similar view over the practical work, he finds it easier to integrate the work

when the team is small. *"We work as parallel as possible, but some issues needs to be managed sequentially, like the medical device regulations, we don't want to verify and validate at the same time. Rather verify first and then validate. Otherwise very much parallel work because it goes much faster but with more risks"*. The work in the company is later integrated by the whole management team who goes through statuses, financials and how to end the project.

Managing projects at the same time also means managing studies at different universities. For the company most studies have been conducted in Scotland and very much depends on the interest of these universities. The product manager says: *"It all depends on the interest, we have been conducting studies in Scotland more than Sweden. Future projects will be held in Sweden. But you must find Standard Bearers, you have to find someone who thinks it is interesting, otherwise it takes time"*. Another major issue is how the studies and projects are perceived, if there is anyone who promotes it. *"It is important to have someone on your back that helps you say: sh*t, this is good. There are many really good products closeby here, but they have been going through hell in order to find Standard Bearers. They have had a rough time, sometimes it is just about pure luck"*.

Depending on what type of company and how large it is the organization and management of innovation projects differ as the risk manager explains: "*Medical device projects are very large, our projects are scaled-down versions compared to how the projects are managed in larger companies"*. According to the product manager the most important is to be fast and efficient. *"I think that for small companies, the most important thing is to be efficient, to be quick, not too many chiefs because then it takes long time, a lot of energy and will eventually run out in the sand"*. The product manager continue explaining that managing these projects require you to show the significance of your products to a number of different actors. *"The train is always going, it is of utmost importance that when you drive innovation projects, people can be really interested but you don't get anywhere. If you cannot show progress for the doctors or the hospitals you work with, they will lose interest. Then it is d*mn difficult to start it all over. You must be quick, boom, boom, boom!"*. Furthermore, he explains that it is more important to do it fast than perfect because then you will receive feedback and are in contact with the hospitals and end-users. If it takes long time, they get bored and nothing happens. Another important issue discussed was the flexibility and continuity in order to improve the products during the projects. *"We started very early, cooling water was leaked in the mouth, but we pressed on. If the device itself is crap, we throw it away and make a new one, by doing that you get continuity. How do you improve all the time?".*

Apart from improvements after feedback from the different actors, the competence required to develop medical devices is high and it is not always easy to integrate and instruct people that have not dealt with medical devices before. *"It is difficult for us to be experts on everything, many times we need to repeat certain subjects, and it involves a wide range of different areas. Many times you also have to integrate and instruct different people on what we expect, everyone has not dealt with medical devices before, and we need to convey the expectations from us and the regulations, what standard you need to live up to, and sometimes it becomes a shock for the involved, when it comes to the degree of documentation and accuracy" - Risk manager.* Thus, the context of medical devices are needed to be understood, and not all actors are familiar with the context as the risk manager explains: *"You can easily say that everybody understood the medical device context in my previous company, but all of our suppliers are not so familiar with the*

context". Since the context is so wide with so many actors, there are special areas that need to be addressed. The company has two large suppliers and they in turn have more sub-suppliers. *"We have two large suppliers, they in turn have 40-60 sub-suppliers" - Project Manager*. If projects are conducted at the same time a wide range of knowledge needs to be managed when developing a medical device as the risk manager explains: *"You can say that the breadth of the special areas in a medical device project is always a challenge to manage. It's not necessary to have a product idea or technical knowledge when developing a medical device, it requires a different set of knowledge when developing a medical device. You cannot just screw together something and hope that it works"*

The project manager emphasizes that it is very important to find the right team in order to conduct projects. He states that every human being is as equally good, but at certain things. In order to manage many projects, the team needs to consist of innovative people but also people that are thorough and can finish things. *"If you get that team which I think we did, you will do well. You cannot have just innovators, then they will find 8 new things, then you will never reach the goals. You have to have beginners and finishers. It is the most important thing, to have a good team with right competence".*

5. Analysis and Discussion

In this chapter, the empirical findings presented in chapter 4 are combined with theory. In the In the section Complexity in projects of different Novelty the two different projects are analysed and in the section Implications of Managing Projects the discussion is about managing projects at the same time and its implications.

5.1. Complexity in Projects of different Novelty

Following sections uses the definition of that a product achieved through a project can be defined as "*a temporary endeavor undertaken to create a unique product, service or result*" (Archibald & Archibald, 2015, p. 3) With new product development (NPD) in mind, which is seen as "*a collection of related activities targeted to convert a new idea, concept, or market opportunity, into a marketed product*" (Karniel & Reich, 2011, p. 20; Cooper, 1996) the projects can be seen to be of different novelty where the incremental project is described as an improvement to an existing product whereas the radical project can be described as a completely new product to the market (Tidd & Boley, 2002). Project complexity can be to "*relate to the novelty of the product, to its development process and performance objectives; and to its technological interdependence and difficulty*" (Yugue & Antonio Cesar, 2013, p. 5) Furthermore, the complexity can either be *external* which concerns market needs and the actors influencing a product, or *internal* which concerns variety in products and internal activities that affects complexity within the company. (Marti, 2007)

5.1.1. Complexity in Incremental Project

Theme 1 presented in the empirical findings illustrates a NPD project, which resulted in a medical device (Archibald & Archibald, 2015). This project can be seen as incremental since it already exists an established market for these types of products and the medical device is developed from an old system. Hence, the novelty of the project is of the incremental type and can be related to exploitation (Tidd & Bessant, 2013; Andriopoulos & Lewis, 2009). Throughout the project there were a number of activities that influenced the development of the project.

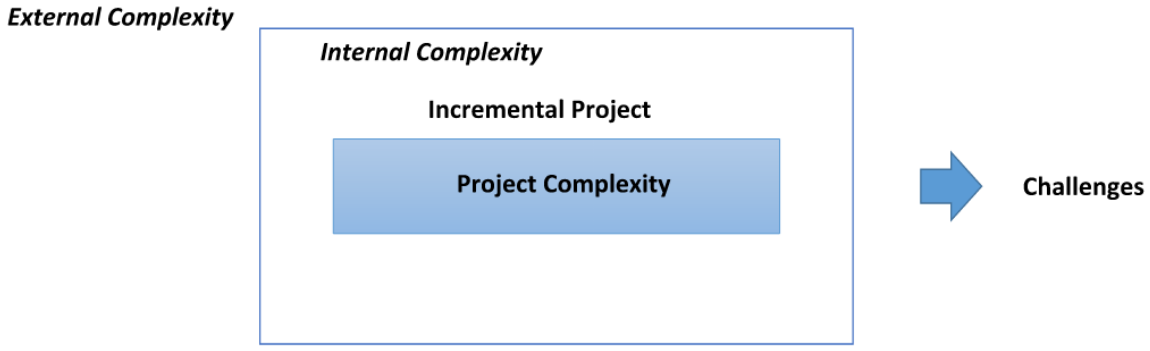

Figure 6. Illustrates the project and the influence of complexity. The project complexity leads to challenges.

During this project, there were many activities that made the project difficult. As the product manager stated *"Well, we should have done more, bottlenecks are always clinical studies and healthy volunteers"* indicated that studies needed to be made in which they were not in control of. These were done by external actors, hence *external complexity*. This type of product was tested

on healthy volunteers, and according to the managers, it was more cost-effective to use them instead of clinical studies. But there is also a certain point to what you are willing to do on a healthy volunteer and there can be activities related to ethical approval and clinical requirements of quality assurance. Thus, the activities related to clinical studies and healthy volunteers were dependent on actors external to the company, these actors could influence the NPD (Marti, 2007; Yugue & Antonio Cesar, 2013).

Activities related to testing of the devices were few as a result from lack to time and limited resources. The project manager said: *"It's like handling 50-100 problems all the time. Then it's important to prioritize them and see which ones that are most important to solve first".* It reveals that there were many activities simultaneously which needed to be managed in order to improve the medical device, this needed to be done by external actors in which the case company not did not have so much influence on, hence *external complexity* (Marti, 2007). Furthermore project manager emphasized that the activities needed to be delegated to the right place which made it difficult since many external actors needed to be managed at the same time. These actors are part of the networked healthcare map suggested by Sobrio and Keller (2007) and Laurell (2015). Hence, these external actors influenced the NPD project resulted in variations in activities that were dependent on each other in order to develop the medical device (Marti, 2007; Yugue & Antonio Cesar, 2013).

All the managers agreed that regulations normally have major influence over the product development process, but as a result from being experienced managers the activities related to regulations, risk management and quality systems were handled efficiently. *"The regulations are made in a way that it should fit all companies, but not all regulations are appropriate to all companies. Then you have to interpret them in a smart way. If you are not familiar with regulations then a project can cost everything from 100 million Swedish crowns to billions - Project Manager"*. The managers in the company made somewhat of a record when it came to handling regulations compared to other medical device companies closeby according to them. "*An example is that the quality system on a large company differs from a smaller company. Here closeby, a company has spent 40 million on their product and quality system, but still they have nothing. They have been operating for 12 years, they have a difficult product and they have done a lot*". Note that the quality system needs to be maintained in order for the company so the notified body chosen by the company are monitoring to ensure that the right standards are followed, hence resulting in activities related to maintaining the quality system. These activities can be seen to relate to *internal complexity* since it concerns variety in products and affects the complexity within the company, the managers have to deal with *internal complexity* since it can refer to handling of documents and activities related to regulations (Marti, 2007). At the same time the activities can also be seen to relate to *external complexity* since the regulations influences the product (Marti, 2007).

According to all of the managers, there are advantages and disadvantages with choosing appropriate notified body. Since they have the power to do audits to for example FDA there are benefits with having good relationships with certain notified bodies, but in turn they are much more difficult to handle and have higher standards, which consequently results in more activities related to the handling of regulations. The managers handled both *internal complexity* since the variety in activities concerns the development of the product, and *external complexity* since the actor is the notified body (Marti, 2007; Yugue & Antonio Cesar 2013).

The device consists of many parts where suppliers was responsible for the delivery of parts drawn by the company. The suppliers in turn, had responsibilities where they have to make purchases from their subcontractors. Even though the company owns all the documents, the suppliers also had inputs regarding component ideas and improvements for the medical device. As the product manager expresses: *"They make all purchases, it's on them, but there we have an expert on pumps, heat exchangers and those things. From the beginning we had put in a too large pump. Out with that and in with a smaller, so we have changed things like that during the project"*. Managing suppliers was important according to the project manager since they were responsible for purchases and responsible for some of the development, but still there cannot be changes to the product that affects the patient's safety, this was a bottleneck since every decision must go through the project manager. Thus, the suppliers are *external actors*, which can influence the NPD project. (Marti, 2007)

The buyers, which were hospitals had inputs from doctors and nurses and they needed to be managed since they possessed the clinical and medical competence that was needed to have an optimal product. Activities related to these actors tended to be difficult to handle according to the managers, the product manager stated: *"They are very thorough with operation, usability and they get furious if you give them a complex product. They want simple and easy to use. We have talked with not just doctors and the functionality, but also cooling-groups, nurses and operators. The plates, how they should be, how it should be packaged. It is very important to make them happy. Then they will use it more"*. This type of *external complexity* where the buyers, i.e. external actors had an influence on the product, consequently, the development was dependent on the buyer's (Marti, 2007; Yugue & Antonio Cesar, 2013).

During this project, there were not inputs from the patients i.e. the end-users. Depending on the type of product normally, there is user integration since they are the ones using the physical product, but this medical device treats stroke patients so there was no user integration as the product manager states: "*There were no inputs from the patients, when we started to scout with doctors regarding comfortability, they said: screw it, you are going to save their brain".* The managers understood this difficulty, and this can be seen to relate to *external complexity* since the actor is the patient, but they could not influence the development of the product (Marti, 2007).

5.1.2. Challenges

It can be seen from the complexity analysis for this type of project that clinical studies is a challenge since it can act as a bottleneck when it comes to the development of the medical device. The clinical studies are costly and must be performed by people with competence in the area in which the company not always have close contact with. It can be a waiting game and thus affect project development and time-to-market. The use of healthy volunteers can be a cheap solution to clinical studies, but the need for ethical approval can be a challenge, since there is a certain limit to what you want to try on a healthy volunteer. At the same time clinicians require quality assurance which adds to the number of activities required to perform the study, if the ethical approval is denied, then third parties will be involved which results in more issues to deal with. Since complexity relates to the novelty of the product and the dependency between the activities (Yugue & Antonio Cesar, 2013), the clinical studies were of *external complexity*, thus it is a challenge to manage this type of complexity, especially when the managers do not have influence over how the studies are conducted.

As a result from being perceived as a complex product with many components including software, many improvements needed to be done and at the same time which also can be a challenge when it comes to the management of the project. By being focused and narrowed down as the case company was resulted in them needing to handle many problems at the same time and they needed to prioritize. This can be seen to relate to *internal complexity* since the components in the product can vary thus influencing how activities are performed within the company (Marti, 2007).

During this project, there were unexpected things happening during the demonstration of the products, which consequently resulted in improvements. Even though there was a clear project plan, the managers understood that projects seldom work out the way as intended from the start. An example is that some of the components in the medical device should have been focused on in the beginning of the project instead of during the last step in the project. After 8-10 months, it is a guessing game according to the project manager. Thus it can be a challenge to point out the important issues that needs to be addressed during early steps in the project. For example, the cooling pads for the head should have been addressed early in the product design, but the patients had no inputs in the development of the product, and the shape of the head varies alot depending on what type of person it is and the age. These challenges can be seen to relate to *internal complexity* in the sense that the activities performed were dependent, concerned the product and affected the complexity within the company (Marti, 2007; Yugue & Antonio Cesar, 2013). But at the same time, even though the patients are the end-users and had no input, there were still *external complexity* as a result from the needs from the patients (Marti, 2007).

In the project, the managers had to manage a variety of people and actors in the medical device context. There was interest from the networked people whom provided ideas and challenging questions, thus it can be a challenge to manage the people, listen to their suggestions and practically make the changes required for the product. It requires managing people with different expertise and knowledge in different areas. The product turned out as a mix, unique but not fully as expected according to the managers. This is seen as project complexity since it relates specifically to the novelty of the device, to the development process and the objectives influenced by external actors that made the project difficult to manage (Marti, 2007; Yugue & Antonio Cesar, 2013).

5.1.3. Complexity in Radical Project

Theme 2 presented in the empirical findings illustrates a NPD process for a new type of medical device that is today an ongoing project. This project can be seen as a project of radical nature since it does not exist a market for the type of product, hence the novelty of the project can be seen as radical and be related to exploration (Tidd & Bessant, 2013; Andriopoulos & Lewis, 2009). Throughout the project so far, there were a number of activities that influenced the development of the project.

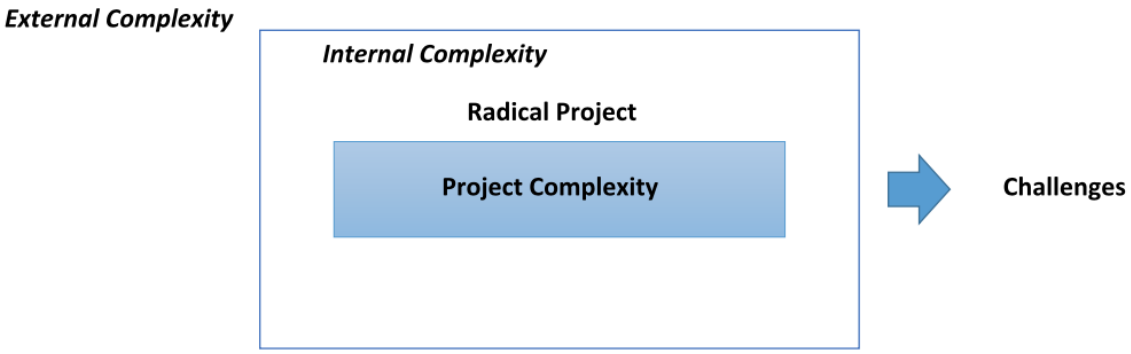

Figure 7. Illustrates the project and the influence of complexity. The complexity leads to challenges.

During this project, there are actors involved, which are dentists that are specialist in the oral cavity, PhD students as well as hospitals and universities. What makes it difficult for the company during this project as well as previous project is that they cannot handle the literature required for these types of studies. Activities related to clinical studies are also of importance during this project. As previously discussed about the incremental project, this radical project faces similar difficulties with the clinical studies, these activities needed to be managed and the responsibility were on these types of actors. Thus, the managers had to deal with *external complexity* (Marti, 2007)

A major difference between this radical project and previously incremental project discussed earlier is the involvement of the end-user i.e. the patients. Since the device is going to be in the mouth, studies have been made on dental students which have another mouth hygiene than the patients which are older and in their 50s compared to the students which are in their 20s. The product manager and the project manager stress the importance of having a tolerable device in the mouth, and developing the optimal device is a complex task. Thus, dependable activities had to be performed in order to develop the mouth device (Yugue & Antonio Cesar, 2013). Firstly, *internal complexity* since the company had to develop the device and the product has been varying as a result from difficulties in the design, these difficulties needed to be managed. Having many cycles of improvements suggests that activities related to the development of this medical device tended to be challenging, hence the activities were varying and dependable (Marti, 2007; Yugue & Antonio Cesar, 2013). Secondly, *external complexity* since an external actor i.e. the patients can influence the development due to the different needs (Marti, 2007).

This project involved the buyers, i.e. the university hospitals these actors needs to be managed since they possess the medical competence similarly to previous incremental project, hence *external complexity* (Marti, 2007).

The company chose a tough notified body in Germany, which consequently has advantages and disadvantages (Kimmelman, 2008). But that means that they have a relationship with the specific notified body and can understand their way of thinking making the handling of regulations somewhat easier. The managers handled both *internal complexity,* which means the documents and *external complexity,* which is related to the notified body and their influence over the NPD (Marti, 2007).

Even though the device itself does not consist of as many parts as previous medical device (incremental project) it was still difficult to develop the product. Recall that the previous medical device consisted of many parts, had software and the cooling pads were difficult to develop as they were developed during a late stage in the process. The suppliers were responsible for delivering and making the purchases necessary, but they are not allowed to make any changes because it can affect patient safety i.e. they have to be managed correctly according to the project manager. *"Even though you think the product is finished, there are always new things emerging. A supplier that cannot handle things correctly and has wrong measures"*. This type of *external complexity* was related to the suppliers and tended to act as a bottleneck for the development of the medical device (Marti, 2007).

5.1.4. Challenges

This type of product is a completely new product that does not have a market, thus a challenge is clinical studies in order to have solid clinical evidence. Products that are similar normally have similar products already on the market, which makes studies and regulations much easier to handle. Therefore, this study progresses slowly since feedback is required from the clinical studies. Additionally, the studies have also been made on healthy volunteers and faces similar challenges as the previously discussed incremental project. That means, that it might be difficult back and forth to obtain ethical approval, otherwise it has to go through the review board and becomes thus more expensive and time consuming. Similarly to the previous project, many inputs need to be dealt with. The managers found it difficult to please all the involved actors in the project since there are many changes that need to be made in order to satisfy the customers and users. Thus, the challenge is a result from *external complexity (*Marti, 2007)

This project has very much end-user focus compared to previously incremental project since much of the inputs are from the patients that are going to use the medical device. It must be tolerable, otherwise the patients will not use it since they will feel nausea from the treatment, and at the same time they will have a medical device in their mouth. The difficulty is that the company does not have direct contact with the end-user, but mostly with the customer (the hospitals and doctors). The end-user satisfaction was of importance during this project, hence the challenge was to develop a tolerable mouth device, hence activities related to the design of the medical device were dependable on the end-user and consequently, *external complexity* (Marti, 2007; Yugue & Antonio Cesar, 2013).

As the project progresses, the managers emphasize that it is important to make the involved actors happy, the suppliers of the materials, the many consultants, the hospitals and universities as well as patients and nurses, hence *external complexity* (Marti, 2007). Managing everything at the same time during this project is thus a challenge. The project manager was aware from experience that new challenges regarding production will emerge as the project progresses.

5.2. Implications of Managing Projects at the same time

5.2.1. Summary of Incremental and Radical Project

Table 2. presents a summary of the characteristics of the two projects of different novelty studied in the thesis. It involves the actors and the complexity associated with the projects.

Table 2. Summary of the projects.

Project Novelty	**Medical Device**	**Regulations**	**Actors**	**Internal Complexity**	**External Complexity**
Incremental	Cooling device for the brain	Notified Body Maintain Quality System Class 2b	Consultants Suppliers Buyers End-Users	Testing of the device Handling regulations Medical device design	Managing Clinical Studies Managing Healthy Volunteers Managing Suppliers Managing Buyers
Radical	Cooling device for the mouth	Notified Body Maintain Quality System Class 2a	Consultants Suppliers Buyers End-Users	Handling regulations Medical device design	Managing Clinical Studies Managing Healthy Volunteers Managing Buyers Managing End-Users

From table 2 it can be seen that the actors influences the development of the medical devices and they can be seen as an *external complexity* that needs to be managed (Marti, 2007). Moreover, the regulations is a result from an *external complexity* since it originates from European directives and the notified body. The handling of documents and activities related to laws, regulations and quality systems can be seen as *internal complexity* (Marti, 2007) since the managers have to maintain quality systems, handle documents and activities as a result from the notified body monitoring them. Moreover, the medical device design can be seen as *internal complexity*. (Marti, 2007)

5.2.2. Managing Projects at the same time

All of the interviewed managers are working parallel with three NPD projects at the same time, this can be seen as innovations achieved through projects (Archibald & Archibald, 2015). It can be stated that NPD is essential for the company to achieve growth and survival and these needs to

be successful (Cooper, 1996; Millson & Wilemon, 1998). Thus, the case company has both activities of exploration and exploitation (Benner & Tushman, 2013).

Previously, the managers have been working likewise with projects with their previous companies and have been working together since the subsidiary started. Working parallel is more efficient, but comes with greater risk as the project manager states. This practice can be seen as process-concurrency, which can be illustrated as self-managing project groups and influences the NPD performance (Ahmad et al., 2013). Even though the managers work parallel as much as possible, there is also team-integration and thus a mix of the practices.

The experienced managers reflected on their previous experiences in managing projects at the same time and similarly answered that being a small company resulted in more efficient management of the projects. Fewer meetings about issues that did not add value to the projects, but more efficient smaller meetings were decisions could be made efficiently. Even though the managers are aware of the cycles of the projects, the project plans, they all seem to agree that time is always an issue no matter the novelty of the project.

The managers were aware of the constant changes that the products in the projects of different novelty required, which consequently resulted in dealing with questions regarding usability for doctors and nurses, and at the same time requirements from the end-users. The brain cooling device was a result from an incremental project, while the mouth cooling device is a radical project, where one of the main difference was the end-user involvement. Thus, the management of the radical project differed from the incremental project in the sense that more activities of *external complexity* needed to be managed (Marti, 2007). The managers stressed the importance of addressing the issues concerning development when they emerge. A project always seemed to be suffering as a consequence of being on hold when for example waiting for clinical studies to be made. Other projects suffer as a result from suppliers dealing with changes to components. Thus, the managers had to prioritize; the implication is that at the same time, areas in other projects are influenced. Even though the problems are delegated and dealt with when they emerge, a consequence from complexity i.e. dependence and variation in activities will make the development challenging. This can be related to Lindemann et al. (2009) where the manager should manage the complexity in the beginning of the product design.

Many of the ideas and suggestions for improvements during the projects of different novelty are from consultants and the network of actors involved (Sobrio & Keller 2007; Laurell, 2015). Decisions needed to be made from the managers and depending on the relationship with the involved actors, making decisions that suits all the involved actors can be a challenge when managing the projects at the same time. Changes that are made as a result from ideas and suggestions, must go through the project manager, and decisions needs to be made by the managers. And since the company operates in a medical device context, every change must be thoroughly investigated and monitored, this tends to make the management of projects at the same time a challenge since the actors needs to be addressed simultaneously as the projects are progressing.

A general challenge for all companies operating in a medical device context is to address the directives and regulations including quality systems (Kimmelman, 2008). Depending on what type of product the company develops, the regulations can be addressed differently. With the notified body constantly monitoring, it can thus be a challenge since the activities can be time

consuming, affect the requirements as well as the intended use of the product. Moreover, the notified body can have high standards, which the company must follow. This includes standards that need to show that all the risk work has been done and at the same time the quality system must be maintained. However, the managers in the case company were experienced and knew how to effectively address the regulations for the two products that were developed, with different classifications comes more activities regarding concerning regulations (Kimmelman, 2008).

6. Conclusion

This chapter concludes and treats answers to the research questions of the thesis. The management of the studied NPD projects are presented together with the identified challenges. The differences between projects are concluded as well as the implications of managing the projects at the same time. Finally, suggestions for the case company are presented together with thoughts on future research.

6.1. Management of New Product Development and identified Challenges

In this thesis, new product development (NPD) for the case company that operates in a medical device context has been studied. The management of NPD projects for the specific product groups of the case company have been studied and it is found that the management of the NPD process deals with specialized knowledge. This type of knowledge is dispersed and scattered among a number of actors in the medical device context, thus, the managers have to deal with NPD and at the same time they have to deal with relationships with different actors, which means both *internal* and *external complexity* (Marti, 2007). It was found that the information regarding the medical device products are re-specified between the actors, thus enables changes to the medical device i.e. the external stakeholders needed to be addressed simultaneously throughout the NPD which means variation in activities that are dependent of each other (Yugue & Antonio Cesar, 2013). This can be illustrated as changes between the interfaces between users and producers as suggested by van Merode et al. (2002) where the authors state that a stability in the interface is required which can enable advantages for both users and producers of the medical device.

A number of challenges were identified during the NPD where the main challenges were in the area of *clinical studies* and *product development*. When it comes to *clinical studies* i.e. studies that involves humans it was found that the studies were perceived as bottlenecks to the development of the medical devices. Furthermore, it was found that clinical studies were costly and time consuming since clinical evidence is a requirement for obtaining CE certificates. These studies are not made by the medical device company and thus require deliberate ways for the company to handle clinical studies which were of *external complexity* (Marti, 2007). During the *product development*, it was found that integrating the actors and their perspectives in the context tended to be a challenge since the development involved continuous improvements as well as testing and evaluation of the medical device. Furthermore, a challenge is the regulations influence on the development of the medical devices, where the company is obligated to follow a quality system, which is monitored by a Notified Body. These challenges influenced the management of the projects for the case company since they first of all, are a small company and the cost for development tends to be high when developing medical devices. Secondly, managing the knowledge distributed amongst the different actors possess a challenge since the information about the functions of the medical device must be specified and re-specified for the involved actors in order to have efficient development. Thus, the choices made by the case company throughout the product design can be related to *internal complexity* (Marti, 2007), which influences the stability between the involved actors in the context. This thesis intended to identify challenges that occur when managing projects in a medical device context, thus the contribution is to the community that operates in this context and develops medical devices. Previous literature on NPD for medical device manufacturers has focused more on factors that influence the success and reduce project failure and resource commitment (Russel & Tippet, 2008).

However, minor literature focuses on novelty and complexity in projects considering medical devices, we found that it might be beneficial to make the distinction between internal and external complexity in order to identify challenges and address the projects in a medical device context.

6.2. Differences between Projects of different Novelty

The thesis studied two different NPD projects, one was incremental and the other was radical. The NPD projects were affected by the characteristic of *complexity*, which was seen as activities that are dependent of each other (Ahmad et al., 2013; Yugue & Antonio Cesar, 2013). It was found that the actors in the medical device context had a tremendous influence over the development of the project no matter the novelty. Furthermore, the different actors lead to an increasing amount of activities, which the development of the medical devices was dependent on. For these types of NPD projects, it was found that the need to acquire competence and knowledge as well as sorting, delegating and prioritizing these resulted in a challenging task for the managers. This was an *external complexity* that influenced the development of the medical devices and needed to be managed (Marti, 2007).

The incremental project in the thesis was shown to have more involvement of actors especially the suppliers, where these tended to have vital part in the NPD due to the knowledge required from each different supplier since the product needed many parts. It was found that the buyers i.e. the hospitals needed to be integrated during the development in order to provide knowledge within the healthcare area for the specific product where the managers had basic understanding, thus, *external complexity* (Marti, 2007). For this type of incremental project, it was found that the end-user was not involved at all in the project and the healthcare providers mainly provided the feedback.

The radical project studied in the thesis faced similar challenges during the development of the medical device. This NPD project also had involvement of actors that had tremendous influence over the development because specialized knowledge was required. Again, it was found that the buyers needed to be integrated during the process in order to provide knowledge within the healthcare area, which resulted in an increase in activities, hence *external complexity* (Marti, 2007). This radical project was very much end-user focused (compared to the incremental) and resulted in an increasing amount of activities related to the design of the medical device, this made the NPD project progress slowly. It was found that for projects of incremental as well as radical character, the activities regarding *external complexity* tended to negatively influence NPD progress.

It was found that the difference between the two studied projects were minor in terms of complexity. It was noticed that the radical project had more interaction with the end-user, which can relate to uncertainty in the function of the product. Since the effect of the medical device on the end-user is not established and uncertain as a result from being a completely new product, it requires more interaction with the end-user.

This thesis intended to study NPD in a medical device context and identified challenges that occur when managing projects of different novelty and the associated complexity. Previous literature that has elaborated NPD as well as project complexity and uncertainty has used a wide range of measures as dependent variables, resulting in difficulties to draw consistent conclusions from the studies (Ahmad et al., 2013, p. 333-334). Furthermore, the Gerwin and Barrowman (as

cited in Ahmad et al., 2013) suggest from a meta-analysis of 17 published papers that they did not find any association between an incremental approach and reduction in development time. In this thesis, it was found as suggested by literature that complexity negatively influences NPD (Ahmad et al, 2013, p. 344), but there might be an association between incremental projects and a reduction in development time since it was found that the radical project studied in the thesis had complexity factors that resulted in an increase in development time. However, this thesis have several limitations as presented earlier in the methodology, the context can influence the findings of this study as well as it being a single-case study.

6.3. Implications of Managing the Projects at the same time

It can be understood that managing projects of different novelty is not an easy task as a result from the challenges the NPD projects are associated with as previously concluded. Since clinical studies are important activities when developing medical devices, the studies are performed by clinicians, thus the implication is that sometimes it can be a waiting game for certain projects, resulting in *external complexity* (Marti, 2007), which slows the development of the medical device associated with the project. It was found that the differences between the incremental and radical NPD project was the end-user interaction. The interaction from end-users resulted in modifications of the medical device of radical character while the feedback from the incremental medical device was from buyers and not end-users, which gives the implication that the projects cannot be treated and managed similarly as a result from uncertainty (Ahmad et al., 2013), thus, it depends on the integration of actors, consequently, influencing time of development and resources.

Operating in a medical device context means that regulations needs to be followed, this results in an *internal complexity* (Marti, 2007) which involves the handling of documents and procedures to ensure that the development of the medical device must meet a certain standard and requirement. It was found that the difference in *internal complexity* was minor for the medical devices of class 2a and 2b, since the managers were experienced and the *internal complexity* can be related to their level of competence and experience.

It should be mentioned that the differences for these two types of projects discussed in the thesis are associated with the two projects, namely the brain-cooling device and the mouth-cooling device respectively. Thus, it should be noticed that the conclusions that are drawn could be applicable to medical devices that are similar to these, in this case, for the case company. The implication is that the differences leads to more varying and dependent activities required to develop the medical devices, thus an increase in complexity that negatively influences the NPD which the managers have to deal with.

6.4. Recommendations for the Case Company

We have found that projects of different novelty can influence how the development of medical devices is managed. Throughout the NPD projects, the company was aware of several challenges that the projects faced during development. Our recommendation for the case company is to very early in the process understand the important areas of development for the medical device in order to reduce complexity. For example, it was found that the focus of developing the cooling pads was addressed late in the project, thus the focus on the development changed during a later stage which makes the process costly and an increase in activities was necessary. By

understanding the important focus areas early in the NPD process, it can save both time and money for the case company.

A major finding in the thesis was the influence from external actors throughout the development of the medical devices which tended to make the development complex i.e. an increase in activities that are dependent of each other. The case company had very experienced managers who was well aware of the context and the different actors involved in the development of medical devices, but it should be emphasized that understanding early in the process who the external actors and to what extent they can influence the medical device can be advantageous for the case company. Many new start-ups in the medical device industry for example might not have experienced managers that can handle all the associated challenges with the projects might find these recommendations useful.

6.5. Thoughts on Future Research

The study performed had several limitations, thus gives us thoughts and suggestions for future research within the field, management of projects in a medical device context. The case company chosen was a small company with limited budget and resources, therefore future research can concern studies on larger companies with more internal actors involved in the project and more financial resources since the approach towards innovations projects might differ.

Another suggestion for future research is regarding the interviewed managers, in this thesis three managers were interviewed, one of them for example had over 15 years of working experience from the medical device context, in other companies there might be more managers involved in a project thus adds more difficulties when performing conducting innovation projects in small companies, since managers might not have the same experience and knowledge about the field of study.

The projects analysed in this thesis were of both incremental and radical character, where one of them had an established market and the other was a completely new product with no existing market. The projects analysed in the thesis were of both incremental and radical character, where the project had a specific product category, which were related to cooling devices, thus a certain classification of risk. Future research can therefore be on projects and products of different categories and classifications.

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Appendix 1 – Interview Guide

Purpose with the Interview

Is to identify the challenges associated with the management of innovation projects in a company that produces medical devices. Find out the project management and the associated challenges and how they differ between projects of different novelty. Also to find out what the implications of these differences for managing a portfolio of projects at the same time.

Interview Guide

Introduction, we present the layout of the interview, our project which is about the management of innovation in companies that produces medical devices. The end goal is to find out the challenges that the companies face when managing innovation projects. If the participant don't understand the question, it is preferred to guide the participant to answering the question within the frame and/or theme of the context. The interview can be held in English or in Swedish depending on what the interviewee finds suitable.

- Is it ok that we record the interview?

Background Information

- Location of the interview
- Name of the interviewee
- Name of the interviewer - Michael Ambrus
- Date of the interview - 10/3-16 & 16/3-16
- Company

General Questions

- Can you please tell me the history of the company including your role?
    - Can you please describe the products do you develop?
    - Can you describe the markets in which you operate?
    - Can you describe your customers and who they are?
    - Can you tell me who your suppliers are?
    - Do you have collaborations with anyone?

Theme 1 - Incremental project (and the complexity)

- Can you please describe your latest project from start to finished product?
    - Can you tell me which people were involved in the project?
        - What was their role in the project?
    - Can you please describe which the major activities were?
        - How was flow during the project? (Did everything go smoothly?)
        - Did you have to deal with any changes to the product during the project?
    - Did you face any issues during the project?
        - If so, how did you deal with them?
    - How was the workload during the project?
    - Can you tell me how you addressed regulations in the project?
    - Did you have any clinical test during the different stages in the project?

        - If so, how did you manage the results from clinical tests?
        - Did the tests influence the development of the product?
    - What was the result of the latest project?
        - Was there anything you would have done differently?
        - What would you consider being difficult tasks when managing the project?
        - How is the quality system maintained for the product?
        - How did you manage suppliers during the projects?
        - Did they have any influence in during the projects?
        - Your customers, did they provide any feedback?
            - Do you have any communication with the customer to your products today?
        - Do you have any feedback from end-users? (Patients)
    - Did the project end up as you planned from the beginning?

Theme 2 - Radical project (with complexity)

- Can you give me a general description about how the current active project started and how it is proceeded?
    - How is flow in this project at this moment? (Does everything go smoothly?)
        - Which people are involved in the current active project?
        - What are their current roles?
    - How is the work divided in the current project?
    - What would you consider are the main challenges you are facing now?
    - Are institutions and universities part of the project?
        - If so, how are they involved?
        - What are their roles? (How much can they influence the project?)
    - How do you work with regulations in the current project?
    - Is the project progressing as expected?
        - If yes, what is the next step?
        - If no, how do are you dealing with the issue right now?
    - Are you planning to have any clinical test in this project?
        - If so, how do you address them?
    - Does suppliers have any part in the current project?
        - If so, how can they influence?
    - So far, do you have any inputs from your customers in this project?
        - Do you have any inputs from potential end-users? (Patients)
    - What are your thoughts on the outcome of this project?
        - What would you consider are difficult tasks when managing this ongoing project?

Theme 3 - Implications of Managing Projects at the same time

- How do you select new projects in general? (Does it start with an idea, has it gone through a selection, etc.)
- Can you tell me how many projects you are managing at the moment?
    - How many projects have you managed at the same time before?
- How do you improve existing products?
- How do you practically work during the projects? (Parallel, Sequential?)
    - How is the work divided in general?
    - How do you integrate the work done?
- What would you consider are the most important issues when managing projects?

Appendix 2 – Pictures

Bachelor and Master degree in Chemical Engineering with a Master of Science in Materials Chemistry & Nanotechnology

Bachelor in Innovation Engineering

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