



Research Methods

Research Proposal

**Integrating Innovation Management Techniques in Medical
Device Development**

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1 Introduction

Increasingly, more and more companies have introduced the term 'innovation' in their overall vision, ethos, and objectives (Kahn, 2018). Tidd & Bessant, 2009 stated that innovation is constantly found to be the most important characteristic associated with success, yet within the medical device industry, many companies have fallen behind when considering innovation in the development of new medical devices. This is because existing medical companies are directed by key stakeholders who are unwilling to take risks and invest in long development lead times and prefer to follow a process which can gain quicker results (Sultan, et al., 2021). The prevention of innovation considerations within the development of medical devices has already been widely researched alongside other highly regulated industries such as aviation. Several barriers to innovation in all highly regulated industries not only include the prevention of new technologies by key business stakeholders, but also the uncertainty of complying with current and new regulatory requirements which are required to provide confidence on the new products and services. These barriers are linked with each other as key requirements of regulators involve extensive real-life testing to assess compliance as new technological uncertainties can only be accessed in the later stages of development (Roca & O'Sullivan, 2022). Thus, innovation management techniques can play a pivotal role in identifying the key requirements of the product at early stages in order for stakeholders to be made aware of possible barriers that need to be overcome during the development stages of a product.

Successful execution of innovation management techniques can further support the consideration of innovation in the development of new products. Innovation management techniques such as carefully defining an innovation strategy at the start of product development can provide a clear path to identifying what is achievable and defining a clear scope for the project at hand (Satell, 2017). This is evident in the requirement of a Quality Management System ISO 13485 for all medical devices which demonstrates that the device meets customer and regulatory requirements.

A stringent documentation of the processes undertaken are required to be provided for each stage that is conducted as part of the development of a medical device (British Standard Institution, 2016). The requirements of ISO 13485 should be easily interpreted as a process to provide key deliverables at each stage of a product's development. However, a key consideration of this research is to introduce and amalgamate the requirements of ISO 13485 as well as the ISO 56002 Innovation Management System (International Organization for Standardization, 2019). The ability for both standards to be interlinked with each other can provide a clear consideration for innovation management at the early phases of a new product's conception, which in turn can provide the Quality Management System (QMS) a clear outline of which stages require focus and regulatory compliances.

2 Problem Statement

To successfully promote the implementation of innovation management techniques in the medical device industry, we must address the key barriers company's face that currently prevent this, identify techniques that will help overcome these challenges, and measure the impact and outcome of innovation management considerations in medical device development.

The medical device industry has developed the propensity of preventing innovation considerations during the development of new devices due to internal and external challenges. There are many barriers to the innovation of a medical device such as having business models which focus mostly on growth and profitability. As a result, unwillingness to invest in new research and technologies continues, which in turn limits the company to only developing products that help sustain their current key competencies (Sultan, et al., 2021).

Regulatory requirements defined by the Food and Drug Administration (FDA) states the development of a QMS as a standard to be followed to gain certification for a medical device product (i.e., CE Mark requirement on products sold in Europe) (Fearis, et al., 2016). Such factors of the QMS are designed by the standard ISO 13485: Medical Device Quality Management Systems Requirements which specifies the requirements for a system where a company is expected to demonstrate its ability to provide medical devices that reliably meets customer and regulatory requirements (British Standard Institution, 2016).

Innovation management considerations can be put in place as part of the key regulatory requirements and processes required for the development of a medical device. The importance of implementing innovation management can provide a company strategic scope which outlines the openness to new technologies and competencies during the stages of a medical device product development. Although not all companies have the proficiencies of implementing such innovation management considerations, the regulatory requirements of ISO 13485 can provide a platform to consider an amalgamated process of introducing ISO 56002: Innovation Management Systems techniques as part of the process of developing a medical device.

Therefore, with these in mind, the following research questions will be addressed as part of this investigation:

1. What are the main constraints and barriers which discourages a company to consider innovation management consideration for the development of a medical device?
2. How can such constraints and barriers be avoided when considering the application of ISO 56002 as part of the standard regulatory process of ISO 13485?
3. What impact does implementing ISO 56002 innovation management techniques provide during the development of a medical device under ISO 13485?

3 Objectives

ISO 13485 currently does not indicate the requirement of considering innovation management techniques as part of its requirements for a QMS. The importance of considering best practice during the early stages of a medical device development allows for the groundwork to be established prior to starting the key development stages of a medical device project. Understanding the perspectives of the users, having a good understanding on how the product will work, assessing early risks associated from the product, and identifying key mitigation to prevent such risks (Fearis, et al., 2016) is important information to acknowledge at the start of a project. Another important consideration is understanding the scope of the project as well as outlining the openness to, and therefore opportunities for, innovation for the identified project.

The considerations of an innovation management system are currently at the control of the company to define or consider if an innovation strategy is suitable for a new project. The Innovation Matrix method (Satell, 2017) illustrates the need to understand the scope in defining the problem of a project. As cited by (Satell, 2017) a company or an organization's innovation strategy will have to adapt, depending on how well the problem of the project is scoped.

The goal of the proposed research is to develop a combined quality management system approach which follows the key regulatory standard requirements of ISO 13485 for the development of a medical device, as well as the incorporation of ISO 56002 innovation management system standards. The objective of the study is to provide a comprehensive understanding of the effectiveness of promoting innovation management techniques consideration at each stage of the product development process of a medical device product. The following sub-objectives to investigate are as follows:

1. To provide a comprehensive understanding of the key requirements of ISO 56002 which can be combined with the requirements of ISO 13485 medical device regulatory requirements.
2. To review current company and organisational methods when considering innovation management strategies during the development stages of medical devices.
3. To outline a medical device quality management system approach which highly considers innovation management system techniques at each stage of the development process.
4. To assess and measure the outcome of innovation during the development of a successful medical device.

4 Literature Review

Sultan, Parodi, Acharya, & Haynes, 2021 stated that the medical device industry is known for producing lifesaving technologies which stands at the forefront of innovation (Sultan, et al., 2021). However, due to strict regulations in place which need to be followed, more and more companies are finding it difficult to develop and consider new technologies within the medical device industry. Additional to the regulatory requirements, an organisation's upper management and executives primarily influence strategic business direction of a medical device company (De Ana, et al., 2013). This leads to executives leading on product development directions which focus heavily on business margins such as sales and profit and improving existing product lines. This then subsequently hinders innovation and new technologies to be considered in favour of optimising products based predominantly on market performance rather than function. Despite Sultan, Parodi, Acharya, & Haynes', 2021 statement, it is true that many new technologies have been developed to be lifesaving treatments to patients, but such new technologies can only come to fruition if the organisation agrees on the challenges and uncertainties that comes with developing a new innovative technology. The regulatory and business requirements of an organisation can be aligned to introduce an innovation strategy approach which considers the early requirements of the QMS of a medical device as well as understanding from the business the challenges and lead times that are required to further introduce a new medical device in the market.

4.1 Innovation Challenges within Medical Device Development

Introducing new innovative technologies in hospitals is frequently complex and is dependent on the agreed guidance of key business stakeholders (Bergsland, et al., 2014). Sultan, Parodi, Acharaya, & Hynes, 2021 identified that innovation is driven by an organisation motivation to create something that does not yet exist. However, they have also acknowledged that existing medical device companies are directed by the business executives who focus on growth and profit and therefore are unwilling to provide investment in developing new innovative ways of treating patients. This further proves that most medical device companies are hampered by the executive decisions of the business and therefore executing innovation consideration within new product development are impeded due to focus on gaining profitability in existing successful products. This correlates with Baruta, 2018's research which focuses on innovation within the air traffic management industry. Baruta, 2018 discovered that organisations with a strong portfolio of successful products or services are often unwilling to innovate in new technologies which leads to established businesses heavily focusing on sustaining existing technologies and innovations at the detriment of new technologies and innovations (Baruta, 2018). Not only do managerial business direction impacts innovation within medical device development, it also further solidifies those other industries, especially aviation, also experiences hindered development of new technologies.

In considering ways to manage innovation within a business, Kahn, 2018 indicated that a way to manage product innovation is to connect new product consideration with the organisations strategic business goals (Kahn, 2018). An organisation will always need to strive to compete with competitor companies by being able to provide a new product that is

able to impact their intended market. This is displayed in medical device companies who need to ensure that a clear R&D direction is executed and that projects that are developed within the department are a balance of sustaining current product lines and working on next generation products progressed using an innovation led development process. A medical device company's executive team must identify and communicate the vision of future business growth and the overall goals of the company, and what it is willing to invest in to provide growth of opportunities (De Ana, et al., 2013).

Another piece of research within this subject matter was from Bergsland, Elle, & Foose, 2014 which explored the lack of cooperation between medical and engineering communities in exchanging and communicating ideas which leads to hindered innovation within the development of medical devices. Stagnation in the development of innovation in medical devices can also be seen in experienced medical professionals who are accustomed to certain medical devices. This user group is often reluctant in accepting new ways of treating patients especially if they must undergo further training to use a new product or device. This subsequently prevents innovation from being considered within the early stages of a medical device development if there is no demand amongst users for a new way of carrying out treatment.

An aspect of providing clear innovation management within the development of medical devices is the development of a theoretical framework of processes that can be implemented to ensure that prior to the initiation of a new project, the scope of the project must be clearly defined which must ensure specified direction that the business is willing to take with the development of such devices. Being able to ensure a project agreed on by all relevant members of a research and development team as well as the wider business from executives to stakeholders, can help provide a clear focus on innovation and identification of new technologies that may be able to be considered during the development stages of a new device.

4.2 Effects of Regulatory Requirements within Medical Device Innovation

Despite several new technologies and approaches to patient treatments, the regulatory requirement of a medical device is a key barrier that prevents innovation in the development of a medical device. Bergsland, Elle, & Fosse, 2014 identified that the process of obtaining medical device approval is significantly longer for new innovative technologies compared to devices that comprises of existing technologies. Similar stringent regulatory evidence was identified by Roca & O'Sullivan, 2022 within the aviation industry, as uncertainties within evolving regulatory requirements can lead to ambiguity on how to ensure new technologies can comply with existing and future regulations (Roca & O'Sullivan, 2022). With an ever-evolving regulatory requirements, approaches to the development of new technologies can still focus on providing innovative solutions with following such innovation management methodologies which can ensure clear business and management directions as well as a clear path to success (success factors which can be analysed include innovation strategy, objective, and successful execution of the innovation processes). A good understanding of

the requirements of ISO 13485 can provide a strong plan and strategy during the start of the development stages of a new medical device.

A key deliverable from ISO 13485 is being able to provide effective clinical efficacy and performance from the device that is being developed. Clinical testing is proving to be the main key aspect that requires investment in both time and money with a small room for failure. Bergsland, Elle, & Fosse, 2014 acknowledged that being able to streamline clinical testing and including more standardised approaches in new technology assessments can streamline the introduction of new devices in the market.

Another key consideration in the effects of regulatory requirements is the potential changes and updates to the regulations themselves. In their investigation on the impact or regulatory changes has on new technologies, Roca & O'Sullivan stated that regulatory uncertainty is a well-known barrier for commercialisation of new products. However, their research also indicated that regulatory agencies play an important role as innovation enablers through the revision of new standards and new ways of verifying and validating product performances, which in turn provides an exchange of technical and regulatory information. Since a medical device cannot be released to the market without the relevant evidence of safety and efficacy, existing technologies with a clear standardised approach in validating performances are able to obtain regulatory approval quicker while it is significantly longer for new technologies. This research further alludes to the innovation challenges of medical device development since organisations are aware of the risk of developing new technologies that may end up failing regulatory clinical testing and product efficacy, losing high amounts of investment of both time and money into the development of such devices.

A clear framework of being able to amalgamate each of the concerns of a new device to be developed can provide early insights into the risks of the project, as well as being able to highlight key regulatory requirements and standards that needs to be successfully adopted to provide clear focus on achieving such performance efficacy prior to investing in large clinical trials.

5 Methods

To determine the effectiveness of integrating ISO 56002 within the ISO 13485 medical device regulatory requirements, a primary research method of conducting a literature review of the two standards will be conducted to further understand the ability of the two to be combined as part of a quality management system. The identification of the key requirements of both ISO 56002 and ISO 13485 will be structured by amalgamating the key stages of early development consideration of innovation management approaches and integrating the process within a Stage Gate product development process (Grönlund, et al., 2010) followed by the company or organization. A conceptual framework of the QMS structure will be developed integrating the findings of the literature review from both standards and producing an outlined approach to the development project. The techniques detailed within the conceptual framework will then be integrated as part of the current product development process followed by the company with each stages considering the effective approach of innovation management.

Case studies on the success of previous projects will also be investigated, purely in understanding the approaches in conducting the project from start to finish and the success the project's completion. An understanding on the effective market impact of the previous developed product will provide key information on the approach performed as part of the development of the device, as well as if innovation was considered during the key development stages of the medical device.

The research method for this study will heavily rely on following a medical device development project from beginning to completion and identifying the effective application of innovation management considerations. Each stage of the development processes will be evaluated for their effective consideration for innovation, how the innovation culture is distributed to the project teams and measuring the success of innovation techniques during the completion of each Stage Gates. The success of the completed medical device project will also be measured on its success on the market, number of units sold, as well as the success of the project in following the timeframes and budgets effectively.

6 Results

The result of this study will be based on assessing and measuring the outcomes of innovation when integrated as part of the product development process of a medical device. The innovation enabling factors, results, performance, and process will be measured with both qualitative and quantitative data to be captured and analysed as per the assessment approach of ISO 56004 Innovation Management Assessment (International Organization for Standardization, 2019). The processes undertaken for the successful regulatory certification of a CE Mark to the medical device will also be measured, regarding the success of the product development process as part of the ISO 13485 requirements as well as the effective amalgamation of both standards when followed as part of a stage gate process approach.

6.1 Qualitative Data

Qualitative data results from the study will be based on internal questionnaire and interviews with key stakeholders that took part in the successful implementation of the product. The information and data that is focused within the questionnaire will be related to the successful execution of the innovation strategy undertaken as part of the project and how it was conducted (International Organization for Standardization, 2019). The information within the qualitative questionnaire and interview will consist of collecting information relating to the achievement of identifying an innovative vision at the start of the product development, key strategies undertaken, and ensuring company and project objectives are met and were able to align with the business goals (International Organization for Standardization, 2019). The qualitative data will be concluded by ensuring that the project teams are able to learn from the previous successes and failures of previous projects undertaken with innovation strategies in mind.

6.2 Quantitative Data

Quantitative data results from the study will be based on the specific information relating to the duration required to complete the project as well as timeframes needed to release the product into the market (International Organization for Standardization, 2019). The expected quantity sold of the product alongside actual quantities sold will also be captured which will give some indication of the successful acceptance of the product within the market. Data comparison of the developed product against a competitor product will also provide good data to understand the success of the innovation. Comparing the product against an existing competitor product can further capture data related to the sales numbers, number of users of the product. The product will also be compared against a benchmark product which was developed before the product and has been in the market for some time, the existing benchmark product along with the newly released product will also provide key information of successes of the product in the market when compared to previously developed devices.

6.3 Result Criteria

Result criteria of the successful implementation of innovation management approach will be based on growth in revenue from the innovation, profit from the device with considerations on the efficiency of resource allocations to achieve the intended outcome of the innovation and accomplishing key deliverable of each stage as per the defined timeframe of the project. The success of the innovation will be compared to the benchmark accomplishments of previous products that have undergone the same development processes as the newly completed product. Assessment questionnaires will also be capture and distributed to the multi-disciplinary teams associated with the development of the medical device and will focus on understanding the effective approach of the company regarding innovation management approached on the project (Tidd & Bessant, 2009).

7 Evaluation

The proposed research proposal when executed successfully can provide a process in which innovation management approaches are considered within medical device product development. A clearly defined scope of the project's innovation consideration can be fully outlined at the early stages of the development, and key business stakeholders will have a clear expectation on the feasibility of the new products and technologies. Market impact as well as an understanding of the impact of new product and technology can also be highlighted at the start of the project which will provide key performance indicators and impact that the product will provide its intended market. The process can also provide an impact within its amalgamation with a medical device QMS, which in turn provides full documentation traceability on how new technologies are considered and how the technology was chosen to provide a clear benefit to the end user of the device.

The proposed research proposal will be planned to consist of following project from start to completion that follows the theoretical framework of amalgamating ISO 13485 Medical Device Quality Management System (British Standard Institution, 2016) and ISO 56002 Innovation Management System (International Organization for Standardization, 2019) to understand how the two standards can work side by side to identify innovation consideration within the new product being developed, whilst making sure that the product is documented as required to acquire the relevant conformity requirements to release a medical device in the market.

Limitation to the research will involve the medical device project being under resourced thus being put below the priority list, which in turn may require an existing product that required improvement instead of a new product range to be developed and followed as part of the research. Ensuring that a new product development project is within reach of commencing will be required as part of this research to achieve the goals and objectives set out for this research. If a clear path to the research is established, the research will achieve its objectives and the goals stated will be answered in a manner that provides clear evidence in the effectiveness of the proposed process framework.

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