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Quality Management Systems in Healthcare

“Implementation of the Medical Device Regulation”

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by

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Master of Science Thesis TRITA-ITM-EX 2022:211
KTH Industrial Engineering and Management
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Kvalitetsledningssystem inom sjukvården

“Implementering av MDR”

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Abstract

This study investigated how a QMS that is compliant with the Medical Device Regulation (MDR) can be constructed and what the most important aspects are when creating a functional QMS at a Swedish hospital. QMS:s are a fundamental part of a healthcare organization and are used to ensure safe and secure patient care. To establish qualitative healthcare, the Swedish National Board of Health and Welfare has created regulations for hospitals to construct their QMS concerning care processes and handling of medical devices. In addition to these, there are also regulations within the European Union, including the MDR. To facilitate QMS:s work, hospitals can also follow international standards created for quality work. The most common for medical device departments is ISO 13485. Regulations are often perceived as difficult to follow and can be hard to interpret. Swedish regulations mention that a hospital should have a "suitable" QMS based on the organization's areas of activity. But what is considered appropriate is up to the organization to decide on, which to some extent has been difficult for Swedish hospitals. Furthermore, several studies depict challenges with hospital QMS implementation and getting the QMS to work functionally.

A qualitative method has been used to answer the research question where the main source of data gathering has been semi-structured interviews. The interviews have been conducted with quality managers and with experts in regulations and standards for hospitals. The questions were mainly focused on how QMS:s that follow regulations should be constructed and how to effectively implement them in a hospital organization. The study concludes that it basically is impossible to construct a general QMS suitable for every hospital without having to adjust it to the hospital's different and specific work areas, which can look very different from hospital to hospital. Regardless, since ISO 13485 is harmonized with the QMS part of the MDR, it can be helpful for a medical technology department. The authors constructed a gap analysis tool to facilitate the development and implementation process for hospital QMS:s. When it comes to aspects that constitute a successful QMS implementation, the study found the most important aspects being culture, value creation, simplicity, and leadership.

Key-words: *MDR; QMS; Implementation; Hospital; ISO 13485; Gap-analysis;*

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Sammanfattning

Denna studie har undersökt hur ett kvalitetsledningssystem (KLS) som uppfyller kraven från Medical Device Regulation (MDR) ska konstrueras och implementeras i svenska sjukhus. KLS är en väsentlig del för att säkerhetsställa en säker och trygg patientvård. För att säkerhetsställa en kvalitativ vård har Socialstyrelsen upprättat föreskrifter för sjukhus att basera sina KLS på samt gällande hantering av medicintekniska produkter. Utöver dessa föreskrifter finns också regelverk gemensamma för Europeiska unionen bland vilket bland andra inkluderar MDR. För att underlätta arbetet med kvalitetsledningssystemet utnyttjar sjukhus i hög grad också standarder för sitt kvalitetsledningssystem. Den vanligaste är ISO 13485 för en medicinteknisk avdelning. Föreskrifterna som svenska sjukhus ska efterfölja kan ibland anses svårtolkade. Svenska föreskrifter nämner bland annat att svenska sjukhus ska ha ett “lämpligt” KLS utefter organisationens verksamhetsområden. Vad som anses lämpligt är upp till organisationen att definiera, vilket till viss del varit en svårighet för svenska sjukhus. Speciellt gällande medicintekniska produkter och hur dessa bör och ska hanteras. Hanteringen av medicintekniska produkter är en viktig faktor när KLS ska upprättas, vilket i vissa fall missats i svenska sjukhus. Utöver detta påpekar flera litterära studier på svårigheterna med implementeringen av KLS på sjukhus samt hur man får dessa att fungera optimalt i organisationen.

För att besvara frågeställningen har en kvalitativ metod använts där främsta datainsamlingsmetoden varit semi-strukturerade intervjuer. Intervjuerna har genomförts med kvalitetsansvariga, samt med personer kunniga inom föreskrifter och standarder. Frågorna rörde i huvudsak hur ett föreskrifts efterföljande KLS ska konstrueras samt hur detta på ett effektivt sätt ska implementeras i organisationen. Studien kommer fram till att det i princip inte går att konstruera ett generellt KLS utan att detta måste anpassat till sjukhusets specifika arbetsområde vilket också kan skilja sig markant mellan olika avdelningar på sjukhuset. Oavsett så kan ISO 13485, som är harmoniserad mot KLS avsnittet i MDR, vara till hjälp för en medicinteknisk avdelning. Författarna konstruerade ett “gap-analysis tool” för att underlätta en första gapanalys som i studien visat sig vara ett första steg när KLS ska konstrueras. Gällande implementationen finner studien att viktigaste faktorerna är kultur, värdeskapande och enkelhet, samt ledarskap.

Nyckelord: *QMS; MDR; Implementering; Sjukhus; ISO 13485; Gap-analys;*

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List of Abbreviation

QM	Quality Management
MDD	Medical Device Directive
MDR	Medical Device Regulation
QMS	Quality Management System
ISO	International Organization for Standardization
ISO 13485	Medical devices - QMS - Requirements for regulatory purposes
SOSFS 2011:9	General Requirements for Systematic Quality Work
HSLF-FS 2021:52	Regulations for usage of Medical Devices in Healthcare
ISO 9001	Quality Management Systems - Requirements
UDI	Unique Device Identification
OC	Organizational Culture
QMSI	Quality Management System Index
TQM	Total Quality Management
DUQuE	Deepening our Understanding of Quality improvement in Europe
G	Goal Attainment
I	Social Integration
QS	Quality Systems
EFQM	European Foundation for Quality Management
S	Subject

Foreword

We would like to thank our support from the Royal Institute of Technology, KTH. Firstly our supervisor Pernilla Ulfvengren for helping us on this master thesis journey and guiding us in the right direction. Secondly, we would like to thank our seminar leader and examiner Matti Kaulio and the seminar group for valuable discussions during the seminars.

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Finally, we must express our deepest gratitude to our friends and family for supporting us during our studies at KTH.

Sincerely,
Jonah Ejheden & Teodor Tapper

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1. Introduction

The background section introduces the reader to the subject of investigation in this report. Healthcare, qualitative system work and necessary regulatory information will be presented and previous research will be addressed and a problem formulation concludes the chapter.

Healthcare institutions effectiveness is often from the outside of the organization perceived by their quality measurement. Quality management (QM) work for hospitals is today a vital part of how hospitals will achieve effectiveness and continuously improve. For patients at hospitals, certifications and QM work is a way for the organization to increase perceived value of the care process. It can also inform people outside of the organization of in what ways procedures and processes are conducted to ensure patient care quality. Implementing QM practices in hospitals can bring benefits to all parts of the organization (Xiong et al., 2017). Medical devices are a fundamental part of today's healthcare system and are used in many areas such as treatment, diagnosis, prevention, monitoring and rehabilitation (Banck, 2021). Healthcare quality, including medical technology, is something that hospitals are constantly working on and there have been many key tipping points in health care systems around the world. Most are familiar with the story about Florence Nightingale and her quality improvement documentation in the 1850s and work towards making hospitals a cleaner and safer place to be at. Other milestones are when Louis Pasteur wrote about how germs cause disease and thus contributed to the art of sterilization in the 1860s, Wilhelm Conrad Roentgen's X-ray discovery in the 1890s or one of the many pharmaceuticals invented since then (Sheingold & Hahn, 2014). These are all examples of previous implementation of technologies and working procedures. Technology, education, pharmaceuticals, healthcare financing and industry mass production are numerous factors that make the healthcare system in Sweden what it is today. All of them are important when discussing healthcare institutional effectiveness and quality measurements. The focus of the government's continuous development and improvement process has now shifted towards a focus on how to best make the already implemented procedures, processes and responsibilities more interlinked and efficient (SOSFS, 2011:9).

The term medical device stretches across many different products. Devices used in Europe have previously been regulated by the European Medical Device Directive (MDD). From May 26 2021, the MDD was replaced with the new European Medical Device Regulation (MDR) which contains regulations for the release of new medical devices on the European market (Regulation (EU) 2017/745). A medical device is in the MDR considered as "*any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including software necessary for its proper application intended by the manufacturer to be used for human beings*" (ibid.). Manufacturers and clinical users are governed by a continuously changing field of international regulations and standards. They must meet these complex and various requirements to uphold their practice. The

European MDR, means a higher level of requirements that has to be met before medical devices can be used in clinical practices (Beckers et al., 2021). One of the main purposes of the MDR is to enhance and improve the existing directives and will have more rigorous requirements on quality and safety as well as complying to the needs of transparency and traceability (Regulation (EU) 2017/745). The new regulations will require healthcare professionals and institutions to adapt their way of work connected to reprocessing of products and instruments. All involved actors will have to change the way they deal with data. Since the regulations were first published in 2017, the existing literature about how hospitals can adapt their organizational work to MDR is rather limited (Vasiljeva et al., 2020). This is a problem since adaptation to new regulations becomes more challenging with limited guidance from existing documents and literature.

When organizations commit to satisfying customers and other stakeholders' interests with quality objectives, a quality management system (QMS) is established to create a sustainable organizational growth in quality. The QMS is established with the help of documenting internal and external processes and procedures to provide the customer with products and services that meet their expectations as well as regulatory requirements (Natarajan, 2017).

In Swedish hospitals the QMS is regulated by the EU and Swedish authorities. This should enhance patient safety and secure a somewhat alike quality level between different hospitals in Sweden. However, it is unclear what good quality means in healthcare. One possible definition is to focus on the patient and claim that good quality is when healthcare services are safe and equitable (Kunkel, 2008). In another way, quality could be defined based on the healthcare activities and how they fulfil some criteria (Ibid.). Measuring quality is a challenging task for hospitals and could be executed in different ways. These measures play an important role in the quality management system since they are the basis for decision making and improvements.

In the MDR, Quality Management Systems are defined as systems that document procedures, responsibilities and processes to make sure the business standards regularly improve and are ensured (Mantra Systems Team, 2022). The EU MDR is, compared to the previous MDD, more direct when it comes to quality management systems. Departments of hospitals dealing with processes, procedures and devices should contemplate upgrading their QMS (Miller, 2022). Some experts believe that when looking at the MDR it is important to start with the QMS piece of it. This since the organizational infrastructure needs to be in place for updating technical files and for required ongoing activities (Sathe & Stauffer, 2021).

In a master thesis by Germundsson and Kvist (2020), the students from KTH examined the new MDR and aimed to identify the most important requirements for manufacturers. Their research resulted in a process description that presents the main steps on how manufacturers of Electronic

Health Record systems are to fulfil the medical device regulations. The authors emphasize on the fact that the process description cannot solely be relied on in order to comply with the MDR. There are still needs for further specific requirements from the European Commission concerning medical device software. This project had its main focus on information regarding the MDR and implementation from a manufacturer's point of view (Germundsson & Kvist, 2020).

The Eurointervention journal published an article from Robert A. Byrne in 2019 where he describes the new features and opportunities for engagement of the new MDR system (Byrne, 2019). The author concludes by saying that the MDR features new promises for increased safety for patients, but there are concerns as regards to how the MDR will be implemented. Especially concerning key infrastructure projects, such as generic hospital implementation of regulatory work. Additionally, an article by Pandit, van Duren and Vasiljeva (2020) argues that there is no exact method of MDR implementation. The industry is heading into an unclear and unchartered territory, implying there is a need for more research into how healthcare professionals and institutions can adapt their organization to the new medical device regulations (Vasiljeva et al., 2020).

The literature field concerning the MDR is relatively comprehensive when it comes to different medical device manufacturers' adaptation to the new regulations. There is likewise substantial information about the different aspects of the MDR and its difference from the previous European directives (Vasiljeva et al., 2020). Nevertheless, there is limited research into how healthcare professionals and institutions will go about their transition from working in line with the previous directives towards following the new regulations (Ibid.). Yet a consensus among researchers exists where they call for more extensive research towards hospital adaptation to the regulations (Byrne, 2019; Vasiljeva et al., 2020).

Hospitals face challenges in constructing processes and procedures for compliance with regulatory texts. Employees in hospital organizations can encounter problems such as how to document their practices in the best possible way. Several main processes in the QMS require comprehensive documentation to enable traceability of medical devices and secure safe working procedures. Other problems surrounding hospital QMS:s work can be employee and leadership engagement. Overall, hospital QMS:s want to increase safety towards patients by securing processes and procedures in a way that is uniform across the whole organization. Quality standards could be described as a common solution for recurring problems (SIS, nd). The main purpose of standards could differ between standards. However, the primary purpose is to create united and transparent routines for organizations to follow, since it is of everyone's interest to increase quality in organizations (Ibid.). The pros with standards are several, for example, they could create more cost-effective processes, increase safety, and provide trustworthiness (Ibid.). It is important to clarify that standards are generally selectable and not mandatory. However, some of them aid organizations to fulfil certain

necessary regulations. Governed by both national and European regulations, the standardization situation for healthcare providers can be very confusing and extensive. Standards may help this situation to some degree, but depending on the healthcare provider, additional research in European regulations might be needed to confirm that all regulated processes are executed in a correct manner.

This research topic is of interest since there are articles out there depicting what MDR is and how manufacturers can adapt their operation to it (Germundsson & Kvist, 2021). But a consensus exists amongst researchers outlining that there is a literature gap when discussing how MDR is implemented in hospital organizations and their different departments. For example, Pandit, van Duren and Vasiljeva (2020) conclude their article on how the MDR impacts research, innovation and clinical practice by saying "the exact method of implementation remains uncertain". Robert A. Byrne (2019) portrays concerns regarding key infrastructure projects such as a generic hospital implementation of MDR in his article about medical device regulations in Europe. Some literature also mentions that QMS work tends to get stuck at higher hierarchical levels in hospitals, at hospital boards and managers. Hospitals also have a varying success rate when it comes to QMS implementation (Zarei et al., 2019; Leggat and Balding, 2018). For actors in the medicine market, the implementation of work procedures and strategies to cope with the MDR regulation can be a challenging task (Maresova et al., 2020). Another challenge with hospital implementation work is the perceived difference of a QMS for compliance or for excellence. Compliance is following criteria in its most simple form and excellence is following and achieving effectiveness in the QMS. In the ORION project on aviation safety management systems maturity, the assessment is ranked on a scale where compliance and excellence are differentiated (Ulfvengren et al., 2021). These aspects will be further investigated in this thesis but towards hospital QMS work and in the form of a gap analysis tool. To investigate the QMS implementation challenges in Swedish hospitals this study seeks answers on how current QMS work is perceived and how it could be improved. The objective of the project is to investigate the MDR and hospital QMS implementation by studying hospitals around Sweden, to understand challenges and opportunities surrounding it. There is also an important distinction between the implementation of QMS:s for compliance and for excellence. Organizational factors that constitute the difference between compliance and excellence will be discussed as an important part of QMS implementation.

1.1 Purpose & Research Question

The purpose is to develop a gap analysis tool for compliance to improve implementation of MDR into hospital QMS:s and to investigate organizational factors needed for achieving excellence. To fulfil this purpose, investigations will investigate how a Swedish hospital can develop a functional QMS that is compliant to the MDR by answering the following research questions:

- **How can a MDR compliant QMS be constructed and what challenges are there?**
- **What are the most important aspects for achieving excellence in the QMS at a Swedish hospital?**

In order to specify the scope of this project, some delimitations will be necessary. Since it is a master's thesis project, the time limit for conducting the research is the duration of the project course, around 20 weeks. With that in mind the following delimitations are set:

- The interviews are to be conducted with relevant personnel at several Swedish hospitals and experts of MDR and QMS.
- The project is going to be limited to the information and literature released regarding MDR up until and during the time of the project.
- The project will not focus too much on MDR itself but rather the processes, governing documents and analysis needed for MDR implementation in hospitals, mostly how the QMS part of MDR should be implemented at a medical device department of a hospital.

1.2 Disposition

Chapter 2 presents all essential information about the master thesis case. The information and documents acquired from the case company, PwC, and some of their previous work in the subject area will be presented along with necessary complementary information such as standards and regulations. This in order to understand the width of quality management systems for hospitals. The "Standards & Regulations" subchapter is relevant for those without previous knowledge about ISO 13485, HSLF-FS 2021:52 and SOSFS 2011:9 and could be bypassed if applicable knowledge already exists.

Chapter 3 presents theory and previous research on hospital organizational practices and QMS. The research on QMS concerns its implementation in hospitals, including: factors that affect implementation, following up on QMS after implementation and whether QMS:s in hospitals work or not. This chapter presents the theoretical results.

Chapter 4 is the method chapter and it presents the research design and selected methods of the master's thesis will be discussed. All stages of the research will be presented in their chronological order as the data collection and method for data analysis is described.

Chapter 5 is the results chapter and is divided into six sections. These sections stem from the themes interpreted in the data analysis. The data was collected from the conducted interview and are solely based on answers given by the interviewees. The empirical results intend to present a deeper understanding of quality work at hospitals and how everything around it could be in order to make the QMS work.

Chapter 6 presents the outcome of the thesis project as an analysis of the literature review, case specific research and interview study. The first section introduces the challenges and complexity concerning QMS. In the second section, a gap analysis tool is presented and thirdly the found key factors that constitute a successful QMS are presented. Comparisons between theoretical and empirical findings are presented. The last part consists of an assembly of the analysis section and the reader is introduced to different sections of the results as a whole in order to understand why every part is relevant. The theoretical model is in this last section extended into a model that based on the results of this study answers the researched questions.

Chapter 7 presents a discussion of the results and analysis section. Sustainability aspects, limitations and suggestions of future research are also discussed.

Chapter 8 presents a conclusion of the findings in order to answer the researched questions.

2. Case Context

In this chapter, all essential information about the master thesis case will be presented. The information and documents acquired from the case company, PwC, and their previous work in the subject area will be presented along with necessary complementary information such as standards and regulations in order to understand the width of quality management systems for hospitals. The "Standards & Regulations" subchapter is relevant for those without previous knowledge about ISO 13485, HSLF-FS 2021:52 and SOSFS 2011:9 and could be bypassed if applicable knowledge already exists.

2.1 Pre-Study & Case Company Guidelines

From the outcome of meetings and correspondence with the thesis supervisor at PwC it became clear that hospitals need to adapt some part of their QMS in order to be compliant with the mandatory regulations. PwC recommended that the QMS should be built upon a combination of regulatory texts together with applicable ISO standards. The regulatory texts are "General Requirements for Systematic Quality Work" (SOSFS 2011:9) together with "Regulations for usage of Medical Devices in Healthcare'' (HSLF-FS 2021:52). The standards were ISO 9001 and ISO 13485:2016. The former is a more general QMS standard that can be used by any company, the latter ISO 13485 is oriented towards QMS for medical devices. The ISO 13485 could be applicable for hospitals depending on their operations. In particular, if the hospitals are manufacturing their own products for release on the open market but also if the hospital constructs products for their own usage, so called "special adapted products".

The regulatory obligations towards MDR varies depending on what the healthcare provider counts as, whether they are users, distributors or manufacturers of medical devices. For a hospital included in all three parts, a QMS should include processes and procedures for among other things:

- Storage of documentation for traceability including UDI (Unique Device Identification) and safety messages
- Possibility to follow-up self made and specially adapted products.
- Guidelines, steering documents and education material
- Documentation and processes related to reporting and risk management
- Technical documentation for self made products
- Market investigations for self made products
- Processes for reporting incident

2.2 Standards & Regulations

When addressing a quality management system aimed at following the MDR (Regulation (EU) 2017/745), it is fundamental to understand the Swedish regulations SOSFS 2011:9 addressing quality management at hospitals and HSLF-FS 2021:52 about medical devices. Both are from the Swedish National Board of Health and Welfare, the government agency Socialstyrelsen. Another aspect is looking at ISO standards that could facilitate a QMS intended at following the MDR.

From January forth 2022, the international QMS standard ISO 13485 for medical devices became harmonized with the MDR (EU) 2017/745. Following harmonized standards means that the organization can expect to meet required EU regulations for the part of the standard that is harmonized. This means that the QMS requirements from the MDR may be fulfilled by committing to the ISO 13485 standard. However, it is important to notice that all clauses of ISO 13485 may not be applicable to all hospitals. This depends on the hospital's role in front of the regulations whether the hospital also serves as a manufacturer, distributor, or only a user of medical devices. The harmonization of ISO 13485 against MDR, is the main reason why ISO 13485 is a large part of this master thesis work. To ensure full compliance with relevant Swedish regulations we also included the regulations SOSFS 2011:9 and HSLF-FS 2021:52 in our work. The MDR should still be utilized in hospitals for specific processes, not directly mentioned in the QMS structure.

The ISO 13485 is based upon one of the most commonly utilized standards, the ISO 9001 for quality management systems (EN ISO 13485, 2016). One purpose of ISO 13485 is to facilitate a global alignment of relevant regulatory requirements for QMS for organizations involved in any part of the medical device life-cycle. The ISO 9001 is used in various organizations and some companies require their suppliers to be certified against the ISO 9001. The ISO 9001s QMS is introduced for consistent compliance with the needs and expectations of customers. This standard is based on seven principles namely: Customer focus, Leadership, Employee engagement, process focus, improvement, fact-based decisions, and relationship management (SIS, ndb). Even though ISO 13485 is based on ISO 9001, an organization could not be certified against ISO 9001 by only implementing ISO 13485. There are additional requirements present in ISO 9001 that are excluded in ISO 13485 (EN ISO 13485, 2016).

2.2.1 SOSFS 2011:9

The SOSFS 2011:9 describes the fundamental regulations for QMS in Swedish hospitals. The regulation entails implications on, for example, the QMS:s fundamental structure, processes, responsibilities, self-control, continuous improvement work, and documentation. The SOSFS 2011:9 requirements should be followed together with other necessary regulations.

2.2.2 HSLF-FS 2021:52

Compared to the SOSFS 2011:9, the HSLF-FS 2021:52 focus on the utilization of medical devices in healthcare. The regulation emphasized processes and routines for how medical devices should be used, prescribed, who should have the permission to prescribe, and lastly processes for negative events or incidents with medical devices.

2.2.3 ISO 13485:2016

ISO 13485:2016 is a published standard by the International Organization for Standards (ISO) and specifies standards and requirements for a quality management system concerning all organizations that deal with medical devices in any of the stages of their life cycle. For an organization to be certified, an accredited third-party body authenticates that the organization's QMS is compliant with all applicable regulatory requirements of the ISO standard. The requirements of ISO 13485:2016 are listed in clauses and clauses 4-8 list the needed requirements.

Clause four is an introductory section describing some general requirements, starting with the need to have an effective QMS that meets the regulatory requirements for the type of medical device and the requirements for the ISO standard itself, you have to identify the processes that make up the QMS and show that they are interconnected and controlled by using a risk-based approach. You have to document your QMS or reference to it in a quality manual, each medical device type of family must be documented in a medical device file. You have to keep records where appropriate and all relevant documentation and records must be controlled according to a documented procedure.

In clause five, top management is required to show their commitment to establishing and maintaining an effective QMS, this means establishing a quality policy and setting a quality objective for the whole organization. Top management also has to define and document responsibilities and authorities for effectively operating the organization in conformity with its QMS. Management representatives shall also report on the effectiveness of the QMS that management then reviews, this is to be conducted at planned intervals.

Clause six sets out the requirements to provide the resources necessary for an effective QMS. The organization has to identify the people and the jobs affecting product quality and ensure that these people are competent. You have to provide the infrastructure and the work environment needed to ensure MD safety and performance such as health, cleanliness, and clothing requirements where these could affect product quality.

Clause seven contains a very large set of requirements, covering the whole of the operations starting with having to plan and develop the processes needed for product realization. The organization has to set quality objectives, identify realization requirements and establish arrangements for

communicating with customers and medical device regulators. You also have to establish design and development procedures and organize design and development activities. Another important requirement at this stage is effective verification and validation. The organization also has to document procedures to control purchasing such as controlling the selection of suppliers, monitoring supplier performance, planning product purchases, and verifying that purchased products conform to specifications. This clause also requires that you plan, monitor, and control production and service provision and document product information and verification requirements. And lastly, you have to develop servicing procedures and reference materials.

Clause eight is about measurement, analysis, and improvement of processes. Firstly, the organization has to plan how it monitors, measures, and analyzes processes to ensure product and QMS conformity and QMS effectiveness. The organization also has to establish methods to obtain and monitor customer feedback and processes to investigate complaints, review risks, take action, and report results, including to regulatory authorities when appropriate. The organization also has to plan and conduct internal audits to determine whether the QMS is in obedience and processes are achieving planned results. Monitoring and measurement of products during the manufacturing process are required to identify nonconforming products and take appropriate action to isolate those products and prevent unintended delivery or use. The last part of clause eight is about the requirements to analyze data about the organization's QMS in order to evaluate its suitability and effectiveness and then improve within needed areas.

These mentioned standards and regulations function as the foundation to the QMS process as they were deemed the most relevant for Swedish hospital QMS by the case company. A gap analysis can be a process where organizations look at their current working ways in order to find gaps where improvement could be made and could potentially be used to improve a QMS. Gap analysis could thus be used to look at what might be missing in a hospital organization when aiming towards certification of a standard.

3. Literature Review

In this chapter, theory and previous research on hospital organizational practices and QMS will be presented. The research on QMS concerns its implementation in hospitals, including: factors that affect implementation, following up on QMS after implementation and whether QMS:s in hospitals work or not. Presented below are the, to this thesis proposal, most relevant parts of the literature review.

3.1 Organizational studies at hospitals

There are several different standards today that organizations can certify themselves against to ensure stakeholders that the quality incentives are implemented throughout the organization. The most commonly utilized standards are, for example, the ISO line-up serving different purposes in various industries. Moreover, these standards affect how the QMS should be structured and work. Continuous updates in both ISO-standards and regulations requires organizations to adapt their QMS. This has led to an increasing interest in research to determine factors that influence the success of QMS implementation. Wardhani et al. (2009) identified six factors that could both support and limit the implementation of QMS. These factors were organizational culture, design, leadership for quality, physician involvement, quality structure, and technical competence. Organizational culture (OC) has been mentioned in several studies in relation to QMS (Fonseca, 2015; Oliveira & Matsuda, 2016; Carman et al., 2010; Wagner et al., 2014). Fonseca (2015) found that OC should be a key consideration when implementing QM initiatives. However, it is important to notice that OC is not by itself a singular key to successful implementation, the implementer should consider several organizational theories (Fonseca, 2015).

Wagner et al. (2014) utilized a questionnaire to categorize the cultures of hospitals according to the model by Mannion et al. (2005). The results indicated no relation between the different model cultures and QMS measurement. However, it did indicate that a more horizontal organizational structure was associated with higher quality management system index (QMSI) score (Wagner et al., 2014). Furthermore, hospitals that place more emphasis on innovation in the care processes receive higher QMSI-scores (Ibid.). Additionally, the QMSI-score was also lower for hospitals with an organizational structure with fewer activities regulated by protocols. Wagners et al. (2014) results indicate that decentralized decision-making could enhance quality improvement. However, the decision-making should perhaps not be fully released to the local level, some formal decision-making guidance is probably needed to help support the local choices .

A study conducted in China investigated the relationship between QM practices and performance in public hospitals. Nine different dimensions were evaluated (Xiong et al., 2017). Top management leadership has a strong relationship to quality policy, role of quality department and the quality information and analysis. This means that leadership affects how functional the quality department

is and the effectiveness of quality training (Xiong et al., 2017). Another important aspect of leadership is that it can affect how quality data is generated and collected for further analysis and optimization of the quality planning. Strategic quality planning has a direct effect on customer focus and employee relations. This since the planning allows optimization of resources, and moreover helps the organization analyze their strengths, weaknesses and opportunities in their quality work (Xiong et al., 2017). Furthermore, process management and employee relations were found to be critical for hospital performance. Therefore, hospitals should focus their effort on employee satisfaction and provide sufficient support for their work (Ibid.). Moreover, hospitals should focus on process innovation to improve efficiency (Xiong et al., 2017). Other researchers have come to the similar conclusion that having quality as a topic on the executive board's agenda more frequently is stimulating quality implementation in hospitals (Botje et al., 2014).

3.2 Quality Management at Hospitals

When it comes to the implementation and adaptation of MDR regulations into hospitals quality work, there is a lack of scientific literature describing the process (Byrne, 2019; Vasiljeva et al., 2020). The most relevant thing is thus to look at QMS and ISO literature concerning their implementation and presence in hospital organizations. When investigating the maturity level of various ISO-certifications there are varying results when it comes to its correlation with organizational performance. Some studies have found that ISO 9001, for example, can enhance financial performance, yet other research concludes that ISO certification does not necessarily imply better performance (Sfreddo et al., 2018). A study about extending QMS practices in order for them to apply to regulatory requirements found that QMS:s are usually well written and tangible, much like some of the results by Groene et al. (2013). However, organizations with limited knowledge of regulatory requirements and with limited resources, for example small and medium enterprises, are deficient in the implementation of regulations and standards into their current organizational structure (Bujok et al., 2016). Another study assessing hospital quality management systems found that private hospital executives pay more attention to quality issues and since private and smaller hospitals have a flatter, more flexible and less complicated structure with greater communication, it is easier for them to incorporate a QMS in their organization (Zarei et al., 2019). Wardhani et al. (2009) also shows that large public hospitals executives are inferior when it comes to successfully implementing QMS compared to small and private hospitals.

In a systematic literature survey done in 2019, Alzoubi et al. (2019) looked at core predictors of total quality management (TQM) and how important these are when looking into successful TQM implementation in hospitals. Some important variables for the successful implementation of TQM in the healthcare context are: Education and training, continuous quality improvement, patient focus/satisfaction, top management commitment and teamwork. TQM implementation in the healthcare context, containing the variables above, will lead to higher levels of performance and can

help healthcare professionals enhance their performance in the long run. The findings indicate how it would be useful for stakeholders to introduce and implement TQM in hospitals (Alzoubi et al., 2019).

In a systematic review of instruments assessing implementation of QMS:s in hospitals, Groene et al. (2013) found that QMS:s are essential for the possibility of quality improving activities in smaller organizational units. The authors saw that even though there are widely employed comprehensive assessment frameworks and quality standards, they found no clear instruments that map the QMS implementation. Better use of far-reaching instruments could notify managers about shortfalls in QMS:s and benefit stakeholders as it displays an effort to improve from the hospital. There is ambiguity with how health-care organizations could apply quality enhancing strategies and this study presents a set of shared domains of instruments that assess QMS implementation. These are: process management, leadership and HR roles and inspection and analysis but they call for further research on instruments measuring QMS as there was, at that time, a shortage of well-established instruments (Groene et al., 2013).

Succeeding the work of Greone et al. (2013), a study with the aim of developing and validating an assessment index of the implementation of QMS:s in European countries was published in 2014 (Wagner et al., 2014). To create this index, a web-based questionnaire to assess the QMS:s development in hospitals was sent out. The aim with the questionnaire was to focus on the managerial aspects of QM like policy documents, formal protocols, analyzing performance and evaluating results. The questionnaire did intentionally not focus on leadership, patient involvement or organizational culture since these are theoretical concepts within the DUQuE (Deepening our Understanding of Quality improvement in Europe) framework. Quality managers of 188 participating hospitals (183 responses) were sent questions. They developed and validated the QMSI, quality management systems Index, which ended up with 46 items that could be answered and summarized as an Index that expresses the extent of implementation of QM activities such as continuous improvement methods, quality policies and procedures for patient complaint handling of staff education (Wagner et al., 2014).

In a 2014 European hospital study on executive board's agenda association with the implementation of QMS the aim was to analyze how having quality on the board's plan would affect QMS implementation. The authors found that hospitals with executives putting quality as a part of their agenda are more probable to review and discuss quality performance more regularly and thus more likely to have a QMS running. Having quality as a part of the executive board's agenda is important for hospital QM (Botje et al., 2014).

In a more recent study on what impact the hospital management boards had on quality management, Pfaff et al. (2021) looked at how adaptation of QMS in hospitals could mediate between hospital management boards and patient care quality. Their results show that in European hospitals, quality management strategies are commonly more often fully implemented in hospitals handled by boards with a high goal attainment (G) and social integration (I), a high GI factor (Pfaff et al., 2021). GI board run hospitals showed a higher score on the QMSI than non-GI board managed hospitals. A hypothetical improvement of 11% on the quality management system index is possible for hospital management boards with a high GI factor. Their empirical result also showed that improving the social capital of hospital management boards as a result of developing a better team climate could prosper strategy implementation processes (Pfaff et al., 2021).

Furthermore, some previous reports of Australian hospitals also suggest that a lack of quality systems in hospitals have resulted in safety and quality failures (Leggat & Balding, 2018). In the study by Leggat and Balding (2018), it was clear that the vision of quality by executives and management was not understood by lower organizational levels, and not many board members and senior managers were conscious about the fact that their vision had not infiltrated the whole organization. Many clinicians and managers even told the authors that there was a feeling of the quality systems (QS) being forced on them. No hospital in their study graded their QS components as thoroughly matured and there was a clear rhetorical gap between what top management said and what middle managers and health professionals experienced. These results showed to be agreeable with studies by Pannick et al. (2016) suggesting that when it comes to quality improvement management participation is considered done, but with little attention on ensuring engagement. The study by Leggat and Balding (2018) concludes with saying *"Without an honest assessment of QS effectiveness, and associated change and improvement at point of care, it is likely that quality and safety will continue to be something that health professionals and managers "do", rather than engage with to create safe, high-quality care for and with consumers."*, implying there is a need for implementation of a well-established assessment tool.

Following this, implementation of hospital accreditation is another part of hospitals QMS work but there is a challenge in maintaining accreditation as the trained professionals in the area may not stay in the company for a long time. It is therefore important to establish an organizational culture towards quality and to reduce employee turnover (Oliveira & Matsuda, 2016). A survey on hospitals in Brazil suggests that accreditation aids health organizations to carry out good quality management practices. The study applied a self-evaluation questionnaire of the EFQM model through structured interviews with managers, board members, or people in charge with QMS in the surveyed organization. The results showed better total and subtotal scores for accredited organizations (Berssaneti et al., 2016).

Hospitals allocate a lot of resources into preparing for quality accreditation and certification. There is a consensus about thinking it will result in improved future service quality, yet little documentation is out there indicating whether it will influence the management processes it is presumed to improve (Yıldız et al., 2019). Braithwaite et al. (2010) found that accreditation forecasts positive executive behavioural changes but had close to no impact on organizational climate or participation of consumers. In Yildiz et al. (2019) study, they evaluated the effects of accreditation and certification with the quality management system index from the DUQuE project. By collecting data from different sized Turkish hospitals, they present findings that suggest that accredited hospitals show substantially higher QMS scores than hospitals with ISO certification and the scores of certified hospitals were better than non-certified and non-accredited ones. Size of the hospital affected almost all of the QMS scores in a positive way, the larger the better. Private hospitals had better average scores than public ones in 6/9 quality dimensions. QMS scores do not necessarily translate into quality of services since this has not been rigorously evaluated (ibid.).

3.3 Theoretical Framework

To summarize the case context and theoretical chapters, QMS work at hospitals is no easy task. Both organizational factors and system content will have a potential impact on how well the QMS performs. What standards to base the QMS on is also not a one answer question but based on the harmonization of ISO 13485 earlier this year, the utilization of ISO 13485 as a way to facilitate MDR compliance looks like a promising way for hospitals to start their QMS:s work. ISO 13485 would not only act as a suitable standard solely due to the harmonization but also because of its distinct clause on top management. Xiong et al. (2017) and Wardhani et al. (2009) implied the importance of leadership and management aspects when looking into quality work at hospitals and by emphasizing this, following ISO 13485 could thus potentially have a positive impact on overall quality work. Furthermore, Botje et al. (2014) sheds light on the fact that a more involved top management will prosper QM. When looking closely into the differences and similarities of ISO 13485:2016, SOSFS 2011:19 and HSLF-FS 2021:52, there are some clear similarities between them and with the latter two being regulations in Sweden, hospital implementation of ISO 13485 should be accelerated by the already followed regulations. Regarding implementation of QMS and standards there seems to be an ambiguity on how such systems should be implemented, and their impacts on business success. Standards could both enhance and decrease performance (Sfreddo et al., 2018). This seems reasonable given that several factors that may contribute to a successful implementation can be found in literature (Wardhani et al., 2009) . How these factors are prominent in Swedish hospitals is interesting to investigate since these otherwise could be areas for investigation and possible improvements in Swedish hospitals quality management. The figure below is a comprehensive view on the QMS implementation process at hospitals based on the literature review and case context, see figure 1.

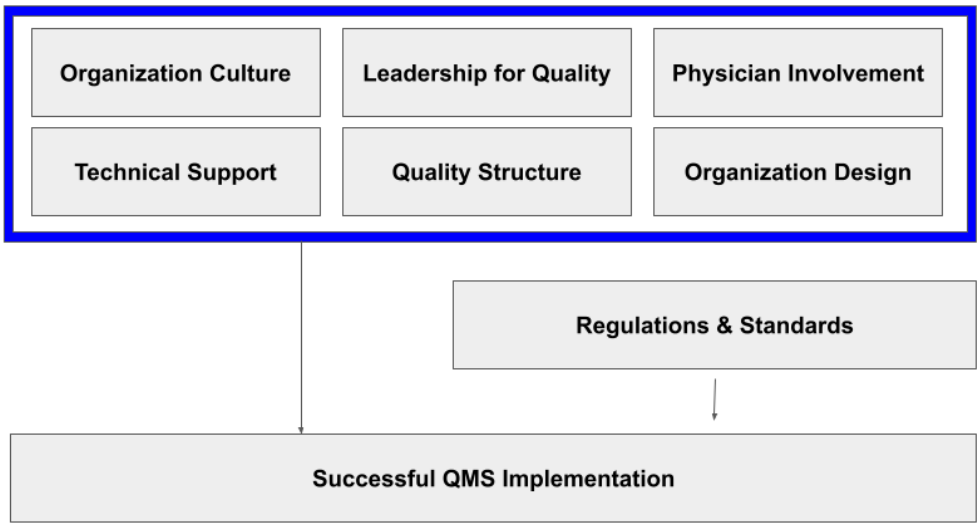

Figure 1: Theoretical framework. How theory depicts a successful QMS implementation based on organizational factors by Wardhani et al. (2009).

Figure 1 presents our proposed theoretical framework for this master's thesis project and is the result of the initial findings from the pre-study, the case context chapter and the literature review. It consists of six organizational factors that are believed to be of importance when addressing a QMS implementation process and the proposed regulations and standards needed to create a MDR compliant QMS are 13485:2016, SOSFS 2011:19 and HSLF-FS 2021:52.

4. Method

In this chapter, the research design and selected methods of the master's thesis will be discussed. All stages of the research will be presented in their chronological order as the data collection and method for data analysis is described.

4.1 Research Design

The aim is to move with a data-driven approach towards theoretical understanding, researching the concrete and specific and arriving at the abstract and general (Eriksson & Lindström, 1997). The research will aim to investigate processes used in a Swedish healthcare provider. The main analysis will be on a functional level (Blomqvist & Hallin, 2015) since this considers processes and production aspects.

Almost all research situations are different and subsequently, research approaches and methods are customized for the context in mind. A method is not to be seen as a recipe that you follow row by row, but rather something that provides scholars with a framework and tools that can be adjusted and used in different ways (Gehman et al., 2017). Given the previously insufficiently investigated area of hospital MDR implementation, a qualitative case study approach was taken with the aim of examining an empirical context and evaluating it alongside previous theories in order to answer the research question. This allows us to explore organizations through complex relationships and explore and describe a phenomenon by using various data sources. Because of its flexibility and accuracy, this approach is relevant for our research to evaluate situations and develop theory (Baxter & Jack, 2015).

The following data collection steps were thought of and seen as an appropriate qualitative approach, containing a preliminary study, literature review and an empirical data collection consisting of interviews with experts within the field of quality management systems, medical device regulations and hospital organizations. The data collected in this thesis project was mostly gathered from primary sources by means of qualitative interviews. Nonetheless, documents provided by the case company also acts as sources of data used to create understanding of the problem and to create interlinkages between the primary data from the interviews and the secondary data from the literature review. The secondary data provided insight into the problem formulation and the learning were used to facilitate gathering of relevant primary data. Figure 2 below visualizes how the study has been conducted and the research questions answered.

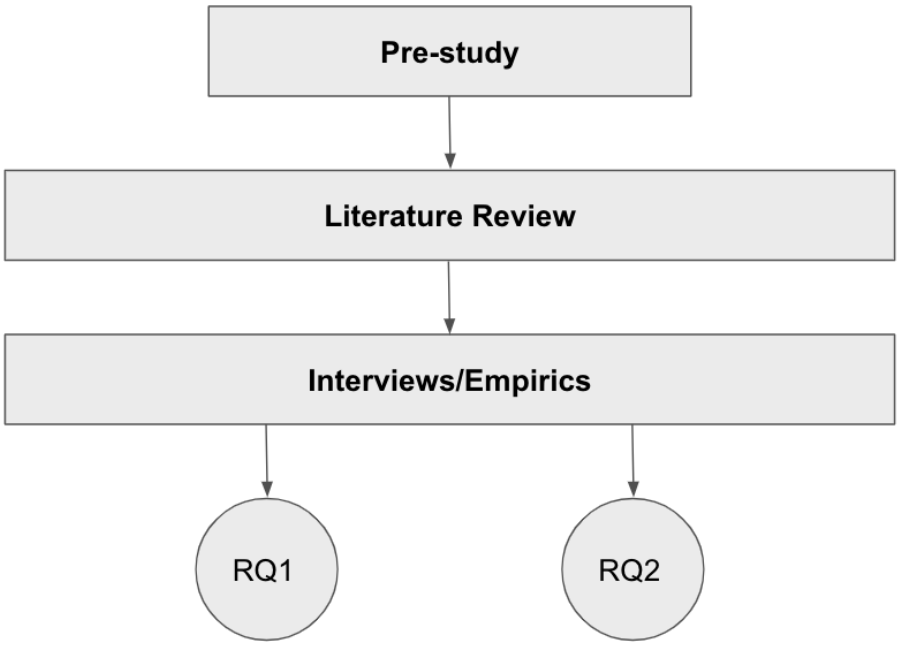

Figure 2: Research Design

4.2 Pre-study

The initial process for this master thesis was conducting a preliminary study. The main purpose of the pre-study was to increase the researcher's knowledge and find a researchable non-trivial research problem. Predefined for the project was to investigate the change needed for hospitals to adapt new regulations. Some techniques presented by Saunders et al. (2015) were utilized to find the project's scope. For example, examining case company interests, scanning the media, exploring relevance to business using the literature, and brainstorming. The initial literature and media search had the main purpose to explore in what ways hospitals worked with quality management and the MDR. Furthermore, the authors wanted to investigate the most prominent research trends in regard to MDR. This search was executed using Google and Web of Science together with keywords, such as "MDR", "hospital quality management", "quality management systems" and many more, see Appendix A. These were used to find relevant articles and media updates. This initial search provided the authors with some guidance for the literature review.

4.3 Introductory Course to MDR

During the research process, an introductory course was attended in order to gain further understanding of MDR and QMS:s. During this introductory course, the course leaders went through the new regulation MDR, the process for CE-certification, and Quality Systems for medical devices (ISO 13485, 2016). With the former and the latter being of most interest in this study, we gained insight and knowledge into application areas, definitions, classification, requirements for

safety and performance, technical contents, risk management, and ways of proving compliance with the regulations. Some of the relevant course content was:

- Directives and Regulations
- Medical Device Regulation
- Introduction to Risk management
- Quality Management Systems around MDR
- Essential demands
- Information about products

The information gathered during this introductory course was applied during the interview study and during the analysis of all empirical data. The course was:

"Introduction to MDR, the medical device regulation" - Swedish Medtech in collaboration with Plant Vision (attended 2022-04-06/07).

4.4 Literature Review

The literature review was conducted through a semi-systematic approach (Snyder, 2019). The purpose of the literature research was to obtain an understanding of the underlying concepts of MDR and QMS implementation in order to create a theoretical framework. The latter concept was important to include since there was not a sufficient amount of literature regarding MDR implementation and MDR compliance in hospitals. Moreover, the authors assumed that the fundamental principles for a successful QMS implementation could potentially also translate into a recipe for a successful MDR based QMS implementation. The scope of the project also required knowledge about other aspects, such as quality standards which plays an important role in hospitals current quality management. The literature search was mainly done using Web of Science due to its extensive offering, and furthermore its user-friendly interface, with appropriate sorting options.

The first step was to execute an initial search on QMS implementation, using the keywords "QMS" and "implementation" together with other keywords, such as "MDR", "hospital", "healthcare", which gave us numerous articles, see appendix A for full list of keywords. After a selection process, where the authors analyzed the title and abstract in relation to the research question, some articles were read more in depth. The main reasons for exclusion in the selection process were too specific cases, or that the article was more focused towards medical device manufacturers. After reading the articles, several organizational factors affecting QMS implementation were identified. Therefore, the next step was to look deeper into the most prominent organizational factors found in the initial

search. This meant a second search in the database using the organizational factors as the keywords. For example, “Process management”, “organizational culture/structure”, “leadership” together with other keywords, previously mentioned, see appendix A.

One important part of the literature review was also snowballing on articles from the search processes that highlighted relevant findings from other articles in the same area of interest. This means that not all articles used in the literature review of this study was a result of the semi-systematic approach, but rather a combination of the Web of Science listed articles and a deeper snowballing process into articles that were cited by the found relevant articles.

4.5 Data collection

The primary data collection was qualitative interviews done with personnel at numerous hospital organizations. Also, conversations with the master thesis company personnel involved with medical device regulatory work, this since the phenomenon under investigation can be multi-sided and complex and cannot easily be described with numbers (Blomqvist & Hallin, 2015). Moreover, interpretive approaches are generally related to utilization of qualitative methods (Saunders et al., 2015, p136). Typically, smaller samples are used with more in-depth analysis (ibid.).

4.5.1 Interview study

To understand how hospitals currently work with quality management, interviews at hospitals with focus on company quality, culture, structure, leadership, and process management were conducted. The authors took inspiration from Saunders et al. (2015) on how to conduct proper qualitative interviews. An interview guide was constructed with a semi-structured format. This since semi-structured interviews are organized around a number of themes (Blomkvist & Hallin, 2015). For our interviews the main topics were QMS implementation, leadership in hospital organization, QMS structure, factors that impact quality work and experiences with QMS at hospitals. The interview template can be seen in Appendix B. The interviews were conducted in Swedish, the interview template was therefore developed in Swedish and has been translated to English in the Appendix B.

With the same approach as to the interviews with quality managers, personnel working with MDR at hospitals or MDR implementation for hospitals where interviewed. This was done as a means to further develop knowledge into what MDR is and what it means for hospital organizations. An interview guide was composed with questions surrounding MDR implementation at hospitals and changes in regulatory work from the previous MDD.

4.5.2 Documents/provided materials

Before the start of this master thesis, the case company conducted a pre-study on MDR in one Swedish hospital which we got our hands on at the project start. The provided pre-study was focused on how the hospital had to adapt in relation to MDR, more particularly a mapping of what departments and current processes that are going to be affected by the MDR. Furthermore, some additional PowerPoints were provided from MDR introductory courses and seminars that consultants at the case company had attended. This material was important for the fundamental understanding of the implications arriving with MDR.

4.5.3 Interview Subjects

All interview subjects work either for or at a Swedish hospital except for subject S2, who works for a large Swedish enterprise and not within hospitals or medical technology. The authors still believe that S2 was valuable to the study since S2 provided interesting information regarding quality work at large enterprises, which is a similar environment to hospitals. S2:s industry is also affected by comprehensive regulations, similar to a healthcare provider.

The hospitals included in this study are large hospitals around Sweden, mostly based around Stockholm. For anonymity reasons the hospital and subject name have been left out of the report since the authors believe that the results section, together with subject role could lead to readers figuring out who each subject is. Still, the authors believe that it is important to provide the reader with this information to interpret the results since including other, for example smaller healthcare institutions could affect the results.

Table 1 below outlines information regarding the conducted interviews. All subjects actively work with quality related aspects. However, some subjects' role might not give the full picture of their expertise in the field. The subjects were chosen for their knowledge within quality management systems, regulations, standards and work experience with implementing such systems.

Table 1: Information about interviewees, their role, type of interview, length and date

Subject	Role/experience	Type	Length	Date
S1	Business development. Has worked with ISO 13485 and 9001	Video -call	90 min	15-03-2022
S2	Responsible for ISO standards	Video -call	44 min	02-03-2022
S3	Quality Strategist	Video -call	50 min	23-03-2022
S4	Specialist within regulations for medical technical departments & standards	Video -call	62 min	23-03-2022
S5	Risk management responsible & staff QM team leader & leader of creating a regional QMS based on MDR	Video -call	45 min	01-04-2022
S6 & 7	Responsible for own production quality & Process owner risk and security & QMS responsible	Video -call	51 min	04-04-2022

4.5.4 Conducting the Interviews

The interview process started with contacting different hospital and healthcare organizations in Sweden. Emails were sent out to all addresses that the authors could find online. Such as regional press or media addresses, regional hospital administration addresses, specific hospital personnel addresses and MDR or hospital experts found when browsing online newsletters about MDR and ISO (International Organization for Standardization) standards. The sent-out emails contained a brief description of the intended work and the asked for necessary background of requested interviewees. Furthermore, an introduction of the authors and that the thesis is conducted on behalf of the Royal Institute of Technology, KTH. Since the emails were sent out to both specific intended

precipitants and administrative posts, the email also contained the request of forwarding the information within the contacted organization if there could be other more suitable personnel available for interviews.

The questionnaire was not sent out beforehand and the subjects only knew the overall topic of the interview, QMS and MDR. Subjects were asked if they would like to conduct the interview over Zoom, Teams or another platform of their choice to establish a comfortable meeting for them. During the interviews, subjects were first asked if the authors could record the audio of the conversation to transcribe important parts. Subjects were informed that the audio files would be deleted as soon as all empirical material had been transcribed and analyzed. All subjects were also informed that their participation in the research project would be anonymous in the report. The interviews were conducted digitally using video links due to the covid-19 situation not allowing us to meet in person, and moreover due to the high pressure on healthcare providers during the spring of 2022. How an interview is performed will impact the quality of the interview (Blomkvist & Hallin, 2015). The interplay between interviewer and interviewee determines how rich the empirics will become. During the interviews the question types, mentioned by Blomkvist and Hallin (2015), worked as a backbone in the discussion using introductory, probing, interpreting and specifying questions. Both authors were always apparent at all interviews, one leading the discussion and the other one taking notes. This strategy reduced the risk of missing important follow-up questions or details. The semi-structure allowed both authors to follow up certain arguments or comments from the subjects with questions not initially intended but that were highly relevant in relation to the subjects' previous answers. The case company was intentionally left out during the interviews, as the authors believed this could have impacted the answers from subjects and the sought-after answers to all questions wanted to be solely from the subjects' own experiences and thoughts. Furthermore, since the research project was initiated by the case company together with the researchers, the researchers received no monetary incentive, meaning that the researchers can perform the study in the way that it unfolds and not in a way to only please the case company. The outcome of the literature and empirical research was not influenced by the case company, more than from the information given by them, and thus withholding the company name from subjects was not seen as withholding information or intentions of the research project.

4.5.5 Seminar, peer-review and supervisor feedback

During the course of the thesis project the authors attended three seminars where we presented the current state of our research. During two of those seminars, we received valuable feedback from groups and from the course examiner listening to the presentation. We also received a more in-depth peer-review of our current work that helped us understand how our work and findings were interpreted from someone not as committed to the research. These insights and discussions were treasured and guided the work further towards being presentable in the most academic and understandable way.

Another important part of the thesis project was the interaction between us and our supervisor at KTH. When needed to, we had meetings where we discussed the current situation of our study and what possibilities or challenges that we could face next. This communication and guidance from someone well-adjusted to research projects was an important part of figuring out the next steps and combining all findings into something that would in the end help answer the researched questions.

4.6 Data Analysis

The thematic analysis of the data gathered in the literature review phase consisted of, once the information was read through, reviewing the data and documenting the most important parts of it needed for the understanding of QMS and MDR surrounding hospital organizations. A separate document was used where either cited sentences or paragraphs with relevant information were written down or a short summary of the findings most applicable to our research question was created and saved. Once a satisfactory, enough to properly conduct a minor research project with, number of articles had been analyzed, we created a summary/conclusion of the literature findings that would act as a guideline in the rest of the research stages.

Since interviews were conducted with both experts in QMS and MDR work, it allowed us to grasp the possible multiple interpretations and meanings of the studied phenomenon. The interviews were conducted using a semi-structured template since it was appropriate for both an exploratory purpose and for explanatory and evaluative research (Saunders et al., 2015, p393). Semi-structured interviews were appropriate given the outlined research questions.

The interviews were recorded for us to review and transcribe the material before deleting the audio files. Furthermore, notes were taken during the interviews to create an understanding of what the interview consisted of. The questionnaire for the interviews remained the same for everyone for transparency reasons, with some questions only appropriate for some interviews. If the interviewee had experiences in both fields, a combination of the questions was used and since the interviews were semi-structured, follow-up questions appeared in most interviews. Only the most relevant findings from each interview were listened to again and transcribed after the interview. This allowed the researchers to only focus on information relevant to the researched questions and not spend time on transcribing everything.

The collected interview data was then analyzed thematically. Everything deemed relevant went through a six-step process as presented by Braun and Clarke (2006). The analysis of the qualitative interviews followed these six steps:

1. *Familiarizing yourself with your data*
2. *Generating initial codes*
3. *Searching for themes*
4. *Reviewing the themes*
5. *Defining and naming themes*
6. *Producing the report*

First all transcribed and noted answers from subjects were read through to create an overview of what the data consisted of. All the transcribed material was analyzed based on content. Relevance between and overlapping of answers created the themes. The found themes were complexity, culture, implementation, leadership, standards & regulations, value creation and case specific. All the relevant transcribed material was categorized into the found themes and colour coded to ensure that it was still clear from what subject the data came from. Once all relevant material had been categorized and colour marked, the results chapter was created where the data was presented in order of relevance to the study. The interview data was then compared and analyzed together with the data from the literature review and other initially acquired material in the analysis section.

4.7 Development of the gap analysis tool

The QMS to MDR gap analysis tool process started with evaluating relevant and important aspects of ISO 13485:2016, SOSFS 2011:9 and HSLF-FS 2021:52 (SOSFS, 2001; HSLF-FS, 2021). Since ISO 13485 is harmonized towards MDR, most of its content is perceived as relevant but some clauses in it, depending on the structure and operation of the hospital organization, are not necessarily applicable for achieving its certification. SOSFS and HSLF-FS are regulations for Swedish hospital quality management and thus became the pillars of the gap analysis tool. The evaluation of ISO 13485 and what aspects of it were of relevance was derived from the interviews and case company material. These were then combined and categorized together with the regulations from Socialstyrelsen to create an overview of what the assessment tool would consist of. Several steps were applied to create a concise tool that covers the most important aspects of either creating or evaluating a hospital quality management system that complies with the MDR.

The creation of the tool followed a simple structure listed below:

- Isolate relevant paragraphs from each regulation
- Combine all paragraphs into one long list
- Categorize by overlay and content
- Merge overlapping paragraphs from different regulations
- Create themes and subthemes
- Rewrite paragraphs into criteria used in the tool
- Create gap analysis tool template
- Evaluate the current state of the assessment tool with relevant interviews

The gap analysis tool was first developed in Swedish and then to some extent translated into English for the purpose of this report. A forward-backward translation process was used for validation purposes. The aim of the gap analysis tool was creating a single, easily accessible, understandable yet comprehensive tool for addressing the current quality management system situation at a hospital to comprehend what changes might be needed in order to comply with regulatory necessities of MDR. The literature review revealed that QMS:s in hospital administrations more than often got stuck at higher hierarchical levels which guided the development of this tool. The tool focuses on the regulatory requirement of MDR and by combining overlapping paragraphs from different regulations, the goal was to ease the QMS transition by creating awareness of necessary clauses in ISO 13485:2016 that might already be satisfied by the current quality work demanded by SOSFS and HSLF-FS. The last step of the tool development would need to be evaluating what had been built by conducting interviews aimed towards content validity with QMS active personnel at hospitals not involved in the assessment tool development.

The structure of the final product was inspired by the Safety Management System Evaluation Tool from the Safety Management International Collaboration Group. This is a tool that has been developed by the SM ICG for enabling assessment of an organization's safety management system in terms of compliance with regulations (SM ICG, 2019).

5. Results

The results chapter is divided into six sections. These sections stem from the themes interpreted in the data analysis. The themes were created after topics that emerged during the interview study and are ordered after how recurring they were, starting with the most common one with the most findings in it. The data was collected from the conducted interview and are solely based on answers given by the interviewees. The results intend to present a deeper understanding of quality work at hospitals and how everything around it could be in order to make the QMS work.

5.1 Complexity

Many of the subjects (S) point out aspects that are challenging for healthcare providers, especially in regard to what aspects to include in the QMS. S1 points out that the departments for medical devices can look very different between hospitals and internal hospital departments and each department has to follow what is necessary for its own operations. The process of determining what regulations the hospital or department has to follow is challenging according to S4. S4 describes the regulations as "*a network*" where you need to find the relevant parts for your operation. S4 believes that the MDR has created more awareness regarding the regulations of medical devices that did not exist before MDR and explains that hospitals have started to realize that they have to deal with medical devices. Moreover, S4 points out that according to the MDR the organization should have an appropriate QMS, which could be difficult to determine. In particular regarding how the hospitals should include regulations for medical devices. It is easier to only read the part relevant for hospital QMS, but this will not lead to a correct QMS. S3 mentions that the regulatory texts can be hard to understand and S3 sometimes has to interpret and translate the regulations for the organization. In relation to this, S5 mentions that it can be challenging to interpret and understand the regulations. Sometimes S5s employer utilizes external help for this process. Another aspect that implies that the regulation is unclear, is that the guiding documents are constructed after the release of new regulations, furthermore, these guidance documents often set even higher demands than the actual regulation, S5 mentions. S4 also believes that the MDR might be more complicated than the previous directive. The quality system should not be overly complicated according to S2. All employees should be able to understand and relate to the system, the system should be helpful and support employees to work correctly. S5 also mentions that having QMS understanding in place makes it simpler to involve new employees.

S4 continues, when it comes to constructing an appropriate QMS, every healthcare provider should ask themselves "*what is appropriate for me?*". It is simpler for an actor working with releasing medical products on the open market, it is written more clearly what to include for compliance with the regulations. This is however not true for a healthcare provider. The healthcare provider must analyze what constraints are necessary for the current operations. Moreover, start thinking about processes,

roles, and responsibilities depending on whether you are counted as a manufacturer or just a user of medical devices. S5 also mentions that what's appropriate is not clearly defined somewhere, you have to review the regulations in their entirety.

S1 believes that ISO 9001 could work as a fundamental QMS, but other things have to be added where it is needed. S4 believes that the majority of all hospitals today could count as manufacturers, but historically, S4 does not believe that many hospitals have complied fully with previous regulations regarding medical devices. S4 believes that many hospitals had missed the MDD, which means a larger work with the MDR. This has created a situation where significant work is required by the hospitals to reach and comply with the new MDR. Another complex task in dealing with different ISO standards is understanding when you should have exceptions in the certification. S6 & 7 mentions they had some exceptions in their ISO 13485 certificate but that it depended on what their auditor had said, "*what needs to be included is decided in discussion with the auditor and has been a bit back and forth*".

Utilization of standards for quality management is a common practice in healthcare, both S1, S3, and S4, the latter ones working in the same hospital, use standards as the foundation of their QMS. Both subjects' hospitals are either aiming for or certified against ISO 9001 while working with ISO 14001 in parallel. S1 also mentions that the medical technology department is working with ISO 13485. S4 says that standards could be an appropriate tool, S4 however continues that it is important that the organization is mature enough when working with standards. If you work towards certification, you might only listen to the auditors on what to improve, thereby you forget your own responsibility to follow up on changes in external requirements. It is important to not forget the main objective, which is the same for everyone, to deliver safe medical devices. S1 points out that executives without knowledge about standards often want to have documents explaining what they should do in the form of a list. S1 mentions this as a problem since a quality system should be improved and changed continuously and should not be seen as a static activity. S4 agrees with this statement and also points out the importance of management, it is one thing to set up the system but another thing to make it work efficiently and monitor the system continuously. S5 mentions that if people within the organization do not know what they are doing, how, and why it should be done it is going to be difficult to achieve some continuity in their deliveries and uphold good quality. Due to the complexity of quality work, S5 puts emphasis on the importance of clarifying goals and missions and why the QM work is being conducted.

5.2 Culture

When talking about quality management systems at hospitals and in other organizations it is important to understand aspects that make them more or less functional. Despite the fact that the interview template contained no direct questions concerning culture, a lot of the interviewees answered questions about what makes a good or bad QMS or questions regarding leadership with cultural aspects in mind. The results from the conducted interviews show that company or organizational culture is important when discussing QMS and the following are statements from interviewed experts in the area of QMS.

S1 says that the toughest challenge with QMS is "*getting everyone to go in the same direction and getting a system in place. The ones that do not see the value of it only perceive it as a lot of work and cannot see why they should do it. The success factor is having as many of the ordinary working staff with you when trying to create a system*". S4 comments on the same topic stating that there are people in the organization who do not even want a quality system and that sometimes, there can exist a cultural resistance towards quality work. S1 says that "*the QMS works better when it is accepted and well known all over the organization and should be used without thinking of it*" which was in line with another statement from S4 saying "*you should not perceive it as a burden but rather as a helpful tool*", both highlighting the importance of how the QMS is seen from different perspectives in the organization. S3 expresses the importance of not only thinking that quality management is about structure and guidelines but rather how important the cultural parts are and "*that not having a shit happens culture where you sweep things under the rug is important, especially when dealing with healthcare*" and then also highlights that a systems perspective is important where one does not throw blame at people but rather talking about how things got to this point. S5 mentions that one of the biggest challenges with QMS at hospitals is the understanding of what a QMS is amongst workers since not everyone has a background in medical technology. Another challenge S5 mentions is that in large organizations, even though most people might think that the QMS works, there is always going to be those that disagree.

"*The more people that are on board with it the better, sometimes the trust in doctors can help other personnel with trusting the QMS*" and "*it works badly when either the board, managers or staff members for some reason do not embrace the management system and instead chooses to do things in their own way, it delivers a feeling of neglecting tasks and that does not help the quality management system*" are statements from S1 depicting how important the view of the QMS work is at the hospital. Meaning that having a set system is not simply enough, the necessary and inviting culture from all workers within the organization is essential for the success of the quality management system. S5 has some similar thoughts saying that "*it is easier to implement a QMS in a culture where people understand why it is important*". S6 & 7 are on the same track, stating that everyone needs to be brought along in order to see the benefits of it, personnel responsible for the QMS needs to be well

read and motivate the normal employees. Furthermore, S6 & 7 mentioned some ways they have worked with including employees and building an exciting culture around their organization's quality work, including newsletters, quizzes, and mentimeter to make a social thing out of it.

S1 have even seen situations where the board and managers have created a QMS and wanted to put resources and opportunities towards implementing it but it has not gotten the acceptance needed all the way down in the organization, people were not keen on doing extra tasks alongside their ordinary routines. S1 also mentions that it is tough to fully avoid any type of complication with the acceptance of quality systems, "*in large workplaces there is always the risk of having people more or less interested, one of the most important factors for success is thus finding those genuinely interested people who take on the work and then spread it across the organization, both from the top and from the bottom of the organization*" also stating that sometimes it is enough with that one enthusiast that drives the quality work forward. S5 says that the quality management group should be there to aid delivery and safety within the organization and not point fingers at people doing things the wrong way.

5.3 Implementation

Some of the questions of the interviews regarded how interviewees had gone about implementing their current QMS and what could be important to think about, understand and actualize when implementing a new QMS. Subjects also talked about the challenges and opportunities with implementation.

All subjects mention that the initial step, when implementing the QMS is to look where you currently stand. S1 describes that this should be done from two perspectives. Firstly, the organization should analyze how the operation currently looks. After that, analyze how much is already in place. S1 refers to this as "*process mapping*" and says that this could be executed through brainstorming. The organization should then connect the related areas in this process. S3 mentions using a similar approach starting with what they have and then analyzing what are the biggest challenges. Thereafter you work with different areas separately. S4 emphasizes the importance of identifying "*what you are, and what you are doing*" for example, manufacturer, special adaptations, providing healthcare, what products are used, and if the products are classified in a higher risk class. This should be the initial step according to S4. After that, you put together the requirements and execute a gap analysis. It is important to clearly differentiate if you create products or provide healthcare. S6 & 7 says that networking is a good thing when new regulations arrive, to comprehend how other actors solve similar problems but also mentions that it could be a long process. S1 differentiates between main- and supporting processes. The approach to processes should be executed with respect to the related risk. S6 & 7 also use a process approach, the main processes have assigned responsible people, for less comprehensive processes one person can be responsible for several processes. S5 says that they have processes describing the system, and how the work should be executed, key figures for these processes

give support to analyzing the delivery in relation to customers. S2 thinks in a similar way, you start with a technical analysis of what is needed, after that you focus on the employee that executes the tasks and ensures that they receive the information and get the necessary education. There are support systems for this process, S2's organization uses a portal for employees where they can get the necessary education and completed education is registered. S5 mentions that healthcare regulations set the framework for what to include in the QMS, but the structure is up to each hospital to decide upon. For example, the QMS should include management responsibilities and a quality policy, but the hospital management decides how these should look. How the structure is constructed can vary, S5 says that the MT-department's QMS structure is based on a product life cycle perspective, for each part of the product life cycle you analyze regulations and applicable standards.

After the processes have been identified you start looking at regulations, not only the standard, says S1. Moreover, you should not begin with how you want the QMS to look, instead start with what you have and then see what is possible to change and improve. The gap analysis should be an ongoing practice, especially when regulations and standards are updated. S3 mentions that they started with the mandatory regulations and then looked into possibilities for certification towards standards. The main idea was to add more standards, for example, standards for medical technology but they have not got there, it is an ongoing process that takes time.

S1 describes that one challenge is to make the agreed routines available and visible. Larger organizations demand better and clearer visual tools to make it easy to work correctly. S1 believes that most employees want to follow the routines and do things correctly, but it has to be simple otherwise people find shortcuts. S6 & 7 also mention the implementation of new routines and instructions as one main challenge. To enhance the information distribution, their department has begun with "*Quality Ambassadors*", which are regular, not quality system involved, workers that attend quality meetings. The quality Ambassadors also provide feedback to the people responsible for the QMS.

S1 also mentions that education and objectives are important factors. Objectives are important to visualize how the quality management supports the operation, without that it can be challenging to achieve support from the employees. S3 believes that their previous work with competence planning, supply, and follow-up was a strength when they began working towards ISO certification. An important thing according to S1 is that the work instructions should be formulated so that the user can easily understand and use them. S3 explains "*it should be easy to do right*", one challenge in regard to this is how to document things so that they are pedagogic and easy to communicate. S4 also views a QMS as a "*system where you do the same thing, good or bad, every time*", it is important to follow-up. S3 says that the IT-systems for documentation and supporting systems are currently dysfunctional in S3:s organization. The QMS should be process oriented, and S3 thinks it is a

problem that they do not have any support system for this aspect. Another implementation challenge mentioned by S5 is that the QMS should not be a one-time happening, it is a continuously ongoing process, and it should be a natural thing to use. Moreover, a successful QMS is one that is fully implemented into the organization, so that the processes are delivering the desired outcome.

When working with QMS it is important to agree whether the aim is to reach standard certification or create routines for quality work, this could determine how the implementation will work out. S1 thinks that if the organization doesn't care about certification, there is no main objective. However, there should be a reason for the certification, it is important to investigate how the department needs the standard.

S2 mentions that there are methods for measuring the QMS. The simplest one is to ask the customers if they are satisfied. Another one is to evaluate if the organization is making enough money. S2 thinks that analyzing customer satisfaction may require deep interviews. To measure the success of quality work S6 & 7 uses quality measures for the processes, the measures are decided by the responsible or the department. The progress is described in quality reports three times every year. The measures can for example be time until an incident has been investigated or satisfied participants from an education. Some measures also have related regulatory restrictions, an incident for example should be investigated hastily according to regulations. S6 & 7 talked a lot about the importance of creating a quality-focused culture, even if the measures do not directly measure cultural aspects, analyzing differences could give an indicator of cultural problems or that the routine is not being followed. S6 & 7 add that this however does not provide a complete picture of the company culture.

S1 mentions that if you don't put in the necessary resources, it will take a longer time to implement the QMS. Moreover, is it important to have some people pushing the work forward. S4 agrees with this and says that implementation difficulties may occur if not enough resources are provided in the beginning. S5 also points out that management must provide time for employees to have quality-related conversations, to enable improvements. This is sometimes missed since management does not see the economic potential from these meetings. S6 & 7 believe that it is important to work actively with the QMS every day and that there are people to ask if there are any questions.

5.4 Leadership

From the initial literature review, articles concerning the role of leadership during QMS implementation, continuous work, and improvement were found. As mentioned in the theoretical framework, implementation studies from hospitals around the world depicted the leadership position as a potential bottleneck for putting a working QMS in motion. In the interview study, interviewees were asked about their experience with leadership and quality work and all subjects had opinions about how leadership affects the potential of QMS:s.

S1, as mentioned before, says that the organizational culture towards QMS affects how well it is implemented, despite a positive leadership towards it. S1 also puts emphasis on the fact that the complete opposite situation can occur where the staff wants to start and actually work with quality management and advocates it towards the board who might say yes but still do not put it into motion. S4 points out that a management system comes from the top management and travels down in the hospital organization and with many very different processes and routines it makes it a complex system. S4 says that "*a contributing factor to having a more or less successful quality management system is having a top management team who understands that you are not doing it because you have to but rather having the drive to try and create an effective production or way of working and can mediate it within the organization*". S3 is on the same track by saying that sometimes the top management knows the goal and content of the QMS but *"it does not reach the bottom of the organization and is forgotten the further you travel down the chain of command*". S5 says that it is important for top management to understand what is important, and what parts is are beneficial for a value-creating purpose. Furthermore, management needs to understand that 2-3 hours spent discussing quality matters might lead to the creation of something more effective in the organization. S5 also mentions that the foundation for a successful QMS is engagement from top management and understanding of important parts and benefits of the QMS. S6 & 7 talk about the importance of having a well spread QMS but despite this it could get stuck at top management. They also mention that information and decisions getting stuck is not always a bad thing, "*it is good that they don't make rash decisions but it cannot take too long either, it is a tough balancing act*" and they believe a middle quality management team/person is a good way to spread information and involve as many as possible.

Both S4 and S3 agree on the importance of creating a QMS that is transcribed into a reality and not just something bureaucratic. Sometimes top management just wants a certificate but it is not communicated properly outside their meetings. "*The QMS has to deliver an actual value, it is one of the most important things to work with*" - S3. S4 ends by saying that sometimes there are clear routines but they are not followed and thus personnel create their own routines instead.

S2 had some insights about the role of leadership and said that "*it does not matter if I am sitting in the board of directors and creating a nice-looking policy if it does not work out in reality in the organization's day to day business, that will not please anyone*". S2 mentions the importance of mandatory education for everyone to solve this problem, workplace environment laws, and that managers are responsible for making people follow them in their respective workplace.

S1 sums up the leadership and QMS correlative outcomes by saying that it is different depending on the size of the organization's top management "*with a top management team consisting of 8-9*

different departments who are all quite large, there is a far greater challenge to forward information all the way down in the organization and a greater chance of information getting stuck at top levels". Yet, S5 disagrees a bit with this, saying that "*it is challenging for smaller organizations with fewer resources, for our large organization, people understand the importance of the work and the importance of working in the right way*".

5.5 Processes & Standards

The interview questions did not only consist of questions regarding how well or when QMS:s work or not, some questions were aimed at gaining insight into how experts in the area go about when deciding on what standards to follow and what regulations are important for their organizations' quality work.

When talking about quality management systems, S1 says that it is not always about standards and mentions that within healthcare you often work with process-oriented care, for several different processes. "*You look at a certain disease and then you look at flows through the care process and you try to quality-assure flows and processes*"-S1. Saying that this is one way to achieve quality and sometimes the end result can be as good as a QMS but you do not have a full QMS put in motion, yet some processes have been secured much like in a proper QMS. S4 also talks about this and says that he/she is not certain about the need for standard certifications. Saying that "*you can do it if you want to, it could be a good benchmark but there are no demands to do it*". S1 mentions that working towards a certificate can be a good thing since it gives management and employees a clear goal to work towards, which might clear up the question many people have of why one should follow a QMS.

S4 mentions different regulations and standards that are of value when talking about a QMS for hospitals. "*There is regulation HSLF 2021:52 that regulates the use of medical devices, it says you have to have routines and management systems in place to simplify and secure appropriate products being used in the correct way, this one is sometimes forgotten and instead you look at SOSFS 2011:9, but that one does not say explicitly how one should bring and supply medical devices to patients and you might miss that it may treat medical devices poorly*".

An important aspect to have in mind according to both S4 and S1 is that which standards a healthcare department decides to try and follow is very situational and which standards are relevant will vary from place to place. S1 says that ISO 13485 was a clear choice for their medical technology department but that they had skipped some parts of it that were not relevant to them. S4 mentions that "*what is written in the MDR is reminiscent of ISO 13485 and what is written in SOS-FS 2011:9 does not write about it at all, because it is so explicit for care and nursing*" and says that there is a chance that you might get lost when looking into several different standards and regulations trying to find a perfect fit. S5 says that their goal is to develop the QMS around ISO 13485.

S6 & 7 talk about their certifications as means of generating an extra income to their department. With certifications, ISO 9001 and 13485 in place, they can work with organizations outside their department that chose them because of the certifications, leading to more external customers and an increase in department income.

5.6 Value Creation

The interviews delivered insights into why experts in the field believe that quality management systems are important and why hospitals should focus on implementing them.

S1 emphasizes the fact that QMS:s are valuable since "*they deliver a uniform way of looking at things, it often turns out that people think they work in the same way, but that's not always the case*". S1 also mentioned the importance of flexibility but the customer always expects the same results. S2 points out the fact that internally, the QMS helps them to understand and get the whole picture together, how different parts of the organization are actually connected, otherwise large organizations can become very complex. S4 believes that the QMS is important in order to create a safe healthcare environment, to ensure the safe use of products, and prevent injuries due to products or processes and says that "*it maintains a reliable work process*". S6 & 7 believe that the most important thing about quality work is having everyone do everything in the same way, documenting it can be tricky but it should be thought of as a security. "*With good documentation and structure, you can keep your back free, it all is about being patient safe*" - S6 & 7, meaning that with a good QMS in place, people following it do not have to be afraid of doing something wrong. S1 also mentions that if you have a working QMS in place, it becomes easier to deal with new policies and demands from the government since you have a greater insight into your organization's operation.

All interviewees talk about the importance of sharing a common ground amongst employees in why the QMS is valuable to them. For example, S1 says "*it is important to keep in mind what we gain from the QMS, in the long run, it is supposed to ultimately benefit the organization*" and S3 mentions that "*ultimately, it is about creating safety, that is the lowest requirement, not to hurt people and then to create satisfied stakeholders in the end*". S2 follows up on this by saying that in order to really create a well working QMS you have to have the customer in mind and really try to understand the QMS and implement it in the whole organization. S4 says that quality ensuring routines and processes are very important since "*it would demand too many resources to reinvent the wheel every time*" and ends by saying that there seems to be a lack of understanding of why the QMS is needed. S4 mentions that some still believe it is only the top management's responsibility and that this makes it important to look at hospitals as one unit and then build the QMS from the top and all the way down in the organization.

S4 talks a lot about how complex the QMS situations at hospitals are and mentions that healthcare institutions have not gotten that far in their QMS work. Saying "*quality work is sometimes seen as a burden*" and believes that people sometimes view it as a cost "*wow it costs a lot to create a QMS*", furthermore, S4 has seen situations where it is only done to receive a certificate or because it is demanded by law and says that this is a very poor driving force for quality work. "*It should instead be created to enable knowledge of how things should be done, quickly get the necessary technique and safety should be the driving force*" - S4. S4 also emphasizes the need to have a QMS due to the more and more technologically demanding structure of working. Saying that if things stop working due to lack of quality guidance, risks for patients occur and that is why you need a QMS, for patient security, robustness, and economical reasons. Furthermore, S5 pointed out that not all people like standards, they are sometimes confusing and difficult to deal with but S5 sees them as an opportunity to actually conduct systematic work.

S6 & 7 talks about the importance of acknowledging who the QMS is for, that it is not just there for the times the auditor is in town, and that people in the organization should know that it is there for them, "*Then of course it also looks good on paper*"- S6 & 7. They think hospitals should put effort into their QMS to create an easier everyday working situation, "*you notice that when you talk to uncertified departments they seem to not have as good structure and control and customers also know what they can expect from you if you are certified*"-S6 & 7.

5.7 Case Specific

With the guidelines from PwC in what different texts a QMS at hospitals could consist of it was interesting to hear what the interviewees said about regulations, standards, and certification.

S4 mentions that historically, different departments used their own quality management systems at this large Swedish hospital, and then a decision was taken that the hospital should follow one ISO standard, but the other systems kept living in their respective department. "*This was done without thinking that they could be contradictory to one another*" - S4. S3 highlights that certificates are voluntary while SOSFS 2011:9 is very important, saying that ISO's is a further step from SOSFS 2011:9 while ISO's deals with more areas.

S4 mentions that the MDR says that you should have a suitable quality management system, but not what constitutes a suitable system, saying that that section of the MDR is not very helpful. But S4 says that you should then look at HSLF-FS 2021:52 for guidance towards a suitable quality management system and that HSLF-FS 2021:52 in turn guides the reader to SOSFS 2011:9 to find a management system for systematic quality work.

S4 also highlights the fact that in order to certificate oneself, you have to be mature. "*You have to on your own decide on what to do, find the demands, no one else will do this for you*" - S4, and ends by saying that to do this, you have to perform a gap analysis to understand what does or does not exist in the organization right now. S4 says that "*The gap analysis is needed to understand what flows and processes you need to bring forward before moving towards a certain certificate*".

S5 explains that the QM work should be anchored in the organization, "*it is a system used within the organization and people there have to know that it is done for them, adjusted to them, easily accessible and clear, simply put it being plain and structured*". Furthermore, mentioning that it cannot be difficult to deal with, it should not take 15 clicks on a computer to find what you are looking for. S6 & 7 agree with S5, saying that it is sometimes difficult to find information about the QMS in their current programs, it has to be made easy.

6. Analysis

This chapter presents the outcome of the thesis project as an analysis of the literature review, case specific research and interview study. The following sections will present analysis of the findings and have been divided into four different areas, Building the QMS, Gap Analysis Tool, Key Factors Surrounding QMS and lastly an extension of the previous theoretical framework to summarize the findings.

6.1 Building the QMS, challenges and what to include

What to include in the QMS can be a challenging task according to the interviews in this study. Basically, it all comes down to what the hospital, or the hospital department, is executing in their processes. As S4 describes it, the regulations is a network and you need to find the parts relevant for your operation. After that remains the challenge of interpreting the actual regulatory texts. In SOSFS 2021:19 it is written that the QMS should be: "adapted to the business orientation and scope". This leaves a lot to the organization to interpret regarding how their departments QMS should be constructed. Simultaneously S4 points out that these vague definitions also exist in the MDR. For example, article 5 in MDR, mentioning that manufacturing and use of medical devices should occur under "appropriate" quality management systems.

So, the first step in this process could be, as S4 mentions, to analyze "what am I" and "what are we doing". One way to execute this is to first analyze the relation to medical devices if the hospitals should be interpreted as a manufacturer, distributor or user of medical devices. This is also how PwC:s pre-study was structured. In many cases, hospitals will realize that they have obligations from all three roles. A special case in regard to this is "specially adapted devices", which are to some extent less affected by the regulations for manufacturing of medical devices. Shortly described, specially adapted devices are devices constructed for an intended use and are only allowed to be constructed if no other product on the market can fulfil the patient's need. One complicating aspect in the hospital structure is that the different departments often have variating quality management requirements depending on their operation.

The subjects S1, S3, and S4's hospitals are either certified or work towards ISO 9001 as their fundamental QMS. S1 believes this is a good start, but other things have to be added where it is needed. S4 believes that this is most challenging for hospitals since it is harder to define their exact role, compared to a medical device manufacturer. For these challenges the authors believe there is a need for new tools aiding QMS construction in healthcare and deciding what to include in the QMS.

In literature there exists an ambiguity regarding how standards enhance performance or not, moreover, how accreditations can affect the QMS success (Berssaneti et al., 2016; Sfreddo et al., 2018; Yıldız et al., 2019). Why standards work or not could probably be partly answered with S4:s reasoning. S4 believed that standards were a good tool only if the organization is mature enough to fully implement it, standards should not just be a checklist for accreditation. Similar aspects were mentioned by all subjects when addressing questions regarding how a successful QMS works. The main point is that the QMS must be embedded in the organization culture so that the organization follows the divided routines. Even though standards are not mandatory, all subjects' hospitals utilized standards in some way which makes us believe that standards are more or less common practice in Swedish hospitals. S1 described that ISO 13485 would never be appropriate for all hospital departments, especially not fully for the business-as-usual work where the hospitals treat patients. This creates a possible extension for the theoretical framework in this thesis, to determine how different standards should be utilized in which part of the organization.

The challenge with finding the relevant regulations to create an "appropriate" QMS mentioned by S4 and S5 is also something not fully addressed in our previous theoretical framework. From the literature search there seems to be no general helping tools for this process. One reason for this is probably the complexity, and that hospital departments, and medical technology departments can look very different, as S1 said. Therefore, studies like Germundsson and Kvist (2020) focusing on one specific manufacturer or organization might be necessary to construct compliant QMS for each hospital department. Our first thought, that came with the harmonization of ISO 13485 towards the QMS part of MDR, was that hospitals as a whole could work more towards ISO 13485 to achieve compliance. However, this seems to have been an optimistic simplification of how to achieve compliance with MDR in hospitals. Still, the ISO 13485 is appropriate for medical departments S1 says, S6 & 7 also mentions that their certification has led to more opportunities outside the hospital where they can get hired from external organizations to service their medical devices.

S6 & 7, S4, and S1 emphasize process management approaches when constructing QMS. How the processes are categorized is dependent on the departments and the hospital operation. S6 & 7 for example have divided the processes into some more comprehensive and some less comprehensive. Whereas S1 divided the processes into main and support processes. Xiong et al. (2017) emphasizes on process management and means that hospitals should focus on process innovation to enhance effectivity. S6 & 7 do this via their process objectives and indices. Subjects were asked whether they knew of or had used tools like the QMSI from Wagner et al. (2014), but no hospital in this study had a specific tool they were using. Depending on where you set the boundaries for what a QMS is, it can be a very comprehensive system. In healthcare, there are standards and regulatory requirements for many specific purposes and processes, S5 mentions that they work with standards for specific

products. This also emphasizes the importance to “identify what you are” like S4 describes it and analyze what to include in the QMS.

Based on this found complexity the authors decided to create a “help tool” for hospital QMS, which is described more in-depth in the next section. This since S1 believed that such a tool could be helpful to include non-quality knowledgeable executives. The tool is based on the mandatory regulation SOSFS 2011:19 and HSLF-FS 2021:52 together with ISO 13485. This visualization perhaps makes the initial gap analysis more visible and easier to comprehend. Moreover, this tool visualizes the similarities and gaps between the regulations and ISO 13485. The tool could be viewed as a first attempt to generalize how a hospital QMS could be built for compliance with MDR in a medical technology department. The authors do see that the management chapter 5 “Management responsibility” in ISO 13485 could be valuable for all hospital departments. This since leadership's impact on quality performance have been investigated in several studies which have shown to have positive impact on QMS performance (Xiong et al., 2017; Wardhani et al., 2009). Furthermore, the subjects emphasized top management involvement and engagement when talking about implementation practices.

6.2 Quality work should be made easy - the gap analysis tool

From the data gathered in the interview study, MDR introduction course and discussions with the case company PwC, one of the most important aspects found concerning quality work is that you have to make it easy. As shown in the results sections, Complexity, Implementation, Processes & Standards and Case Specific all present data concerning how different, complex and difficult quality work can be. Together with the findings in literature about previous QM research at hospitals it is clear that QMS:s are built differently and their value creating outcomes vary across organizations. S3, amongst others, mentioned that quality work should be made easy and that has been a frequently recurring topic during the data gathering of this project.

Another recurring topic of the interviews was the initial step towards quality work at hospitals. Many subjects agreed with the need to look where they currently stand and then apply a gap analysis to their current working ways in order to understand how to move forward in their quality work. With this in mind and with the initial intentions of the case company to create something concrete towards QMS work at hospitals, a gap analysis tool was created. The intention of this tool is to create something that makes the complex and comprehensive quality work more manageable for everyone without extensive knowledge in quality work. The tool is thought to be the first step of creating a MDR compliant QMS for medical device departments at Swedish hospitals. It is based on the regulations that were found the most relevant in this study, SOSFS 2011:9, HSLF-FS 2021:52 and the international standard ISO 13485:2016. With the former two being mandatory in Sweden, combining them with ISO 13485 is a thought through step of deliberately creating a tool that

encourages QMS implementation. This by already being able to check boxes in the gap analysis, intentionally making it easy to get started. During the research stage of this project, the authors found similarities in the above-mentioned Swedish regulations and the international standard. By combining these we follow up on the comments and thoughts of subjects, like S1 saying that it should be formulated in an easy and understandable way. Another goal is to make the user of the tool understand that some parts of the MDR harmonized ISO 13485 standard might already be implemented in their current quality work. An additional reason for the combining of clauses was due to another comment from S1 when discussing implementation, that you should try to combine process areas that are interrelated. The empirical investigation also found standards to be complicated. Sometimes hospitals need external personnel to understand what MDR or ISO 13485 mean in their clauses, this is another reason for the need of something easily accessible, clear and plain to begin the extensive work that surrounds QMS:s.

The gap analysis tool presented below, see table 2, is the result of the empirical and theoretical findings. Since the study has been conducted towards Swedish hospitals, with the intention of investigating quality work at Swedish hospitals, the full gap analysis tool was created in Swedish as it is intended towards medical device departments at Swedish hospitals, see appendix C for the full version. Presented below is the first section of the tool translated into English in order to grant the readers an understanding of how the gap analysis tool is built.

The idea of the tool in table 2 is to in a implicit way grant the user awareness of how their current quality work compares to a quality system based on SOSFS 2011:9, HSLF-FS 2021:52 and ISO 13485:2016, thus being compliant with the QMS requirements of the MDR. The listed criteria have been taken out from the different texts and sometimes they have also been rewritten and combined if there were similar criteria in two or more texts. Being a gap analysis tool, it is supposed to be used in the start of a QMS implementation process or improvement project at a medical device department of a Swedish hospital. It has been created for everyone to understand it, since some subjects mentioned that QMS work tends to be complicated and not understood by those without education in the area. The different columns in table 2 display the criteria number, criteria content, three boxes to check named M, P and F and lastly a comment section of how the criteria is achieved. In the three columns with letters, the M stands for “Missing”, P for “Present” and F for “Functioning”. The idea is showing a criterion from the regulations necessary of a MDR compliant QMS and then having personal checking one of the boxes, missing, present or functioning and lastly writing a comment of either why it is missing, how it is present or how it is functional. The lettered checkable boxes stem mostly from the finding of the interview study where subjects talked about the importance of simplifying quality work and looking at what processes are already in motion within the organization's quality work. The first two boxes are simply a yes or no option where the investigating party can achieve a quick overview of what criteria are present today and the third box

is intended towards the very important challenge with QMS:s, that they should be alive and always improving, based on the findings in section 7.1. Both the interview study findings of section 7.1 and previous literature findings in section 4.2 about measuring QMS development displays the complexity around QMS:s at hospitals. The quality work has to be both present and constantly worked with to be compliant with regulations and standards, a system in place that is only present will not help anyone, like the outcome from DUQuE project in 2014 that resulted in an index to measure the extent of QMS implementation at hospitals such a continuous improvement, the QMSI (Wagner et al., 2014).

Table 2: Translated first section of the Gap Analysis Tool

1. Responsibility for and utilization of a quality management system					
Nr	Criteria	M	P	F	How?
1.1	The organization shall create, organize and document a QMS and with it plan, lead, control, follow up, evaluate and improve the organization and its efficiency. The system shall be continuously developed and secure quality within the organization.				
1.2	The organization shall manage the quality management system processes in accordance with the requirements from SOSFS 2011:9, HSLF-FS 2021:52 and ISO 13485.				
1.3	The organization shall document its different roles, developer, authorized representative, importer or distributor, according to the texts above. It shall also determine, implement and sustain all demands given in those texts.				
1.4	The organization shall determine and provide the resources needed to implement the quality management system and to maintain its effectiveness, also meet applicable regulatory and customer requirements.				
1.5	The organization must adapt the management system to the focus and scope of its activities.				
1.6	The organization shall continuously determine if there is a risk for events that could occur and thus lead to shortcomings in the quality of the organization.				
1.7	If an investigation of activities in the organization shows that the processes and routines are not appropriate for ensuring the quality of the business, the processes and routines must be improved.				

Involvement in the quality work was another important issue found during the empirical investigation. S5 talked about the importance of having a QMS understanding in place to make it easier to involve new employees and S6 & 7 worked with "Quality Ambassadors" to involve more people in quality work. Our intention with the "How" column of the gap analysis tool is for QMS responsible personnel to, in their own words, document how the criteria/process is active and

working in the organization. Thus, making it easier for non-quality systems involved personnel to comprehend how the quality work is conducted. S1 mentioned that there are challenges with making the agreed routines available and visible and that most employees want to follow the routines and do things in the correct way but if it is not straightforward, people will find shortcuts. There is always going to be a need for quality education for all employees but this tool could minimize the distance between the knowledge of quality systems responsible personnel and regular employees. Furthermore, the tool will, as explained earlier, act as a guiding instrument towards the implementation of a MDR compliant QMS in a medical device department at Swedish hospitals.

As seen in appendix C, the gap assessment tool consists of twelve different chapters. All criteria stem from the two Swedish hospital regulations and the ISO 13485 standard but have, as explained in the method, been divided into categories and put in separate chapters in order to create a better overview of each area of interest within the QMS. One chapter that has been especially discussed during the interview study is the one about the criteria concerning top management. Both the empirical and theoretical investigation showed that the extensive management criteria in ISO 13485 are highly relevant for a medical device department at a Swedish hospital, even relevant for any other department as well in creating a suitable environment around the QMS by engaging either top management, the board of directors or the executive board in the quality work.

6.3 Key factors to constitute a successful QMS - creating excellence

The most important findings of the interview study were just how critical value creation, leadership and cultural aspects are when it comes to quality work at Swedish hospitals. A lot like the results from the literature review on organizational studies at hospitals, it became clear that a QMS:s at hospitals is worth close to nothing if there is not a welcoming and nurturing culture and leadership there to support it.

As presented in the theoretical framework, some factors could support or limit the QMS implementation process, two of which were organizational culture and leadership (Fonseca, 2015; Oliveira & Matsuda, 2016; Carman et al., 2010; Wagner et al., 2014). These two were also frequent topics during interviews with quality system experts at different hospitals in Sweden. Almost all subjects in this study talked about challenges with culture and QMS:s. Cultural differences can quickly halt quality work or make implementation even more difficult. All subjects except for S2 had experiences with how culture affected their quality work and the success of their QMS and the result of the empirical investigation clearly shows that cultural aspects have to be a large part of hospitals future quality work systems. Just how much emphasis should be put on culture has not been investigated in this study but some subjects believe that the more people that are invested in their hospitals' quality work, the better the outcome will be. Culture has thus become one of this

study's main factors that constitute a successful QMS at Swedish hospitals. Creating a comprehensive QMS for everyone to follow is clearly not enough. Even though a gap analysis tool will aid the process of implementing an extensive and MDR compliant QMS, good culture, among other aspects, is needed to transform the QMS into something adopted and cherished by everyone in the organization.

There are many ways of creating a nurturing culture surrounding quality systems and systems aimed at following the MDR at medical device departments are, as seen in the interview study, no different. Subjects talked about including culture in different ways, the most interesting discussion in regard to the research question around this topic were with subject 1 and subjects 6 & 7. These were the ones who presented concrete examples of how they had worked with cultural aspects to increase the success of their QMS. These subjects were also from hospitals with ISO 13485 certification in their medical device department. Other subjects also emphasized the value of cultural aspects in hospital quality work. Which is why culture has become such an important factor in this thesis work. The examples given by, for example, S6 & 7 highlight the importance of creating an involving and exciting culture around the QMS work. S6 & 7 had tried to stimulate the involvement by including newsletters, quizzes and mentimeter in their spreading of the quality work at their medical device department. These simple things are interesting examples of how to create a quality-oriented culture. This kind of involvement is probably one of the most important aspects for evolving the QMS work to an excellent level. The literature review showed that employee satisfaction is very important for hospital overall performance and that education, training and teamwork are important when looking at quality work at hospitals (Alzoubi et al., 2019). S1 really put emphasis on the need for everyone to share the same view and culture surrounding their QMS and have had experience with situations where management has found that one person who is really interested in quality work and allowed her/him to spread a positive QMS culture. A good way to create an accepting culture towards quality work could thus be to focus on teamwork and allowing those who are more interested in QM to be ambassadors and work more with it rather than just assigning tasks and positions.

Another valuable insight from S1 was that quality work does not function properly when either board members, managers or staff members do not embrace the management system and do things in their own way instead. This corresponds to Pfaff et al. (2021) research on how hospital management boards can affect the implementation rate with greater goal attainment and social integration. Furthermore, doing things in their own way delivers a feeling of neglect of the QMS and this brings us into the importance of top management and leadership when it comes to hospital QMS in Sweden, much like Xiong et al. mentioned (2017). Subjects were asked about experiences with leadership and quality work and results show that leadership can have an impact on how well a QMS is implemented or how well the QMS works after implementation. Almost all subjects talked

about how leadership can affect the management system in one way or another and the relationship between employees and top management becomes an essential part of a functional QMS. S4 said that since the QMS comes from the top and then is executed within the organization, a highly contributing factor towards a successful QMS is having a top management team that understands why quality work is important and why they should try and involve everyone in it. This corresponds with what Botje et al. (2014) found in their study on European hospitals and executives' board role in creating a functional QMS. Leadership can also be a determining factor when it comes to allowing and advocating for a positive organizational culture towards QMS. Top management have to, according to S5, understand why and what parts are important for value creating purposes. S3, S6 & 7, S1 and S4 all value the need for top management to not only create a QMS but also follow it down in the hierarchy of the organization to ensure it is not forgotten. One factor in regard to leadership mentioned by Wardhani et al. (2009) was Physician involvement. This aspect was also included in our theoretical framework. However, physician involvement was not a recurring aspect during the interviews therefore has physician involvement impact on QMS implementation not been included in the final model. Nonetheless, this does not imply that their possible impact is invaluable in the implementation, just that our study did not find any proper relation. Hospital structure can impact quality work and literature showed that flat hospital organizations and private hospitals performed better in their quality work than large public hospitals (Zarei et al., 2019), but subjects 1 & 5 had different experiences with leadership and hospital structures impact on QM. S1 believes it is easier to forward information and involve everyone in smaller organizations but S5 says that the larger resources of a bigger organization can aid quality work and this proves even more just how complex the quality work situation is when it comes to hospitals. S5 was in line with the literature from Bujok et al. (2016) where smaller organizations with limited resources are facing more challenges. With that said, no clear results were found regarding how organization design affects the QMS implementation, since the opinion varied between the subjects. Therefore, organization design has been left outside the final framework presented in the next section.

Another important factor disclosed during the interview study was the understanding of the QMS:s value creation. Literature did talk about many factors, including the six factors by Wardhani et al. (2009) but the importance of value creation understanding was not in focus. Another finding from Alzoubi et al. (2019) was the importance of education and training. According to all subjects, it is important for employees to understand why the QMS is important for them and to share a common ground, often gained by education and training. This further builds on the cultural aspects mentioned above about creating an acceptance towards QMS and getting everyone involved in it to really understand the value of quality work. S4, 5, 6 & 7 all talked about why QMS are important and why the knowledge of its value creation needs to be spread within the organization. S4 said that sometimes quality work is seen as a burden or a cost and thus puts emphasis on the importance of getting everyone to understand what the benefits are with quality work, even when the results might

not reveal themself until further in the future. Sharing a vision of why the QMS is important and engaging everyone was by most subjects believed to be an essential part and this could also be seen in the literature findings from Leggat and Balding (2018) and Pannick et al. (2016).

6.4 Extended framework for QMS implementation

The empirical and theoretical investigation generated valuable insights in how quality work is conducted and perceived at hospitals. With the purpose of investigating how to create a well-functioning QMS for a hospital in Sweden, by answering the questions of what the most important aspects of QM work is and in what ways a MDR compliant QMS can be built. All of the findings and outcomes of this thesis can be summed up in figure 3 below. It describes the most relevant aspects of a QMS and the work surrounding QMS at Swedish hospitals.

The initial theoretical framework presented in figure 1 consisted of six organizational factors affecting QMS implementation. The factor not commented on above is the technical support factor. Technical support seems to be important for quality measures. For example, S6 & 7 utilized support systems for measuring their KPI related to the quality system and S2 kept track of education via their employee platform. However, for the implementation purpose there was limited support found for the technical support aspect. S3 thought that their technical systems for process management were dysfunctional but better systems could make it easier to locate and follow work instructions. Nonetheless, the impact on implementation was not further analyzed in this study and was therefore left outside the updated framework. As described earlier in this section was not all found as important in this study as it appeared in literature. The research conducted in this thesis mainly highlighted some of these aspects which are seen in figure 3. Besides the implementation factors the study found significant support from the interview subjects for the differentiation between a complaint and excellent working QMS.

The regulations and standards can create a QMS template or in our case a QMS gap analysis tool, which then acts as a MDR compliant QMS. But in order to advance towards a fully functional and excellent QMS, aspects such as culture, leadership and simplicity & value are of utmost importance.

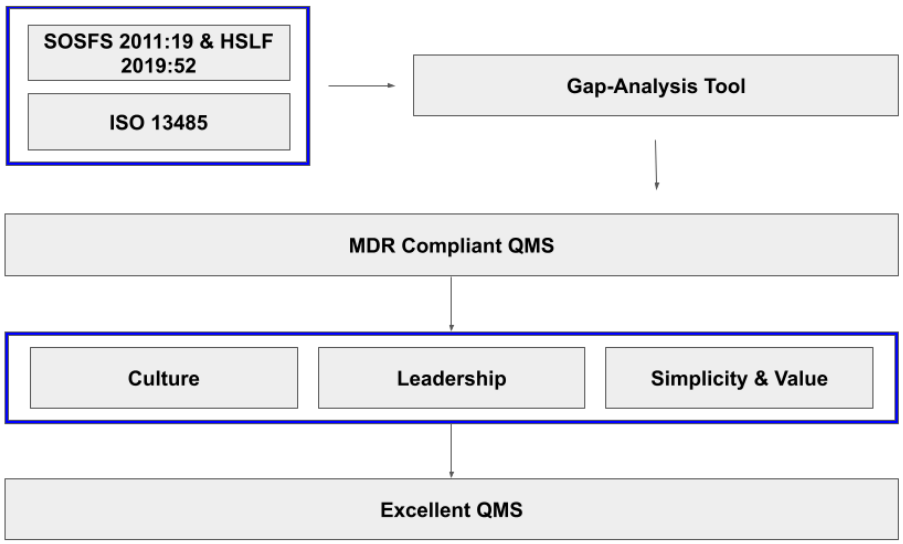

Figure 3: Building and Implementing a QMS in Swedish hospitals

As seen in figure 3, culture, leadership, simplicity & value and the importance of a gap analysis are the foundation of this paper's result. A QMS is a complex system and even relying on only these aspects might not be enough but for the purpose of this thesis project, these are the most important aspects for achieving excellence in the QMS at a Swedish hospital.

7. Discussion

This chapter presents a discussion of the results and analysis section. Sustainability aspects, limitations and suggestions of future research are also discussed.

When the project was initiated, the initial hypothesis was that the ISO 13485 could be valuable to more than an organization or hospital department working solely on manufacturing or with service of medical devices. The hypothesis was that the user of medical devices could also work towards ISO 13485 to comply with regulations. However, this showed to be a significant simplification of reality. Moreover, when constructing an appropriate QMS it is important to consider where the QMS boundaries are set. If the QMS is interpreted as all processes and procedures, or just the main backbone of documentation steering how the operation should be executed in general terms. The former interpretation expands the complexity of QMS since there are a lot of specific standards and regulations that could be used for specific healthcare processes and procedures. This master thesis has not addressed QMS in that level of detail.

Nonetheless, as shown in the literature review, there are going to be many different deciding factors to whether a QMS at a hospital works or not. This study has looked into some of these and found those most important for Swedish hospitals when addressing MDR implementation and general QMS work. Had different aspects of quality work at hospitals been investigated, the results could have looked different with either more or less important aspects shown. It is important to understand that quality work at hospitals is a very complex and also interesting topic. Results have shown that unlike what this study anticipated, it is difficult to create a "one size fits all" QMS for Swedish hospitals. Of course, there is always going to be common denominators among different hospital organizations and their departments, building the QMS around the need for ensuring patient security being the most prominent one. However, even medical device departments at large hospitals in Sweden can look different from one another and their different organizational structure makes the creation of a general and duplicable QMS an unrealistic goal for now. One of this study's subjects was in the midst of working with a regional network in order to create a regional management system based on MDR and said that this was no easy task. Thus, even contemplating creating a national management system compliant to the MDR right now felt, during the course of the interviews, like an improbable goal. Just looking at what standards could be applicable to one's organization is a challenging task and to then say that one standard should suit everyone unfortunately seems like wishful thinking.

The gap analysis tool is a development by the researchers of this study based on the results of the empirical investigation, thus not evaluated in the empirical investigation. Furthermore, the tool is merely a suggestion by the researchers of how the first step of a QMS implementation could be simplified to incorporate the MDR into a medical device department's QMS. There is a need for

further research on whether the proposed tool could be useful for actual workers within healthcare that are struggling with their current quality work. The tool in appendix C can be considered a prototype or a draft in the process of creating something truly useful for hospital organizations. It is believed to answer the wishes from experts in hospital QMS work by delivering something concrete, easy and combined. Yet since it is not an official document it cannot simply be checked off and then assumed to be equivalent to a certification of ISO 13485. There could potentially be many more standards or regulations to keep in mind when creating a QMS for hospitals. Since the QMS is a living system, in need of constant evaluation, the gap analysis has to be used with caution as a means of understanding what parts are in motion today and what parts need to be accounted for before even starting a ISO 13485 certification process. We do believe that the tool can be useful for understanding where the hospital organization or department stands today concerning MDR QMS compliance but the intention is not to merely look at the list, check some boxes and then continue with the ordinary day to day organizational work.

7.1 Limitations

There have been some limiting factors to the outcome of this thesis project. Firstly, since the area under investigation in this report are Swedish healthcare organizations and there was an ongoing Covid-19 pandemic during the course of this research project, it has been a bit harder than anticipated to get in contact with relevant personnel to interview at hospitals. Sweden had an infection peak during the initial two of this five-month project and this had a clear effect on the responses to emails about conducting interviews. Many subjects answered by saying that they would like to help out but they could not schedule an interview nor they thought they would have time for it before the end of the thesis. Even more responses were left out and never got back to us. More responses and more interviews would probably have given this study more valuable information to answer the research questions with and we do now believe that it would have been good to interview more “normal” people within hospital organizations and not just the ones responsible for their QMS. Would it have been a larger project, the effort put towards contacting subjects to interview would have been far greater. Once a perceived satisfactory number of initial interviews had been planned, we did not try to contact new people to schedule more initial interviews, both due to the reasons mentioned above but also due to the aim of the authors of conducting a thesis project within a certain timeframe.

Secondly, as briefly mentioned earlier, we had time enough to build a tool after conducting the initial interviews of this study but there was not enough time to schedule a second round of interviews. Where we could have evaluated our findings, the resulting gap analysis tool and the most important found aspects of QMS work at Swedish hospitals. Some interviewees could only schedule interviews 3-4 weeks ahead of time and the time period between the tool creation and deadline was too short for that. A second round of interview would have been very interesting to conduct since it would

have given us insight from employees that have to work with hospital QMS:s and thus being able to evaluate whether the tool is useful or not. Without proper education in the area of investigation, it is tough for us to properly evaluate the tool impartially, we can only address the content and intention of the gap analysis tool based on our results, not experiences in the field. Furthermore, the gap analysis tool is merely a construct of combined regulations and standards and built-in line with the purpose of this thesis project. Would it have been a larger research project with a bigger timeframe, more emphasis would have been put on evaluation of the tool, and if not by interviews but at least to literature.

Lastly, with the initial aim of investigating if it was possible to construct a MDR compliant QMS for every hospital in Sweden to be able to use, it had proved to be far too complex. The research area turned out to be more comprehensive than anticipated once the interviews were conducted and it became clear QMS at hospitals is no easy task. With this knowledge now, we do believe that the research questions and areas could have been altered towards something even more specific. The scope of the project had to be narrowed down as research was gathered and the intent of looking at the bigger picture became too complex and difficult; it would have been beneficial to limit the research area earlier. It is also important to understand that the authors of this study had no previous knowledge in QMS, MDR or hospital organizations. Thus, a lot of research has been conducted into exploring and understanding the fundamentals of these areas. Research time that could have been redirected towards the purpose of the thesis if prior knowledge would have been greater.

7.2 Future Research

This broadly executed study has resulted in some further research thoughts on QMS structure and implementation in Swedish hospitals. As previously mentioned, for future research it is possible to test and let experts analyze the value of a gap analysis tool for Swedish hospitals QMS. Given the challenges of constructing an "appropriate" QMS found in this study it could be interesting to test whether similar tools would be helpful in addition to guiding documents (MDCG) that are usually released together with new regulations. Another interesting topic that we came across during the interviews was "flow based" quality assurance. This has been tried for some processes at the hospitals and seemed interesting to investigate further. The main idea is that you follow the movement of patients with a specific disease between the different hospital departments and then work toward securing quality for that flow. This came up to us at a later stage in the project and was therefore not researched, thereby we leave that topic as a possible future research area. Also, the largest challenge for achieving an excellent quality is embedded in the organization culture as our results indicate. The distribution of routines and procedures and making employees follow these are the main ongoing challenges. One of the hospitals mentioned that they have been trying to use newsletters, quizzes and mentimeter questions to make the quality work a more social thing to involve more employees. Based on this the authors thought that it could be interesting in future studies to investigate if

strategies from gamification theories could be utilized to enhance the culture towards quality work at Swedish hospitals. Further research into creating a general QMS based on the MDR for Swedish hospitals is also an interesting topic and it will be curious to see if S5 and that working team can create something that can be used by everyone.

7.3 Sustainability aspects

The QMS may be seen as the backbone to enable appropriate quality in healthcare. Remaining up to date on new regulations, implementing those efficiently in the organization can be a large challenge as we have seen in this project. However, it is important to remember the purpose of these comprehensive regulations is that they are supposed to improve the quality and ensure that safe and reliable practices are utilized in healthcare. A dysfunctional QMS in healthcare increases the risk of harm for patients and thereby limits citizens' right to health and safety. This thesis has aimed to improve the implementation of quality practices and simplify QMS compliance to regulations. Because of that the authors mostly see positive possibilities with this thesis from a sustainability and ethical point of view. Still, there are some risks that will be discussed regarding how the results of this report should be used and interpreted. The consequences of the potential risks in this project are mostly decreased QMS performance which is a severe consequence for patient safety.

Firstly, as previously mentioned, the gap analysis tool should not be seen as a one time checklist for managers. It is important to understand that quality work is ongoing and continuous improvements are the cornerstone in QMS performance. If this is not understood could the gap analysis tool actually impair the QMS performance significantly. Secondly, it is important to notice the limitations of the tool. The tool should be used for a medical device department, even though some parts of the tool have been discussed to possibly be advantageous for other departments. Lastly, a user of the tool should not ignore the full regulatory and standard text. One reason for this is that these change over time. Moreover, is it important to note that ISO 13485 is a standard and thereby not mandatory. One could, of course, build an appropriate and compliant QMS without using standards. Still, the authors believe that one strength with the tool is that it is based on an ISO standard, since this should imply that appropriate practices are included.

Besides the risks discussed above the authors believe that the result of this report stimulates social sustainability. This by contributing to enhancing quality in the healthcare sector and thereby stimulating the development towards safe and reliable patient care. The results could also contribute to equality in healthcare since tools similar to the one developed in this thesis could lead to a more even quality in healthcare on a national level. Another important social sustainability aspect of creating a tool that more than one organization can utilize is the benefit of minimizing resource requirements for new implementation processes and thus being able to maintain more resources towards patient care.

8. Conclusion

To answer the question of how a MDR compliant QMS should be constructed the simple answer is that it depends. It depends on the healthcare provider's specific relation to medical devices, how they are used, if they are developed, and distributed. The categorisation is one of the main challenges since this determines what your "appropriate" QMS should include. For manufacturers of medical devices, the answer could be as simple as to begin work towards ISO 13485 and analyze which part of ISO 13485 to exclude and include. For hospitals this could also be the case for some specific medical device departments. However, when it comes to QMS:s at hospitals there is no one size fits all. ISO 13485 does not work as the simple answer for the rest of the hospital to achieve MDR compliance. Moreover, would it not be reasonable for other than MedTech departments to work towards ISO 13485 certification. For the business-as-usual work at hospitals where patients are treated one need to look more at the specific processes and how medical devices are used in these processes. SOSFS 2011:19 and HSLF-FS 2021:52 sets the fundament for the QMS and how to deal with medical devices. The rest is up to the process responsible and hospital personnel to analyze the requirements for the used medical devices.

From the empirics it was clear that the first step when setting up the QMS is to execute a gap analysis of the current state. Because of the harmonization of the ISO 13485 towards the QMS parts of the MDR, the authors decided to develop a tool for the gap analyses based upon SOSFS 2011:19, HSLF-FS 2021:52 and ISO 13485:2016. Hopefully, this tool can be helpful in the QMS building process. Even though ISO 13485 might be mostly useful for a MedTech department, the authors believe that this tool could be useful in the remaining hospital departments using medical devices. As elaborated in the analysis, part two of the tool could be valuable for any QMS since these criteria address important aspects for successful implementation. Moreover, the tool could work as a first insight into how QMS for medical devices work, which could be valuable for responsible people with limited experience within the field.

When investigating the most important aspects that constitute an excellent QMS at a Swedish hospital, this study's literature and empirical research has shown that simplicity, culture and leadership are the most prominent ones. As previously mentioned, quality work at hospitals is complex. Thus, there is a clear need for making the surrounding work into something simplistic that is easy for everyone to follow. A high personal involvement rate has been shown to be a particularly important factor for achieving excellence in the QMS. It also has to be easy for everyone to get involved. Another constituting aspect to this is the organizational culture around quality work. The QMS is according to experts in the area worth close to nothing if there is not an accepting culture among employees that encourages the implementation and use of a QMS. How this culture is created can vary but without it the quality work risks turning into something only written on a piece of paper. One way of nurturing culture is with value creation. Knowledge sharing and understanding

the value creation aspect of a quality work has shown to be an especially important way of creating employee recognition of the QMS. Without knowledge of why those extra steps in a normal work routine are necessary, shortcuts are going to be taken and the QMS will eventually stop working. To push towards the culture needed for excellence in the QMS and to increase awareness of its value creation, leadership or top management commitment to the QMS becomes an essential aspect. The literature and the empirical investigation showed that leadership, in combination with culture, value creation and the need for simplicity is the way forward in QMS implementation and work.

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Appendix

Appendix A: Literature search strategy and keywords

The following databases were searched in the Pre-study:

- Google
- Web of Science

The keywords used were:

- MDR
- Medical Device Regulation
- Hospital quality management
- QMS at hospitals
- Quality management systems and MDR
- QMS hospital MDR
- QMS hospital implementation
- MDR implementation

The following databases were searched in the literature research:

- Web of Science

The keywords used were:

- QMS
- Implementation
- MDR
- Hospital
- Healthcare
- Quality management
- Quality management system
- Medical Device Regulation
- Process management
- organizational culture
- organizational structure
- leadership
- Regulatory frameworks for medical devices

Appendix B: Interview template

Name:
Date:

"We would like to record the conversation in order to transcribe the necessary material after the interview and would therefore need to ask you if you are okay with this? the recorded file will be deleted as soon as the interview has been transcribed"

Character Questions:

Tell us a little bit about yourself, previous education, work and current work?
Answer:

What is your relation to quality management systems today?
Answer:

QMS:

Do you follow or try to follow any specific standards today? (such as ISO 9001 etc.)
Answer:

What are the biggest challenges with QMS:s
Answer:

What do you believe is the most prominent reason for someone to put effort into their QMS?
Answer:

How does/did it go by when you determine what the QMS is going to look like?
Answer:

To what extent are you affected by regulations?
Answer:

Within healthcare there are often changes to regulations, how often do you have to make changes to the QMS in order to fulfill new or changed regulations?
Answer:

What does one of those changes/implementations look like?
Answer:

Do you see it as a challenging task to maintain and control the QMS towards new regulations?
Answer:

How do you sort out the most important parts of standards to achieve the best possible solution to your organization?
Answer:

Implementation of QMS

What challenges and/or opportunities are there when you start working towards creating a QMS for an organization?
Answer:

What is your view on QMS and performance, when does it work or not work?
Answer:

When we have read about QMS at hospitals we often encounter articles depicting QMS:s getting stuck at top management levels, have you ever encountered anything like this?

- **How have you avoided it?**

Answer:

We try to research the differences between compliance and excellence when it comes to QMS work. What are your experiences here and do you believe the division between them is feasible?
Answer:

How do you believe one can achieve excellence in an organization?

- **What are the most important factors?**
- **Have you or do you know how one can measure if excellence is achieved?**

Answer:

Is there anything that you would like to add regarding our conversation today and its topics that you believe might be relevant to our study?
Answer:

Appendix C: Gap Analysis Tool

1: Ansvar för och användning av ett kvalitetsledningssystem					
Nr	Kriterium	S	N	F	Hur?
1.1	Vårdgivaren ska skapa, organisera och dokumentera ett kvalitetsledningssystem. Med detta ska vårdgivaren planera, leda, kontrollera, följa upp, utvärdera och förbättra verksamheten och dess effektivitet. Systemet ska kontinuerligt utveckla och säkra verksamhetens kvalitet.				
1.2	Vårdgivaren ska dokumentera de roller som vårdgivaren har utifrån gällande regelverk, tex som tillverkare, auktoriserad representant, importör eller distributör. Vårdgivaren ska fastställa, implementera och underhålla alla krav som finns under denna standard.				
1.3	Vårdgivaren ska bestämma och tillhandahålla resurser som behövs för att implementera kvalitetsledningssystemet, bevara dess effektivitet samt för att möta tillämpliga regulativa och kundkrav.				
1.4	Vårdgivaren ska anpassa ledningssystemet till verksamhetens inriktning och omfattning.				
1.5	Vårdgivaren ska fortlöpande bedöma om det finns risk för att händelser skulle kunna inträffa som kan medföra brister i verksamhetens kvalitet.				
1.6	Om utredning av aktiviteter i verksamheten visar att processerna och rutinerna inte är ändamålsenliga för att säkra verksamhetens kvalitet, ska processerna och rutinerna förbättras.				

2: Ledning					
Nr	Kriterium	S	N	F	Hur?
2.1	Ledningen ska kunna påvisa bevis för åtaganden gällande utveckling och implementering av kvalitetsledningssystemet samt upprätthållande av dess effektivitet genom att kommunicera till organisationen vikten av att möta kundkrav och relevanta regulationer				
2.2	Ledningen ska kunna påvisa bevis för åtaganden gällande utveckling och implementering av kvalitetsledningssystemet samt upprätthållande av dess effektivitet genom att etablera kvalitetspolicyn				
2.3	Ledningen ska kunna påvisa bevis för åtaganden gällande utveckling och implementering av kvalitetsledningssystemet samt upprätthållande av dess effektivitet genom att försäkra att kvalitetsmål är etablerade				
2.4	Ledningen ska kunna påvisa bevis för åtaganden gällande utveckling och implementering av kvalitetsledningssystemet samt upprätthållande av dess effektivitet genom att genomföra lednings utvärdering.				
2.5	Ledningen ska kunna påvisa bevis för åtaganden gällande utveckling och implementering av kvalitetsledningssystemet samt upprätthållande av dess effektivitet genom att försäkra tillgänglighet av resurser.				
2.6	Ledningen ska säkerställa att kundkrav och tillämpliga regulativa krav är bestämda samt uppfyllda.				
2.7	Ledningen över kvalitetspolicy ska säkerställa att kvalitetspolicyn är tillämplig för syftet hos organisationen				
2.8	Ledning över kvalitetspolicy ska säkerställa att kvalitetspolicyn inkluderar ett engagemang				

	att följa krav och för att bevara effektiviteten hos kvalitetsledningssystem				
2.9	Ledning över kvalitetspolicy ska säkerställa att kvalitetspolicyn tillhandahåller ett ramverk för att sätta och utvärdera kvalitetsmål				
2.10	Ledning över kvalitetspolicy ska säkerställa att kvalitetspolicyn är kommunicerad och förstådd inom organisationen				
2.11	Ledning över kvalitetspolicy ska säkerställa att kvalitetspolicyn är granskad för fortsatt lämplighet.				
2.12	Ledningen ska säkerställa att kvalitetsmål, inkluderande de mål som krävs av relevanta regulationer samt krav på produkter, är etablerade på relevanta nivåer/avdelningar i organisationen. Kvalitetsmålen ska vara mätbara och i enlighet med kvalitetspolicyn.				
2.13	Ledningsgruppen ska säkerställa att: Planeringen av kvalitetsledningssystemet är utförd sådant att det möter kraven samt kvalitetsmålen.				
2.14	Planering av kvalitetsledningssystem Ledningsgruppen ska säkerställa att: kvalitetsledningssystemets integritet upprätthålls under förändringar av kvalitetsledningssystemet är planerade och implementerade.				
2.15	Ledningen ska säkerställa att ansvar och auktoritet är definierade, dokumenterade och kommunicerade inom organisationen.				
2.16	Ledningen ska dokumentera inbördes förhållanden mellan all personal som hanterar, utför och verifierar arbete som påverkar kvalitet och ska säkerställa självständigheten och auktoriteten som behövs för att utföra dessa uppgifter.				
2.17	Ledningsgruppen ska utse medlem/ledningsrepresentant i ledningen som, oberoende av annat ansvars, har ansvar och befogenhet som inkluderar: Försäkra att processer nödvändiga för kvalitetsledningssystemet är dokumenterade				
2.18	Ledningsgruppen ska utse medlem/ledningsrepresentant i ledningen som, oberoende av annat ansvars, har ansvar och befogenhet som inkluderar: rapportering till ledningsgruppen gällande effektiviteten av kvalitetsledningssystemet och behov av förbättring.				
2.19	Ledningsgruppen ska utse medlem/ledningsrepresentant i ledningen som, oberoende av annat ansvars, har ansvar och befogenhet som inkluderar: Försäkra främjande av medvetenhet gällande relevanta regulations krav och kvalitetsledningssystemets krav genomgående i organisationen.				
2.20	Ledningen ska säkerställa att lämpliga kommunikationsprocesser är etablerade inom organisationen och att kommunikation angående effektiviteten hos kvalitetsledningssystemet äger rum.				

3: Processer och Rutiner					
Nr	Kriterium	S	N	F	Hur?
3.1	Vårdgivaren ska kunna ange hur uppgifterna som ingår i arbetet med systematisk och fortlöpande förbättring av kvalitetsledningssystemet är fördelade i verksamheten.				
3.2	Vårdgivaren ska ha en metod för att identifiera, beskriva och fastställa processer som behövs för att säkerställa verksamhetens kvalitet och för varje process identifiera de ingående aktiviteterna samt bestämt dess ordning.				

3.3	Vårdgivaren ska bestämma de processer som behövs för kvalitetsledningssystemet och genomförande av dessa processer genom organisationen med organisationen olika roller i åtanke. Samt bestämma sekvensen och samspelet mellan dessa processer.				
3.4	Vårdgivaren ska använda ett riskbaserat tillvägagångssätt för kontroll av lämpliga processer som behövs i kvalitetsledningssystemet.				
3.5	Vårdgivaren ska fastställa och vidare utarbeta rutiner för att säkra verksamhetens kvalitet. Rutinerna ska beskriva hur en aktivitet ska utföras samt vart i verksamheten ansvaret för utförande är fördelat. Detta gäller för varje aktivitet och för medicintekniska produkter i verksamheten.				
3.6	För medicintekniska produkter gäller följande: Vårdgivaren ska se till att: organisering som möjliggör säker användning och hantering av medicintekniska produkter och att endast säkra produkter och anslutna informationssystem används, förskrivs och lämnas ut till patienter.				
3.7	För medicintekniska produkter gäller följande: Vårdgivaren ska se till att: Produkter och anslutna informationssystem ska vara korrek kontrollerade och installerade och information kring dem finns tillgänglig för berörd personal. Rutiner inom ramen för ledningssystemet ska finnas tillgängliga för berörd personal och produkter som är förskrivna, utlämnade eller tillförda patienter kan spåras				
3.8	Vårdgivaren ska för varje process i kvalitetsledningssystemet ska organisationen: Bestämma kriterier och metoder för att försäkra att användning och kontroll av dessa processer är effektiva.				
3.9	Vårdgivaren ska för varje process i kvalitetsledningssystemet ska organisationen försäkra att tillräckligt med information och resurser finns tillgängliga för att övervaka dessa processer				
3.10	Vårdgivaren ska för varje process i kvalitetsledningssystemet ska organisationen implementera nödvändiga aktiviteter för att nå de planerade resultaten och upprätthålla effektivitet i processerna				
3.11	Vårdgivaren ska för varje process i kvalitetsledningssystemet ska organisationen övervaka, mäta, och analysera dessa processer.				
3.12	Vårdgivaren ska för varje process i kvalitetsledningssystemet ska organisationen skapa och upprätthålla dokumentering för att påvisa efterlevnad av denna standard (ISO 13485) samt andra regulativa krav.				
3.13	Vid förändringar av kvalitetsledningssystemet ska dessa: Utvärderas map dess påverkan på kvalitetsledningssystemet				
3.14	Vid förändringar av kvalitetsledningssystemet ska dessa: Utvärderas map dess påverkan på medicintekniska produkter producerade under detta kvalitetsledningssystem				
3.15	Vid förändringar av kvalitetsledningssystemet ska dessa: Kontrolleras med avseende på kraven i detta verktyg.				
3.16	Om tillämpligt, ska vårdgivaren planera och dokumentera åtgärder för kontroll av kontaminerade eller potentiellt kontaminerade produkter i avsikt att hindra kontaminering av arbetsplatsen, personal och produkter.				
3.17	Gällande sterila medicinska apparater så ska vårdgivaren dokumentera kraven för kontroll av kontamination med mikroorganismer eller partiklar och upprätthålla renlighetskraven under monterings- eller packeteringsprocesser.				
3.18	Vårdgivaren ska säkerställa att verksamhetens personal arbetar utifrån ledningssystemet och hälso- och sjukvårdspersonalen är skyldiga att bidra till att hög patientsäkerhet upprätthålls.				

3.19	Den personal som använder och hanterar medicintekniska produkter och till dessa, anslutna informationssystem ska ha kunskap om produkternas funktion och hantering av dem, riskerna vid användning av produkterna och om vilka åtgärder som krävs för att begränsa vårdskadors omfattning vid negativ händelse.				
3.20	Personalen ska även kontrollera medicintekniska produkter innan de används på patienter utifrån tillverkarens instruktioner, om sådana finns.				

4: Patienter					
Nr	Kriterium	S	N	F	Hur?
4.1	Varje vårdgivare ska fastställa rutiner för förskrivning, utlämnande och tillförande av en medicinteknisk produkt till en patient. Vårdgivaren ska genom rutinerna säkerställa att: Patientens behov identifieras och att produkten motsvarar hans eller hennes behov.				
4.2	Varje vårdgivare ska fastställa rutiner för förskrivning, utlämnande och tillförande av en medicinteknisk produkt till en patient. Vårdgivaren ska genom rutinerna säkerställa att: produkten provas ut och anpassas till patienten,				
4.3	Varje vårdgivare ska fastställa rutiner för förskrivning, utlämnande och tillförande av en medicinteknisk produkt till en patient. Vårdgivaren ska genom rutinerna säkerställa att: produkten samordnas med produkter som tidigare har förskrivits, lämnats ut eller tillförts till patienten,				
4.4	Varje vårdgivare ska fastställa rutiner för förskrivning, utlämnande och tillförande av en medicinteknisk produkt till en patient. Vårdgivaren ska genom rutinerna säkerställa att: en bedömning görs av behovet av anpassning av patientens hemmiljö för att produkterna ska kunna fungera tillsammans på ett säkert sätt,				
4.5	Varje vårdgivare ska fastställa rutiner för förskrivning, utlämnande och tillförande av en medicinteknisk produkt till en patient. Vårdgivaren ska genom rutinerna säkerställa att: säkerhetsåtgärder vidtas för anpassning av patientens hemmiljö, om det behövs,				
4.6	Varje vårdgivare ska fastställa rutiner för förskrivning, utlämnande och tillförande av en medicinteknisk produkt till en patient. Vårdgivaren ska genom rutinerna säkerställa att: information ges till användaren om hur produkten ska användas och vilka åtgärder som ska vidtas i enlighet med tillverkarens säkerhetsföreskrifter,				
4.7	Varje vårdgivare ska fastställa rutiner för förskrivning, utlämnande och tillförande av en medicinteknisk produkt till en patient. Vårdgivaren ska genom rutinerna säkerställa att: användaren instrueras och tränas i att använda produkten.				
4.8	Varje vårdgivare ska fastställa rutiner för förskrivning, utlämnande och tillförande av en medicinteknisk produkt till en patient. Vårdgivaren ska genom rutinerna säkerställa att: produkten registreras i vårdgivarens system för underhåll.				
4.9	Varje vårdgivare ska fastställa rutiner för förskrivning, utlämnande och tillförande av en medicinteknisk produkt till en patient. Vårdgivaren ska genom rutinerna säkerställa att: förskrivningen, utlämnandet eller tillförandet till patienten följs upp och utvärderas fram till dess att behovet upphört eller ansvaret för patienten har övertagits av en annan vårdgivare.				
4.10	Vårdgivaren ska lämna information enligt artikel 18 i förordning (EU) 2017/745 till patienter med implantat. Informationen ska lämnas på ett sätt som gör den snabbt tillgänglig för de patienter i vilka en produkt har implanterats, tillsammans med ett implantatkort som ska omfatta uppgifter om identitet.				

5: Hantering av dokument					
Nr	Kriterium	S	N	F	Hur?
5.1	Vårdgivaren ska kontrollera dokument nödvändiga för kvalitetsledningssystemet. Register är en speciell typ av dokument och ska kontrolleras enligt kraven nedan.				
5.2	En dokumenterad procedur ska definiera de kontroller som behövs för att granska och godkänna ett dokuments riktighet före utfärdande.				
5.3	En dokumenterad procedur ska definiera de kontroller som behövs för att granska, uppdatera vid behov, samt godkänna dokument på nytt.				
5.4	En dokumenterad procedur ska definiera de kontroller som behövs för att säkerställa att senaste granskningarna av och förändringar i dokument är identifierande.				
5.5	En dokumenterad procedur ska definiera de kontroller som behövs för att säkerställa att relevanta versioner av nödvändiga dokument finns tillgängliga vid användning.				
5.6	En dokumenterad procedur ska definiera de kontroller som behövs för att säkerställa att dokumenten är läsbara och lätta att identifiera.				
5.7	En dokumenterad procedur ska definiera de kontroller som behövs för att säkerställa att dokument av extern bakgrund, som av vårdgivaren beslutats vara nödvändiga för planering och drift av kvalitetsledningssystemet, är identifierade samt dess distribution kontrollerad.				
5.8	En dokumenterad procedur ska definiera de kontroller som behövs för att förhindra försämring eller borttappande av dokument.				
5.9	En dokumenterad procedur ska definiera de kontroller som behövs för att förhindra oavsiktlig användning av uråldriga dokument, samt tillämpa lämplig identifiering av dem.				
5.10	Vårdgivaren ska försäkra sig om att förändringar i dokument är utvärderade och godkända antingen av den ursprungliga godkännande funktionen eller av annan utsedd funktion som har tillgång till relevant bakgrundsinformation att basera sina beslut på.				
5.11	Vårdgivaren ska definiera den period under vilken minst en kopia av föråldrade dokument ska bevaras. Denna period ska säkerställa att dokument för vilka medicintekniska produkter har tillverkats och testats finns tillgängliga under åtminstone livslängden för den medicintekniska produkten enligt vårdgivarens definition, men inte mindre än lagringsperioden för eventuella uppgifter (se krav nedan). eller enligt tillämpliga myndighetskrav.				
5.12	Kontroll av register Register ska föras för att bevisa överensstämmelse med kraven och att kvalitetsledningssystemet fungerar effektivt.				
5.13	Organisationen ska dokumentera rutiner för att definiera de kontroller som behövs för identifiering, lagring, säkerhet och integritet, hämtning, lagringstid och disponering av register				
5.14	Organisationen ska definiera och implementera metoder för att skydda konfidentiell hälsoinformation som finns i register i enlighet med tillämpliga myndighetskrav.				
5.15	Register ska förbli läsbara, lätt identifierbara och återtagbara. Ändringar av ett register ska förbli identifierbara. Organisationen ska bevara journalerna under åtminstone den medicintekniska produktens livslängd enligt definitionen av organisationen eller enligt tillämpliga myndighetskrav, men inte mindre än två år från det att den medicintekniska produkten släpptes av organisationen.				

6: Egenkontroll

Nr	Kriterium	S	N	F	Hur?
6.1	Vårdgivaren ska utföra egenkontroll, denna ska göras i den frekvens och omfattning som anses nödvändig för att säkerställa verksamhetens kvalitet.				
6.2	Vid mätning av kvalitetsledningssystemet ska organisationen samla och övervaka information om kundkraven är uppfyllda. Metoderna för insamling och användning av informationen ska finnas dokumenterad.				
6.3	Feedback processer ska finnas dokumenterade. Feedback processen ska inkludera anskaffande av data från produktion samt efter-produktions aktiviteter. Den insamlade informationen ska kunna användas som input i risk management för övervakning och upprätthållande av produktspecifikationer, såväl som produktframtagning och förbättringsarbete				
6.4	Om specifika regulationer kräver att organisationen får reda på händelser gällande efter-produktions aktiviteter, ska genomgång av dessa händelser vara en del av feedback-processen.				

7: Behörighet					
Nr	Kriterium	S	N	F	Hur?
7.1	Vårdgivaren ska kontrollera samt bedöma huruvida personalen har utbildning och kompetens som krävs för att vara utbildningsansvarig.				
7.2	Vårdgivaren ska kontrollera samt bedöma huruvida personalen har utbildning och kompetens som krävs för att förskriva och lämna ut medicintekniska produkter till patienter.				
7.3	Vårdgivaren ska kontrollera samt bedöma huruvida personalen har utbildning och kompetens som krävs för att ta fram skriftliga anvisningar för specialanpassade produkter.				
7.4	Vårdgivaren ska kontrollera samt bedöma huruvida personalen har utbildning och kompetens som krävs för att vara anmälningsansvarig, vilket innebär att göra anmälningar avseende negativa händelser och tillbud med medicintekniska produkter.				
7.5	Vårdgivaren ska utse vilka som ska få förskrivningsrätt enligt 7.13-15. Detta ska även dokumenteras.				
7.6	Personal som utför arbete som påverkar produktkvaliteten ska inneha passande utbildning, träning, kunskap samt erfarenhet.				
7.7	Vårdgivaren ska dokumentera de processer som krävs för att upprätta kompetenser, nödvändig träning samt säkerställa medvetenhet hos personalen.				
7.8	Vårdgivaren ska bestämma nödvändig kompetens för arbete som påverkar kvaliteten av produkten.				
7.9	Vårdgivaren ska ge nödvändig träning, eller annan åtgärd för att följa bestämmelsen ovan.				
7.10	Vårdgivaren ska utvärdera effektiviteten av åtgärderna ovan.				
7.11	Vårdgivaren ska säkerställa att personalen är medvetna om hur deras aktiviteter är bidragande till att uppnå kvalitetsmålen.				
7.12	Vårdgivaren ska upprätthålla ändamålsenlig dokumentation av utbildning, träning, kunskap och erfarenhet.				
7.13	Läkare som är anställda hos en region ska vara behöriga att förskriva förbrukningsartiklar som används vid urininkontinens, urinretention eller tarminkontinens.				

7.14	Sjuksköterskor, fysioterapeuter och barnmorskor ska vara behöriga att förskriva förbrukningsartiklar som används vid urininkontinens, urinretention eller tarminkontinens om de är 1. anställda hos region, kommun eller vårdgivare som har avtal med region eller kommun, och 2. utsedda av en vårdgivare.				
7.15	Sjuksköterskor ska vara behöriga att förskriva förbrukningsartiklar som behövs vid stomi, för att tillföra kroppen ett läkemedel eller för egenkontroll av medicinering om de är 1. anställda hos en vårdgivare, och 2. utsedda av en vårdgivare.				

8: Utredning av avvikelser					
Nr	Kriterium	S	N	F	Hur?
8.1	Vårdgivaren ska kunna ta emot och utreda klagomål och synpunkter på kvalitet, från vård- och omsorgstagare och deras närstående.				
8.2	Vårdgivaren ska kunna ta emot och utreda klagomål och synpunkter på kvalitet, från personal och vårdgivare.				
8.3	Vårdgivaren ska kunna ta emot och utreda klagomål och synpunkter på kvalitet, från de som bedriver socialtjänst och de som bedriver verksamhet enligt LSS.				
8.4	Vårdgivaren ska kunna ta emot och utreda klagomål och synpunkter på kvalitet, från myndigheter, föreningar, andra organisationer och intressenter.				
8.5	Organisationen ska ha dokumenterade hanteringssätt för skyndsam hantering enligt relevanta regulationer. Minst ska det finnas fastställda krav och ansvariga för: mottagande och dokumenterande information				
8.6	Organisationen ska ha dokumenterade hanteringssätt för skyndsam hantering enligt relevanta regulationer. Minst ska det finnas fastställda krav och ansvariga för: utvärdering information för att bestämma om feedback räknas som ett klagomål				
8.7	Organisationen ska ha dokumenterade hanteringssätt för skyndsam hantering enligt relevanta regulationer. Minst ska det finnas fastställda krav och ansvariga för: Utredning av klagomål				
8.8	Organisationen ska ha dokumenterade hanteringssätt för skyndsam hantering enligt relevanta regulationer. Minst ska det finnas fastställda krav och ansvariga för: rapporteringsskyldighet till reguljära myndigheter				
8.9	Organisationen ska ha dokumenterade hanteringssätt för skyndsam hantering enligt relevanta regulationer. Minst ska det finnas fastställda krav och ansvariga för: hantering av klagomål relaterad produkt				
8.10	Organisationen ska ha dokumenterade hanteringssätt för skyndsam hantering enligt relevanta regulationer. Minst ska det finnas fastställda krav och ansvariga för: bestämma behovet av att initiera förändringar				
8.11	Alla förändringar som kommer av en felanmälan ska dokumenteras. Protokoll ska föras enligt kap 5.				
8.12	Om utredningen leder till extern part, ska relevant information utbytas mellan organisationen och den utanförstående organisationen. Protokoll ska föras enligt kap 5.				
8.13	Om ett klagomål inte utreds så ska ett berättigande finnas dokumenterat. Protokoll ska föras enligt kap 5.				

8.14	Vårdgivaren ska ha en rutin för när negativa händelser eller tillbud inträffat med en medicinteknisk produkt, och då snarast inleda en utredning och göra en bedömning huruvida det inträffade ska anmälas. Innan utredningen av händelsen eller tillbudet slutförs ska orsakerna till det inträffade så långt som möjligt fastställas. Om utredningen visar att det finns brister i verksamhetens kvalitet, ska förbättringsåtgärder vidtas. Utredningen, bedömningen och vidtagna åtgärder ska dokumenteras.				
8.15	Anmälan om negativa händelser och tillbud med medicintekniska produkter som inte är egentillverkade ska göras till Läkemedelsverket och tillverkaren. Anmälan till Läkemedelsverket ska göras på det sätt som myndigheten anvisar. Anmälan ska göras snarast efter det att en händelse har inträffat och genomföras av anmälningsansvarig				
8.16	Vårdgivaren ska ha rutin för när anmälan om negativa händelser och tillbud med egentillverkade medicintekniska produkter ska göras till Inspektionen för vård och omsorg. Anmälan ska göras på det sätt som myndigheten anvisar. Anmälan ska göras snarast efter det att en händelse har inträffat och genomföras av anmälningsansvarig.				
8.17	Vårdgivaren ska ha rutin för att göra anmälningar vid funktionsfel och försämring av en produkts egenskaper eller prestanda samt vid felaktigheter och brister i märkning eller bruksanvisning som kan leda till eller har lett till 1. en patients, en användares eller någon annan persons död, eller 2. en allvarlig försämring av en patients, en användares eller någon annan persons hälsotillstånd.				
8.18	Vårdgivaren ska se till att produktidentiteten ska säkerställas för varje medicinteknisk produkt som har varit inblandad i en negativ händelse eller ett tillbud. Produkten eller produkterna ska, tillsammans med bruksanvisningen och förpackningen, tas till vara för att möjliggöra en fortsatt utredning av händelsen eller tillbudet.Produkten eller produkterna får dock fortfarande användas innan utredningen är avslutad, om alternativa medicintekniska produkter saknas i verksamheten och syftet är att skydda människors liv och hälsa.				
8.19	Vårdgivaren ska ha rutin för att biträda Läkemedelsverket och tillverkaren med den ytterligare information, utöver anmälan, som kan behövas för att utreda en negativ händelse eller ett tillbud. Vårdgivaren ska även, snarast möjligt efter en inkommen anmälan och på villkor som denne anger, bereda tillverkaren tillfälle att i vårdgivarens lokaler undersöka den medicintekniska produkt som har tagits till vara.				
8.20	Vårdgivaren ska rutin för att biträda Inspektionen för vård och omsorg med den ytterligare information, utöver anmälan, som kan behövas och ge myndigheten möjlighet att vid behov undersöka den egentillverkade medicintekniska produkt som har varit inblandad i den negativa händelsen eller tillbudet.				
8.21	Vårdgivaren ska säkerställa att anmälningsansvarig ska följa upp de utredningar som görs med anledning av en negativ händelse eller ett tillbud och föra resultaten åter till verksamheten.				

9: Förbättrande åtgärder i verksamheten					
Nr	Kriterium	S	N	F	Hur?
9.1	Vårdgivaren ska ha en rutin för hur Inkommet material kring hur verksamheten drivs ska sammanställas och analyseras för att urskilja brister i verksamhetens kvalite. Åtgärder som krävs för att säkra verksamheten kvalitet ska vidtas.				
9.2	Vårdgivaren ska identifiera och införa nödvändiga ändringar för att bibehålla lämpligheten, tillräckligheten och effektiviteten av kvalitetsledningssystemet och medicinsk utrustnings säkerhet.				

	Detta kan göras genom användning av kvalitets policies, kvalitetsmål, granskningsresultat, postmarketing övervakning, dataanalys, korrigerande åtgärder, förhindrande åtgärder och lednings granskning.				
9.3	Organisationen ska planera och implementera övervaknings-, mätnings-, analys- och förbättring processerna som behövs för att: Demonstrera produktöverensstämmelse				
9.4	Organisationen ska planera och implementera övervaknings-, mätnings-, analys- och förbättring processerna som behövs för att: Säkerställa överensstämmelse av kvalitetsledningssystemet				
9.5	Organisationen ska planera och implementera övervaknings-, mätnings-, analys- och förbättring processerna som behövs för att: bibehålla effektiviteten av kvalitetsledningssystemet				
9.6	De tre punkterna ovan ska inkludera bestämmelse av lämpliga metoder, inklusive statistiska tekniker, och utsträckningen av deras användning				

10: Förbättrade processer i verksamheten					
Nr	Kriterium	S	N	F	Hur?
10.1	Vårdgivaren ska genomföra interna granskningarna vid planerade intervall för att bedöma huruvida kvalitetsledningssystemet överensstämmer med planerade och dokumenterade bestämmelser, kraven från ISO 13485, kvalitetsledning krav hos verksamheten och tillämpliga regulativa krav.				
10.2	Vårdgivaren ska genomföra interna granskningarna vid planerade intervall för att bedöma huruvida kvalitetsledningssystemet är effektivt implementerad och underhållit.				
10.3	Vårdgivaren ska dokumentera en procedur för att beskriva ansvar och krav för planering och genomförande av revisioner samt registrering och rapportering av revisionsresultat.				
10.4	Vårdgivaren ska upprätta ett revisionsprogram, programmet ska planeras med hänsyn till status och betydelse för de processer och det område som ska granskas, samt resultatet av tidigare revisioner.				
10.5	Vårdgivaren ska definiera och registrera revisionskriterierna, omfattningen, intervallet och metoderna (se kap 5).				
10.6	Vårdgivaren ska välja revisor objektivt och opartisk för att säkerställa objektivitet och opartiskhet i revisionsprocessen. Vårdgivaren ska även se till att revisorer inte granskar sitt eget arbete.				
10.7	Vårdgivaren ska föra register över revisionerna och deras resultat, inklusive identifiering av de processer och områden som granskats och slutsatserna, ska upprätthållas (se kap 5).				
10.8	Ledningen som ansvarar för granskat område ska vidta nödvändiga och korrigerande åtgärder av avvikelser och deras orsak utan dröjsmål . Uppföljnings aktiviteter ska inkludera verifikationen av tagna åtgärder och dokumentation av verifikationens resultat.				
10.9	Vårdgivaren ska dokumentera procedur för att bestämma, samla och analysera lämplig data för att demonstrera lämpligheten och effektiviteten av kvalitetsledningssystemet. Proceduren ska inkluddera bestämmelse av lämpliga metoder, inkluderande statistiska tekniker och deras utsträckning.				
10.10	Dataanalysen ska inkludera data genererad som resultat av övervakning och mätningar samt andra relevanta källor, minst inkluderande: feedback				
10.11	Dataanalysen ska inkludera data genererad som resultat av övervakning och mätningar samt andra relevanta källor, minst inkluderande: Överensstämmelse med produktkrav				
10.12	Dataanalysen ska inkludera data genererad som resultat av övervakning och mätningar				

	samt andra relevanta källor, minst inkluderande: Egenskaper och trender hos processer och produkter, inkluderande förbättringsmöjligheter,				
10.13	Dataanalysen ska inkludera data genererad som resultat av övervakning och mätningar samt andra relevanta källor, minst inkluderande: Leverantörer				
10.14	Dataanalysen ska inkludera data genererad som resultat av övervakning och mätningar samt andra relevanta källor, minst inkluderande: Revisioner				
10.15	Dataanalysen ska inkludera data genererad som resultat av övervakning och mätningar samt andra relevanta källor, minst inkluderande: servicerapporter, som lämpligt.				
10.16	Om analysen av data visar att kvalitetsledningssystemet inte är lämpligt eller effektivt så ska organisationen använda den analyses som input till förbättringsåtgärder. Uppgifter om resultaten av analysen ska bevaras, se kap 5.				
10.17	Vårdgivaren ska applicera passande metoder för övervakning och, när det är nödvändigt, mätning av processer i kvalitetsledningssystemet. Dessa metoder ska demonstrera processernas förmåga att uppnå planerade resultat. Om de planerade resultaten inte uppnås ska, när det är lämpligt, korrigering och korrigerande åtgärder vidtas.				
10.18	Vårdgivaren ska dokumentera rutiner för ledningens granskning. Ledningen ska granska organisationens kvalitetsledningssystem, detta ska genomföras enligt planerade dokumenterade intervall för att försäkra dess fortlöpande lämplighet och effektivitet. Granskningen ska innehålla möjlighet att bedöma förbättringsmöjligheter samt behov av förändring av kvalitetsledningssystemet, inkluderande kvalitetspolicy och kvalitetsmål. Protokoll från ledningens granskning ska ska föras. (se kap 5)				
10.19	Vårdgivaren ska se till att det finns input till ledningens granskning inkluderande, men inte begränsad till, information som kommer ifrån feedback och klagomålshantering.				
10.20	Vårdgivaren ska se till att det finns input till ledningens granskning inkluderande, men inte begränsad till, information som kommer ifrån rapportering till reguljära myndigheter och revisioner.				
10.21	Vårdgivaren ska se till att det finns input till ledningens granskning inkluderande, men inte begränsad till, information som kommer ifrån övervakning och mätningar av processer samt produkter.				
10.22	Vårdgivaren ska se till att det finns input till ledningens granskning inkluderande, men inte begränsad till, information som kommer ifrån korrigerande och förebyggande åtgärder.				
10.23	Vårdgivaren ska se till att det finns input till ledningens granskning inkluderande, men inte begränsad till, information som kommer ifrån uppföljningsåtgärder från tidigare lednings granskning				
10.24	Vårdgivaren ska se till att det finns input till ledningens granskning inkluderande, men inte begränsad till, information som kommer ifrån förändringar som skulle kunna påverka kvalitetsledningssystemet och förbättrings rekommendationer.				
10.25	Vårdgivaren ska se till att det finns input till ledningens granskning inkluderande, men inte begränsad till, information som kommer ifrån tillämpliga nya eller reviderade regulationer/myndighetskrav.				
10.26	Vårdgivaren ska säkerställa att utfallet av ledningens granskning ska bevaras (se kap 5) och inkludera granskningens input och alla bestämmelser och åtgärder relaterade till förbättring som behövs för att bibehålla lämpligheten och effektiviteten av kvalitetsledningssystemet och dess processes.				
10.27	Vårdgivaren ska se till att utfallet av ledningens granskning inkluderar alla bestämmelser och åtgärder relaterade till förbättring av produkter relaterade till kundkrav.				
10.28	Vårdgivaren ska se till att utfallet av ledningens granskning inkluderar alla				

	bestämmelser och åtgärder relaterade till resursbehov och ändringar som behövs för att svara på tillämpliga nya eller reviderade regulativa krav				

11: Dokumentationsskyldighet					
Nr	Kriterium	S	N	F	Hur?
11.1	Vårdgivaren ska säkerställa att arbetet med att systematiskt och fortlöpande utveckla och säkra verksamhetens kvalitet dokumenteras.				
11.2	Vårdgivaren ska senast den 1 mars varje år upprätta en patientsäkerhetsberättelse.				
11.3	Patientsäkerhetsberättelsen ska innehålla hur: ansvaret har varit fördelat,				
11.4	Patientsäkerhetsberättelsen ska innehålla hur: patientsäkerheten genom egenkontroll har följts upp och utvärderats				
11.5	Patientsäkerhetsberättelsen ska innehålla hur: samverkan har möjliggjorts för att förebygga att patienter drabbas av vårdskada,				
11.6	Patientsäkerhetsberättelsen ska innehålla hur: risker för vårdskador har hanterats.				
11.7	Patientsäkerhetsberättelsen ska innehålla hur: rapporter har hanterats, och inkomna klagomål och synpunkter enligt som har betydelse för patientsäkerheten har hanterats.				
11.8	Av patientsäkerhetsberättelsen ska det vidare framgå hur många händelser som har utretts under föregående kalenderår och hur många vårdskador som har bedömts som allvarliga.				
11.9	Patientsäkerhetsberättelsen ska ha en sådan detaljeringsgrad att det går att bedöma hur det systematiska patientsäkerhetsarbetet har bedrivits i verksamhetens olika delar, och att informationsbehovet hos externa intressenter tillgodoses.				
11.10	Vårdgivaren ska dokumentera vilka förbrukningsartiklar inom läkemedelsförmånerna som var och en av dem som har förskrivningsrätt får förskriva med utgångspunkt från vars och ens kompetens.				
11.11	Vårdgivaren ska dokumentera rutiner för validering av tillämpningen av datorprogram som används i kvalitetsledningssystemet. Sådana mjukvaruapplikationer ska valideras innan initial användning och, i förekommande fall, efter ändringar av mjukvaran eller dess tillämpning. De specifika förhållningssätten och aktiviteterna som associeras med mjukvaru validering och förlängning ska vara proportionella till risken som medföljer vid användning av mjukvaran. Uppgifterna ska bevaras, se kap 5..				
11.12	Dokumentation (se kap 5) av kvalitetsledningssystemet ska inkludera: Dokumenterade uttalanden/statements av en kvalitetspolicy samt kvalitetsmål				
11.13	Dokumentation (se kap 5) av kvalitetsledningssystemet ska inkludera: En kvalitetsmanual				
11.14	Dokumentation (se kap 5) av kvalitetsledningssystemet ska inkludera: dokumenterade procedurer och protokoll som krävs av denna standard.				
11.15	Dokumentation (se kap 5) av kvalitetsledningssystemet ska inkludera:dokument samt protokoll, som enligt organisationen är nödvändiga för en försäkra effektiv planering, drift, samt kontroll av processer.				
11.16	Dokumentation (se kap 5) av kvalitetsledningssystemet ska inkludera:Övrig dokumentation specificerad av tillämpbara regulations krav.				
11.17	Vårdgivaren ska dokumentera en kvalitetsmanual som inkluderar omfattningen av				

	kvalitetsledningssystemet, inklusive detaljer om och motivering för eventuella undantag eller uteblivna tillämpningar.				
11.18	Vårdgivaren ska dokumentera en kvalitetsmanual som inkluderar de dokumenterade procedurerna för kvalitetsledningssystemet, eller referenser till dem.				
11.19	Vårdgivaren ska dokumentera en kvalitetsmanual som inkluderar en beskrivning av samspelet mellan processerna i kvalitetsledningssystemet. Kvalitetsmanualen ska beskriva strukturen för den dokumentation som används i kvalitetsledningssystemet.				
11.20	För varje medicinsk utrustning eller utrustningsgrupp så ska vårdgivaren upprätta och bibehålla en eller flera filer som antingen innehåller eller refererar till dokument som skapats för att bevisa efterföljsamhet till de krav som finns enligt ISO 13485:2016 och efterlevnad till lämpliga regulativa krav.				
11.21	Innehållet i filen(erna) ska inkludera men inte begränsas till: En generell beskrivning av medicinska utrustningen, dess tänkta användningsområde och märkning, inkluderande användarinstruktioner				
11.22	Innehållet i filen(erna) ska inkludera men inte begränsas till: Specifikationer för produkten				
11.23	Innehållet i filen(erna) ska inkludera men inte begränsas till: Specifikationer eller procedurer för tillverkning, packning, lagring, hantering och distribution				
11.24	Innehållet i filen(erna) ska inkludera men inte begränsas till: Procedurer för mätning och övervakning				
11.25	Innehållet i filen(erna) ska inkludera men inte begränsas till: Om lämpligt, krav för installation				
11.26	Innehållet i filen(erna) ska inkludera men inte begränsas till: Om lämpligt, procedurer för underhåll				
11.27	Vårdgivaren ska dokumentera kraven för den infrastruktur som behövs för att uppnå överensstämmelse med produktkrav, förhindra blandning av produkter och försäkra korrekt hantering av produkten. Infrastrukturen inkluderar, om tillämpligt, byggnader, arbetsytor, tillhörande verktyg, processutrustning (mjukvaror och hårdvaror) och stödjande tjänster (som transport, kommunikation eller informationssystem)				
11.28	Vårdgivaren ska dokumentera kraven för underhållande aktiviteter, inkluderande i vilket intervall underhållet sker, när en sådan underhållande aktivitet, eller brist på aktivitet, kan påverkade produktkvalitén. Om tillämpligt, så ska kraven gälla för utrustning som används i produktion, kontroll av arbetsplatsen och övervakning och mätning. Uppgifter om sådant underhåll ska bevaras, se kap 5.				
11.29	Vårdgivaren ska dokumentera kraven som finns för att arbetsmiljön ska uppnå överensstämmelse med produktkraven. Om arbetsmiljö förhållandena har en ogynnsam effekt på produktkvalitet så ska organisationen dokumentera kraven för arbetsmiljön samt procedurer för övervakning och kontroll av arbetsmiljön.				
11.30	Vårdgivaren ska dokumentera kraven för hälsa, renlighet och kläder hos personal om kontakt mellan sådan personal och produkten eller arbetsmiljön kan påverka säkerheten eller prestandan hos medicinsk utrustning.				
11.31	Vårdgivaren ska försäkra att all personal som behöver jobba temporärt under speciella miljöförhållanden inom arbetsmiljön är kompetenta eller övervakade av en kompetent person.				
11.32	Om tillämpliga myndighetskrav kräver anmälan av klagomål som uppfyller specificerade rapporterings kriterier för oönskade händelser eller utfärdande av rådgivande meddelanden, ska organisationen dokumentera rutiner för att lämna underrättelse till lämpliga tillsynsmyndigheter.				

	Register över rapportering till tillsynsmyndigheten ska föras (se kap 5).				

12: ISO 13485 Kap 7					
Nr	Kriterium	S	N	F	Hur?
12.0	Vårdgivaren ska planera och skapa de processer som behövs för produktförverkligande. Planering av produktförverkligande ska vara konsekvent med kraven för andra processer inom kvalitetsledningssystemet. Organisationen ska dokumentera en eller fler processer för riskhantering inom produktförverkligandet. Register av riskhanteringsaktiviteter ska bevaras, se kap 5.				
12.1	Inom planering av produktförverkligande så ska vårdgivaren, när så är lämpligt, bestämma kvalitetsmål och krav för produkten				
12.2	Inom planering av produktförverkligande så ska vårdgivaren, när så är lämpligt, bestämma behov av att upprätta processer och dokument (se kap 5) och att förse resurser specifikt till produkten, inkluderande infrastruktur och arbetsmiljö				
12.3	Inom planering av produktförverkligande så ska vårdgivaren, när så är lämpligt, bestämma nödvändig verifikation, validering, övervakning, mätning, inspektion och testning, hantering, lagring, distribution och spårningsaktiviteter specifikt till produkten tillsammans med kriterierna för produkt acceptans.				
12.4	Inom planering av produktförverkligande så ska vårdgivaren, när så är lämpligt, bestämma uppgifter som behövs för att tillhandahålla bevis för att förverkligande processen och resulterande produkt möter kraven (se kap 5). Utfallet från denna planering ska dokumenteras i en form lämplig för organisationens arbetssätt. Notering, ytterligare information kan hittas i ISO 14971.				
12.5	Vårdgivaren ska fastställa a) krav specificerade av kunden, inklusive kraven för leverans av produkt och krav för aktiviteter efter leverans.				
12.6	Vårdgivaren ska fastställa krav som inte angetts av kunden men nödvändiga för känd avsedd användning.				
12.7	Vårdgivaren ska fastställa tillämpliga myndighetskrav relaterade till produkten.				
12.8	Vårdgivaren ska fastställa användarutbildning som behövs för att säkerställa specificerad prestanda och säker användning av den medicinska produkten.				
12.9	Vårdgivaren ska fastställa eventuella ytterligare krav som bestäms av organisationen.				
12.10	Vårdgivaren ska se över kraven relaterade till produkten. Granskningen ska utföras innan organisation åtar sig att leverera produkten till kunden (t.ex. inlämnande av anbud, godkännande av kontrakt eller beställningar, godkännande av ändringar av kontrakt eller beställningar) och ska säkerställa att produktkrav är definierade och dokumenterade.				
12.11	Vårdgivaren ska se till att granskningen ovan även säkerställer att kontrakt eller order krav som skiljer sig från de tidigare nämnda löses.				
12.12	Vårdgivaren ska se till att granskningen ovan även säkerställer att tillämpliga myndighetskrav är uppfyllda.				
12.13	Vårdgivaren ska se till att granskningen ovan även säkerställer att användarutbildning som identifierats är tillgänglig eller planerad att vara tillgänglig.				
12.14	Vårdgivaren ska se till att granskningen ovan även säkerställer att organisationen har förmågan att uppfylla de definierade kraven.				

12.15	Vårdgivaren ska utifrån granskningarna ovan föra register över resultaten av granskningen och åtgärder som härrör från granskningen, dessa ska bevaras (se kap 5).				
12.16	Vårdgivaren ska säkerställa att när kunden inte tillhandahåller något dokumenterat krav, ska kundkraven bekräftas av organisationen innan godkännande och när produktkraven ändras ska vårdgivaren försäkra att relevanta dokument ändrats och att relevant personal blir medveten om de ändrade kraven.				
12.17	Vårdgivaren ska planera och dokumentera åtgärder för kommunikation med kunder i relation med produktinformation samt förfrågningar, kontrakt eller order hantering, inklusive ändringar.				
12.18	Vårdgivaren ska planera och dokumentera åtgärder för kommunikation med kunder i relation med kundfeedback, inklusive klagomål samt rådgivande meddelanden.				
12.19	Vårdgivaren ska kommunicera med regulativa myndigheter i överensstämmelse med lämpliga regulativa krav.				
12.20	Vårdgivaren ska dokumentera rutiner för design och utveckling				
12.21	Vårdgivaren ska planera och kontrollera design och utvecklingen av produkter och utifrån behov, ska design och utvecklingsdokument bevaras och uppdateras alltefter design och utveckling fortskrider.				
12.22	Under design och utvecklingsplaneringen ska vårdgivaren dokumentera design- och utvecklingsstegen samt granskningen(arna) som behövs vid varje steg.				
12.23	Under design och utvecklingsplaneringen ska vårdgivaren dokumentera verifierings-, validerings- och designöverföringsaktiviteter som är lämpliga vid varje design- och utvecklingsstadium				
12.24	Under design och utvecklingsplaneringen ska vårdgivaren dokumentera ansvar och befogenheter för design och utveckling.				
12.25	Under design och utvecklingsplaneringen ska vårdgivaren dokumentera resurserna som krävs, inklusive nödvändig kompetens hos personalen.				
12.26	Under design och utvecklingsplaneringen ska vårdgivaren dokumentera metoderna som möjliggör spårbarhet av design och utvecklingsresultat till insatser.				
12.27	Vårdgivaren ska se till att Indata relaterade till produktkrav ska fastställas och register upprätthållas (se kap 5). Dessa indata ska inkludera krav på funktion, prestanda, användbarhet och säkerhet, enligt den avsedda användningen.				
12.28	Vårdgivaren ska se till att Indata relaterade till produktkrav ska fastställas och register upprätthållas (se kap 5). Dessa indata ska inkludera tillämpliga regulatoriska krav och standarder samt tillämpliga resultat av riskhantering.				
12.29	Vårdgivaren ska se till att Indata relaterade till produktkrav ska fastställas och register upprätthållas (se kap 5). Dessa indata ska inkludera, om tillämpligt, information från tidigare liknande konstruktioner.				
12.30	Vårdgivaren ska se till att Indata relaterade till produktkrav ska fastställas och register upprätthållas (se kap 5). Dessa indata ska inkludera andra krav som är väsentliga för design och utveckling av produkten och processerna. Dessa indata ska ses över för att vara tillräckliga och godkännas. Kraven ska vara fullständiga, entydiga, kunna verifieras eller valideras och inte stå i konflikt med varandra.				
12.31	Design- och utvecklingsresultat ska möta ingångskraven för design och utveckling samt förse med lämplig information för inköp, produktion och tillhandahållande av tjänster. Resultaten av design och utveckling ska vara i ett formulär lämpligt för verifikation mot design och utvecklings indata och ska vara godkända före release. Uppgifter om design och utvecklingsresultat ska bevaras (se kap 5)				

12.32	Design- och utvecklingsresultat ska innehålla eller referera till kriterier för produktacceptans.				
12.33	Design- och utvecklingsresultat ska specificera produktegenskaperna som är nödvändiga för dess säkra och rätta användning.				
12.34	Vårdgivaren ska i lämpliga skeden genomföra systematisk granskning av design och utveckling i enlighet med vad som planerats och dokumenterats för att utvärdera resultaten från design och utveckling uppnår kraven samt identifiera and föreslå nödvändiga aktiviteter. Deltagare i sådana granskningar ska inkludera representanter från funktioner som berörs av design- och utvecklingsstadiet under granskning, samt annan specialistpersonal.				
12.35	Register över resultaten från granskningarna ovan och eventuella nödvändiga åtgärder ska upprätthållas och inkludera identifikation av designen som granskas, vilka deltagare som är involverade och datum för granskningen (se kap 5).				
12.36	Design och utveckling verifikation ska utföras i enlighet med planerade och dokumenterade åtgärder för att säkerställa att design och utvecklingsresultaten har mött indata kraven.				
12.37	Organisationen ska dokumentera verifikationsplanerna vilket ska inkluderar metoder, acceptanskriterier och, om tillämpligt, statistiska tekniker med logisk grund för provstorlek.				
12.38	Om den tänkta användningen kräver att medicinska utrustningen är ansluten till, eller har ett gränssnitt med, annan medicinsk utrustning så ska verifikationen inkludera bekräftelse över att design resultatet möter design indata vid anslutning eller gränssnitt.				
12.39	För punkterna under 12.36-38 ska uppgifter om resultat och slutsatser av verifikationen och nödvändiga åtgärder bevaras (se kap 5)				
12.40	Vårdgivaren ska säkerställa att design- och utvecklingsverifiering utförs i enlighet med planerade och dokumenterade arrangemang för att säkerställa att design- och utvecklingsresultaten har uppfyllt konstruktions- och utvecklingsinsatskraven.				
12.41	Design- och utveckling validering ska utföras i enlighet med vad som är planerat och dokumenterat för att säkerställa att den resulterande produkten är kapabel att uppfylla kraven för den specificerade tillämpningen eller avsedda användningen.				
12.42	Organisationen ska dokumentera valideringsplaner som inkluderar metoder, acceptanskriterier och, om lämpligt , statistiska tekniker samt skälen till urvalets storlek.				
12.43	Designvalidering ska utföras på representativ produkt. Representativ produkt inkluderar initiala produktionsenheter, partier eller motsvarande. Skälen för valet av produkt som används för valideringen ska registreras enligt (kap 5).				
12.44	Som en del av design- och utveckling validering ska organisationen utföra kliniska utvärderingar eller prestanda utvärderingar av den medicintekniska produkten i enlighet med tillämpbara myndighetskrav. En medicinteknisk produkt som används för klinisk utvärdering eller prestationsutvärdering anses inte vara utgiven för användning av kunden.				
12.45	Om den avsedda användningen kräver att den medicintekniska produkten är ansluten till, eller har ett gränssnitt med, annan medicinteknisk produkt, ska valideringen innefatta en bekräftelse på att kraven för den angivna applikationen eller den avsedda användningen har uppfyllts när den blir är ansluten eller integrerad.				
12.46	Validering ska slutföras innan produkten släpps för användning av kunden. Register över resultat och slutsatser från validering och nödvändiga åtgärder ska upprätthållas (se kap 5).				
12.47	Organisationen ska dokumentera procedurer för överföring av design och utvecklingsresultat till tillverkningen. Dessa procedurer ska säkerställa att design och utvecklingsresultat är verifierade som lämpliga för tillverkningen innan de blir slutliga produktions specifikationer och så att produktionskapaciteten kan möta produktkraven. Resultat och slutsatser av överföringarna ska dokumenteras (se kap 5).				
12.48	Organisationen ska dokumentera rutiner för att kontrollera design- och utvecklingsändringar.				

	Organisationen ska bestämma signifikansen av ändringen av funktion, prestanda, användbarhet, säkerhet och lämpliga regulativa krav för medicinsk utrustning och dess tänkta användning. Granskningen av ändringar ska inkludera utvärdering av de effekter ändringarna har på beståndsdelar och produkter under bearbetning eller redan levererade, indata och utdata av riskhantering samt produktförverkligande processer. Uppgifter om ändringar, deras granskning och nödvändiga åtgärder ska bevaras (se kap 5).				
12.49	Design- och utvecklingsändringar ska identifieras. Före implementation ska ändringarna: a) granskas b) verifieras c) om tillämpligt valideras d) godkännas				
12.50	Granskningen av ändringar ska inkludera utvärdering av de effekter ändringarna har på beståndsdelar och produkter under bearbetning eller redan levererade, indata och utdata av riskhantering samt produktförverkligande processer. Uppgifter om ändringar, deras granskning och nödvändiga åtgärder ska bevaras (se kap 5).				
12.51	Organisationen ska upprätthålla en design- och utvecklingsfil för varje medicinteknisk produkttyp eller medicinteknisk produktfamilj. Denna fil ska innehålla eller referera till register som genererats för att visa överensstämmelse med kraven för design och utveckling samt register för design- och utvecklingsändringar.				
12.52	Organisationen ska dokumentera rutiner (se kap 5) för att säkerställa att inköpt produkt uppfyller specificerade inköpskriterier. Organisationen ska fastställa kriterier för utvärdering och urval av leverantörer. Kriterierna ska vara: baserade på leverantörens förmåga att tillhandahålla en produkt som uppfyller organisationens krav;				
12.53	Organisationen ska dokumentera rutiner (se kap 5) för att säkerställa att inköpt produkt uppfyller specificerade inköpskriterier. Organisationen ska fastställa kriterier för utvärdering och urval av leverantörer. Kriterierna ska vara: baserade på leverantörens prestation;				
12.54	Organisationen ska dokumentera rutiner (se kap 5) för att säkerställa att inköpt produkt uppfyller specificerade inköpskriterier. Organisationen ska fastställa kriterier för utvärdering och urval av leverantörer. Kriterierna ska vara: ta hänsyn till hur produkten påverkar kvaliteten på den medicinska produkten;				
12.55	Organisationen ska dokumentera rutiner (se kap 5) för att säkerställa att inköpt produkt uppfyller specificerade inköpskriterier. Organisationen ska fastställa kriterier för utvärdering och urval av leverantörer. Kriterierna ska vara: proportionell mot risken förknippad med den medicintekniska produkten				
12.56	Organisationen ska planera övervakning och genomföra återkommande utvärderingar av leverantörer. Leverantörens förmåga att uppnå kraven för den köpta produkten ska övervakas. Resultaten av övervakningen ska ge input till processen för utvärdering av leverantörer. Misslyckande att uppfylla inköpskrav ska åtgärdas med leverantören i proportion till risken förknippad med den köpta produkten, och efterlevnaden av tillämpliga myndighetskrav. Protokoll över resultaten från utvärdering, urval, och övervakning av leverantörskapacitet eller prestanda och alla nödvändiga åtgärder som härrör från dessa aktiviteter ska upprätthållas (se kap 5).				
12.57	Köpinformation ska beskriva eller referera till produkten som köpes, inklusive om tillämpligt: produktspecifikationer				
12.58	Köpinformation ska beskriva eller referera till produkten som köpes, inklusive om tillämpligt: krav för produktacceptans, rutiner, processes och utrustning				
12.59	Köpinformation ska beskriva eller referera till produkten som köpes, inklusive om tillämpligt: kvalifikationskrav hos leverantörspersonal				
12.60	Köpinformation ska beskriva eller referera till produkten som köpes, inklusive om tillämpligt: kvalitetsledningssystemkrav				

12.61	Organisationen ska säkerställa lämpligheten hos specifika köpkrav innan de kommuniceras till leverantören. Köpinformation ska inkludera, som tillämpligt, en skriven överenskommelse att leverantören ska informera organisationen om ändringar hos den köpte produkten innan implementering av ändringar som påverkar den köpta produktens möjlighet att möta specifika köpkrav. Utifrån det som beskrivs i 12.98-99 gällande spårning så ska organisationen bevara relevant köpinformation i dokumentform (se kap 5) och register (se kap 5).				
12.62	Organisationen ska rutin för att upprätta och implementera inspektion eller andra nödvändiga aktiviteter för att säkerställa att köpta produkter möter specificerade köpkrav. Omfattningen av verifikationsaktiviteterna ska baseras på leverantörsutvärderingsresultat och vara proportionell mot risken kopplad med den köpta produkten.				
12.63	När organisationen blir medveten om ändringar hos den köpta produkten ska organisationen ha rutin för att bestämma huruvida dessa ändringar påverkar produktframtagningsprocessen eller medicinska utrustningen.				
12.64	När organisationen eller dess kunder ämnar utföra verifiering hos leverantörens lokaler så ska organisationen förklara de tänkta verifieringsaktiviteterna och metod för produktsläpp i köpinformationen. Uppgifter av verifieringen ska bevaras (se kap 5).				
12.65	Produktion och tillhandahållande av tjänster ska planeras, genomföras, övervakas och kontrolleras för att säkerställa att produkten överensstämmer med specifikationen.				
12.66	När så är lämpligt ska produktionsstyrningen innefatta men är inte begränsade till:dokumentation av rutiner och metoder för kontroll av produktionen (se kap 5);				
12.67	När så är lämpligt ska produktionsstyrningen innefatta men är inte begränsade till: Kvalifikation av infrastruktur.				
12.68	När så är lämpligt ska produktionsstyrningen innefatta men är inte begränsade till: Implementaion av övervakning och mätningar av processparametrar och produktegenskaper;				
12.69	När så är lämpligt ska produktionsstyrningen innefatta men är inte begränsade till: Tillgänglighet och användning av övervaknings- och mätutrustning.				
12.70	När så är lämpligt ska produktionsstyrningen innefatta men är inte begränsade till: Implementering av definierade processer för märkning och förpackning.				
12.71	När så är lämpligt ska produktionsstyrningen innefatta men är inte begränsade till: genomförande av produktsläpp, leverans och efterleveransaktiviteter.				
12.72	Organisationen ska upprätta och föra ett register/protokoll (se kap 5) för varje medicinteknisk produkt eller batch av medicintekniska produkter som innebär spårbarhet på det sätt som anges i 12.98-99 och identifierar den tillverkade mängden och den mängd som godkänts för distribution. Journalen/registret ska verifieras och godkännas.				
12.73	Organisationen ska dokumentera kraven för produktrenlighet eller kontaminationskontroll av produkt om: produkten är rengjord av organisationen innan sterilisering eller användning Om produkten är rengjord i enligt ovan så gäller inte kraven i 11.29 innan rengöringsprocessen.				
12.74	Organisationen ska dokumentera kraven för produktrenlighet eller kontaminationskontroll av produkt om: produkten är levererad icke steril och utsätts för en rengöringsprocess innan sterilisering eller användning Om produkten är rengjord i enligt ovan så gäller inte kraven i 11.29 innan rengöringsprocessen.				
12.75	Organisationen ska dokumentera kraven för produktrenlighet eller kontaminationskontroll av produkt om: produkten kan inte be rengjord innan sterilisering eller användning och dess renlighet är mycket viktig under användning				

12.76	Organisationen ska dokumentera kraven för produktrenlighet eller kontaminationskontroll av produkt om: produkten är levererad för att användas icke sterilt och dess renlighet är mycket viktig under användning				
12.77	Organisationen ska dokumentera kraven för produktrenlighet eller kontaminationskontroll av produkt om: agens ska borttas från produkten under tillverkning				
12.78	Organisationen ska, när det är nödvändigt, dokumentera krav för installation av medicintekniska produkter och acceptanskriterier för verifiering av installation				
12.79	Om de överenskomna kundkraven tillåter att installation av medicinprodukten utförs av annan extern part än organisationen eller dess leverantör, ska organisationen tillhandahålla dokumenterade krav på medicintekniska installationen och verifiering av installationen.				
12.80	Register över installationer av medicintekniska produkter och verifiering av installation utförd av organisationen eller dess leverantör ska föras (se kap 5).				
12.81	Om underhåll av medicinsk utrustning är ett specificerat krav ska organisationen dokumentera underhållsrutiner, referensmaterial, och referensmått, som nödvändigt för att utföra service och verifiera att produkten är mötta.				
12.82	Organisationen ska analysera uppgifter om serviceaktiviteter som utförs av organisationen eller dess leverantör: a) för att bestämma om informationen ska hanteras som ett klagomål b) om tillämpligt, för input till förbättringsprocessen Uppgifter om underhållsaktiviteter som utförs av organisationen eller dess leverantör ska bevaras (se kap 5)				
12.83	Särskilda krav på steril medicinteknisk utrustning Rutiner ska finnas för att organisationen ska kunna föra register över de steriliseringsprocessparametrar som används för varje steriliseringssats (se kap 5). Steriliseringsjournaler ska kunna spåras till varje produktionssats av medicintekniska produkter.				
12.84	Organisationen ska validera processer för produktion och tillhandahållande av tjänster där resultatet inte kan bli eller inte är verifierad genom efterföljande övervakning eller mätning och, som en konsekvens, så blir brister tydliga endast efter produkten är i användning eller att tjänsten har levererats.				
12.85	Valideringen ska demonstrera processernas förmåga att konsekvent uppnå planerade resultat. Organisationen ska dokumentera procedurer för validering av processer, inklusive: definierade kriterier för granskning och godkännande av processerna				
12.86	Valideringen ska demonstrera processernas förmåga att konsekvent uppnå planerade resultat. Organisationen ska dokumentera procedurer för validering av processer, inklusive: utrustningkvalifikation och personalkompetens				
12.87	Valideringen ska demonstrera processernas förmåga att konsekvent uppnå planerade resultat. Organisationen ska dokumentera procedurer för validering av processer, inklusive:: användning av specifika metoder, procedurer och acceptanskriterier				
12.88	Valideringen ska demonstrera processernas förmåga att konsekvent uppnå planerade resultat. Organisationen ska dokumentera procedurer för validering av processer, inklusive: om tillämpligt, statistiska tekniker med motivering för urvalsstorlekar				
12.89	Valideringen ska demonstrera processernas förmåga att konsekvent uppnå planerade resultat. Organisationen ska dokumentera procedurer för validering av processer, inklusive:: krav på register, se kap 5.				
12.90	Valideringen ska demonstrera processernas förmåga att konsekvent uppnå planerade resultat. Organisationen ska dokumentera procedurer för validering av processer, inklusive: omutvärdering, inklusive kriterier för omutvärdering				
12.91	Valideringen ska demonstrera processernas förmåga att konsekvent uppnå planerade				

	resultat. Organisationen ska dokumentera procedurer för validering av processer, inklusive:: godkännande av ändringar i processerna				
12.92	Organisationen ska dokumentera procedurer för validering av tillämpningen av datorprogramvara som används vid produktion och tillhandahållande av tjänster. Sådana programvaruapplikationer ska verifieras före första användning och, när det anses nödvändigt, efter ändringar av sådan programvara eller dess tillämpning. Det specifika tillvägagångssättet och aktiviteterna förknippade med programvaruverifiering och omvalidering ska vara proportionella med risken som förknippas med användning av programvaran, inklusive effekten på produktens förmåga att överensstämma med specifikationerna. Register över resultaten och slutsatserna av verifieringen och nödvändiga åtgärder från verifieringen ska upprätthållas (se kap 5).				
12.93	Särskilda krav gäller för validering av processer för sterilisering och sterila barriärsystem. Organisationen ska dokumentera procedurer (se kap 5) för validering av processer för sterilisering och sterila barriärsystem. Processer för sterilisering och sterila barriärsystem ska valideras före implementering och följa produkt- eller process ändringar, beroende på vad som är lämpligt. Register över resultat och slutsatser av validering och nödvändiga åtgärder från valideringen ska upprätthållas (se kap 5). OBS Ytterligare information finns i ISO 11607-1 och ISO 11607-2.				
12.94	Organisationen ska dokumentera rutiner för produktidentifiering och identifiera produkten på lämpligt sätt under hela produkt framtagningen.				
12.95	Organisationen ska identifiera produktstatus med avseende på övervaknings- och mätningskrav under hela produktförverkligandet. Identifiering av produktstatus ska upprätthållas under produktion, lagring, installation och service av produkten för att säkerställa att endast produkt som klarat inspektionerna och testerna eller släppts under auktoriserat medgivande skickas, används eller installeras.				
12.96	Om det krävs enligt tillämpliga myndighetskrav ska organisationen dokumentera ett system för att tilldela den medicintekniska produkten unik identifiering av produkten.				
12.97	Organisationen ska dokumentera rutiner för att säkerställa att medicintekniska produkter som returneras till organisationen identifieras och särskiljas från annan fungerande produkt.				
12.98	Organisationen ska dokumentera rutiner för spårbarhet. Dessa rutiner ska definiera omfattningen av spårbarheten i enlighet med lämpliga regulativa krav och de uppgifter som ska föras (se kap 5)				
12.99	Specifika krav för implanterbar medicinsk utrustning De register som krävs för spårbarhet ska innehålla uppgifter över komponenter, material och förhållandena för den använda arbetsmiljön, om dessa delar skulle kunna göra så att den medicinska utrustningen inte uppfyller sina specifika säkerhets- och prestandakrav.				
12.100	Organisationen ska kräva att leverantörer av distributionstjänster eller distributörer för register över distributionen av medicinsk utrustning för att möjliggöra spårbarhet och att dessa uppgifter är tillgängliga för inspektion. Register över namn och adress till paketets mottagare ska föras (se kap 5)				
12.101	Organisationen ska identifiera, verifiera, och skydda kundegendom som tillhandahålls för användning eller integrering i produkten medans den är under organisationens kontroll eller används av organisationen. Om någon kundegendom försvinner, skadas eller på annat sätt visar sig vara olämplig för användning, ska organisationen rapportera detta till kunden och föra register (se kap 5)				
12.102	Organisationen ska dokumentera rutiner för att bevara produktens överensstämmelse med kraven under bearbetning, lagring, hantering och distribution. Bevarande ska gälla för de beståndsdelar som ingår i den medicintekniska produkten.				
12.103	Organisationen ska skydda produkten från förändring, kontaminering eller skada när den utsätts för förväntade förhållanden och faror under bearbetning, lagring, hantering och distribution genom att:				

	• designa och konstruera lämpliga förpacknings och transportbehållare; • dokumentera krav på särskilda förhållanden som behövs om förpackningen ensam inte kan ge tillräckligt skydd. Om särskilda förhållanden krävs ska de kontrolleras och registreras (se kap 5).				
12.104	Organisationen ska fastställa vilken övervakning och mätning som ska utföras och vilken övervaknings- och mätutrustning som behövs för att bevisa att produkten överensstämmer med fastställda krav. Organisationen ska dokumentera rutiner för att säkerställa att övervakning och mätning kan utföras och utförs på ett sätt som är förenligt med övervaknings- och mätningskraven.				
12.105	Organisationen ska ha en process för att kunna säkerställa giltiga resultat, mätutrustning ska: a) vara kalibrerad eller verifierad, eller båda, vid specificerade intervall, eller före användning, mot mätstandarder som kan spåras till internationella eller nationella mätstandarder: när inga sådana standarder finns, ska grunden som används för kalibrering eller verifiering registreras (se kap 5); b) justeras eller omjusteras vid behov: sådana justeringar eller omjusteringar ska registreras (se kap 5). c) ha identifiering för att fastställa dess kalibreringsstatus; d) skyddas från justeringar som skulle ogiltigförklara mätresultatet; e) skyddas mot skador och försämring under hantering, underhåll och lagring.				
12.106	Organisationen ska utföra kalibrering eller verifiering i enlighet med dokumenterade procedurer. Dessutom ska organisationen bedöma och registrera giltigheten av de tidigare mätresultaten när utrustningen visar sig inte överensstämma med kraven.				
12.107	Organisationen ska vidta lämpliga åtgärder med avseende på utrustningen och alla berörda produkter. Register över resultaten av kalibrering och verifiering ska upprätthållas (se kap 5)				
12.108	Organisationen ska dokumentera rutiner för validering av tillämpningen av datorprogramvara som används för övervakning och mätning av krav. Sådana programvaruapplikationer ska valideras före första användningen och, i förekommande fall, efter ändringar av sådan programvara eller dess tillämpning.				
12.109	För punkter ovan: Det specifika tillvägagångssättet och aktiviteterna förknippade med programvaruvalidering och omvalidering ska stå i proportion till risken förknippad med användningen av programvaran, inklusive effekten på produktens förmåga att överensstämma med specifikationerna. Register över resultaten och slutsatserna av valideringen och nödvändiga åtgärder från valideringen ska upprätthållas (se kap 5). OBS Ytterligare information finns i ISO 10012.				