# How to Fully Obtain the Potential Benefits of a Digital Document Management System

## A Guide to Successful Implementation

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# Preface

This Master Thesis project was conducted in collaboration with CodeIT AS. It is the author's final academic project graduating from Industrial Engineering and Management at the Faculty of Engineering of Lund University.

The project combined academia and research with insights from real world business problems. However, due to the fact studied area is still fairly unexplored, the project required the author to apply his analytical skill set in order to draw conclusions based on information that has not always been in direct relation to the subject at hand. Furthermore the area explored in the Master Thesis, i.e. digitalisation of organisational processes and operations, is becoming increasingly important, and the Master Thesis project has consequently prepared the author well for a career outside the university.

# Acknowledgement

The Master Thesis has been written in collaboration with a Norwegian software company, CodeIT AS, with great expertise within the areas of industrial identification, data capture and traceability. I would like to thank the company for letting me gain insight in their organisation, and a special thanks goes to CEO Bjørnar Torsnes for contributing with insightful input, feedback and support throughout the writing of the Master Thesis.

Furthermore I would like to express my sincerest gratitude towards P. Magnus Olsson for his mentoring, support and encouragement throughout the project. I would also like to thank Charles Lawrence from Nordic Innovators, for providing me with very much appreciated feedback.

Finally a special thanks is addressed to the project supervisor, Bertil I Nilsson. Senior Lecturer Nilsson, who possesses over 20 years of work experience within the field of quality control and surveillance and has been assigned the title of Senior Inspector by Intertek/Moody, has not only contributed with valuable input and mentoring but has also guided me throughout the entire project.

Lund, December 2016.

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# Abstract


**Title** How to Fully Obtain the Potential Benefits of a Digital Document Management System – A Guide to Successful Implementation

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**Background** Technological advancements over the last decades have resulted in an increased degree of digitalisation within as well as in between companies around the world. As a result, requirements on companies in general are growing and global competition is steadily increasing. One area for which this is highly relevant, and for which there is still a lot of potential for improvement, is industrial document management.

In many industries, it has now become more or less a mandatory requirement for companies to keep transparent and comprehensive in-depth documentation on specific company processes and operations. In order for companies to comply with these requirements, they need functioning document management systems (DMSs). A company's DMS defines its ability to create, store and manage documentation, and if utilised properly the system also helps companies assure a certain level of quality in their operations. As documentation is closely related to quality management, the DMS consequently affects the level of quality control and assurance activities within the company as well. In turn, a well-functioning DMS increases a company's chances of obtaining certain forms of certification (for example ISO).

The need for proper document management should not be overlooked as a well-functioning DMS enables companies to improve both effectiveness and efficiency of document management-related processes. This consequently enables improved financial as well as operational results, and thus also improves a company's performance in general. However, in order for companies to survive in an environment in which competition is steadily escalating, optimisation is crucial. For companies to be able to achieve optimal results, increased digitisation (i.e. the implementation of a digital DMS solution) is inevitable.

**Purpose**

The purpose of the Master Thesis project is to develop a generic framework supporting the implementation of a digital DMS. The aim of the framework is to provide guidelines that facilitate the process of effectively and efficiently implementing a digital DMS, and in turn enable companies to fully obtain the potential benefits related to such a system.

**Research Questions**

The research questions that the Master Theses aims to answer are:

RQ1: *What are the main issues related to manual DMSs?*

RQ2: *How does document management influence quality assurance and quality control activities?*

RQ3: *What are the incentives for companies to develop effective and efficient DMSs?*

RQ4: *What are the potential benefits of implementing a digital DMS?*

RQ5: *What aspects should be considered when implementing a digital DMS?*

**Delimitations**

This Master Thesis project was limited to investigating and analysing document management processes within manufacturing and service providing companies. The effects of implementing a digital system for document management, i.e. a digital DMS, have been studied and focus was set on investigating how companies can achieve a successful implementation. The Master Thesis was conducted with a generic approach, and did therefore not aim to improve nor develop any of the existing systems for document management. Furthermore, it does not either go into detail or provide complete descriptions regarding the technical features of the existing digital solutions for document management.

The project was limited to conducting a single-case study at the Norwegian software company CodeIT AS (CodeIT). Any areas that are not covered are suggested for future research.

**Methodology**

The Master Thesis has been conducted with a qualitative approach since in-depth knowledge and understanding of the problem had to be obtained. Since the research questions and sources of data were not fixed in advance, a flexible research process has been used throughout the project. The research purpose is mainly descriptive and exploratory but also partially improving, since the study aims to create a

framework that aims to facilitate (i.e. improve) the process of implementing a digital DMS within companies. Furthermore, the data analysis technique utilised throughout the project was *Grounded Theory*.

This Master Thesis is based on an extensive literature review and a qualitative case study regarding the software system *CodeIT eMRB* at CodeIT. Empirical data was collected from the case study, which was based on a series of open and semi-structured interviews with the CEO and founder of CodeIT, Bjørnar Torsnes, as well as a set of business documents from the company. The secondary data was collected from thorough review of literature on areas relevant to the subject.

**Conclusion**

The Master Thesis identified a number of issues related to non-digital DMSs. The main issues that were identified are:

- Difficulties with generating and processing large volumes of documents.
- Difficulties regarding processes for checking and validating document content
- Non-digital systems are prone to error
- Inability to create, find, access and deliver relevant information on time
- Complicated tracking and tracing

During the project a number of incentives for developing effective and efficient DMSs were identified. Some of these incentives are presented below:

- Potential improvements of quality assurance and control activities.
- Quality Management System (QMS) improvements.
- Increased chances of obtaining certain forms of certification (e.g. ISO certification) as well as the related benefits.
- Increased supply chain transparency, which enables companies to address ethical and labour issues as well as environmental challenges.

Furthermore, the Master Thesis project concluded that digitisation of paper-based processes, within the area of document management, is necessary in order for companies to be able to compete and survive as competition steadily increases. This is especially true for companies that are handling complex products. Hence, the Master Thesis identified a number of benefits related to the implementation of a digital DMS solution. Some of these are:

- Elimination of time and resource consuming paper-based processes.
- Improved track and traceability.

- Ability to automate processes.
- Improved communication and collaboration with supply chain partners.
- Reduced need for 'industrial tourism' (i.e. the need for staff to be onsite to control, document and evaluate production).
- Ability to leverage more advanced technological capabilities.

Lastly, the Master Thesis project resulted in the creation of a framework supporting the implementation of a digital DMS. The framework that was created consists of four phases (*Pre-Installation, Installation, Post-Installation* as well as *Evaluation and Corrective Action*) and each phase was consequently divided into a set of *critical steps* that companies should follow in order to assure successful implementation results.



**Keywords** Connected Manufacturing, Digitisation, Documentation, Document Management, Industry 4.0, Internet of Things, ISO, ISO 9000

# Terminology and Acronyms

## Terminology

The following section contains terminology used throughout the Master Thesis report and defines how the expressions have been used in the report. Some of the definitions might therefore differ from the general agreed-upon definition.

| | |
|---|---|
| *Bill of Materials* | List of materials that may be required by a contractor in order to complete a contract, or by a supplier/vendor in order to complete an order. Contains information regarding the raw materials, parts, intermediates and subassemblies that are required to construct, overhaul or repair something. |
| *CodeIT* | CodeIT AS |
| *Complex Manufacturing* | Manufacturing that is characterised by a mix of long design and/or production cycles, many components and the use of multiple production departments or facilities. |
| *Complex Product* | A product that is a result of complex manufacturing. |
| *Customer* | Anyone who is affected by the product or by a process used to produce the product. Customers may be external or internal. |
| *Customer dissatisfaction* | A state of affairs in which customers feel that their expectations have not been met due to deficiencies in goods or services. May result in customer annoyance, complaints or claims**.** |
| *Customer satisfaction* | A state of affairs in which customers feel that their expectations have been met by the product features. |
| *Digitalisation* | Refers to the implementation of digital or computer technology. Throughout the Master Thesis report, the term may also refer to *digitisation,* i.e. the conversion of analogue data into digital form. |
| *Deficiency* | Any fault (defect or error) that impairs a product's fitness for use. Deficiencies take such forms as office errors, factory scrap, power |

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| | outages, failures to meet delivery dates, and inoperable goods. |
| *Discrete Manufacturing* | Production of a discrete category of goods (for example automobiles, aircrafts, computers, component assemblies etc.). |
| *Document* | Information and its supporting medium. A document could be any written item (for example a book, letter or computer data file) of a factual or informative nature. |
| *Document Management System* | A system for creating, storing and managing documentation within for example a company or organisation. May be either completely or partially digitalised. |
| *Enterprise Resource Planning System* | Software tool for identifying and planning the resource needs of an enterprise or organisation. The software tool provides one user-interface for the organisation to manage for example product planning, purchasing, inventory control, distribution and logistics, production as well as tracking and tracing. |
| *Industrial Tourism* | The need for staff to be onsite to control, document and evaluate production. |
| *Inspection and Test Plan* | A set of documents containing a detailed step-by-step list of operations and requirements where a supplier identifies the process of how, why, when and who will perform tests or inspections of produced products throughout the supply chain. |
| *Instruction and Operating Manual* | A guide used to describe activities regarding for example the handling of a produced product or a certain piece of equipment (i.e. a 'user guide'). |
| *Key Performance Indicator* | A means of measuring the efficiency of a process. |
| *Manual system* | System in which certain processes and activities have not been digitised or automated, and to some extent still are performed 'by hand' (i.e. manually). May also be referred to as a paper-based or non-digital system. |
| *Manufacturing Execution System* | A computerised system used for documenting, controlling and managing manufacturing processes. The system includes machines, |

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| | personnel and supporting activities. System applications aid in the tracking of activities as well as resources and may be integrated with other applications used in purchasing, inventory control, maintenance, scheduling and so on. |
| *Manufacturing Record Book* | A collection of all verifying documentation necessary in order to ensure that a company's equipment, material and products comply with company, customer and authoritative regulations. May also be referred to as a Manufacturing Data Record. |
| *Material Safety Data Sheet* | Document containing important information regarding the characteristics as well as actual and/or potential hazards of a material or substance. Identifies the manufacturer of the material and commonly includes information regarding chemical identity, hazardous ingredients, physical and chemical properties, fire and explosion data, reactivity data, exposure limits data, precautions for safe storage and handling, need for protective gear as well as disposal and clean-up procedures. |
| *Material Test Report* | A quality assurance document (often used for metals) that certifies a material's chemical and physical properties as well as states its compliance to a specific set of specifications or standards. |
| *Overall Equipment Effectiveness* | A tool for business performance management that critically evaluates how effectively a manufacturing operation is utilised. |
| *Operational Level Agreement* | Agreements between IT service provider and other internal part of the same organisation. |
| *Procedure* | Specified way of carrying out an activity or process. |
| *Product* | Throughout the Master Thesis report, the term is used to describe the output of any process and includes both goods and services. |
| *Product Feature* | A property possessed by goods or services that is intended to meet customer needs. |

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| *Project Quality Plan* | Detailed, step-by-step list of operations and requirements where a supplier identifies a process of how, what, why, when and who will perform tests or inspections. The applicable acceptance criteria are also listed. It is also referred to as an Inspection and Test Plan (ITP). |
| *Quality Assurance* | Activity conducted to evaluate quality of a produced product (during fabrication) by comparison it to its quality goals. The prime purpose is to serve those who are not directly responsible for conducting operations but who have a need to know. |
| *Quality Control* | Similarly to quality assurance, quality control is also conducted in order to evaluate quality of a produced product by comparison it to its quality goals. The prime purpose is to serve those who are directly responsible for conducting operations in order to help them regulate current operations . |
| *Quality Management System* | A set of policies, processes and procedures within a company required for reaching the pre-set goals regarding quality management. |
| *Quality Manual* | A Document specifying an organisation's quality management system. |
| *Quality Plan* | The quality plan constitutes a document that specifies the processes of the quality management system (including the product realisation process) and the resources to be applied to a specific product, project or contract. |
| *Record* | A specific type of verifying document stating achieved results or providing evidence of performed activities. |
| *Traveller* | A list or record of instructions that follows a component, part or product throughout a manufacturing process. |

# Acronyms

The following section contains acronyms used throughout the Master Thesis report.

| | |
|---|---|
| *AIDC* | Automatic Identification and Data Capture |
| *ASME* | American Society of Mechanical Engineers |
| *AutoID* | Automatic Identification |
| *BOM* | Bill of Materials |
| *CSF* | Critical Success Factors |
| *DHP* | Document Hierarchy Pyramid |
| *DMS* | Document Management System |
| *DOSH* | Department of Occupational Safety and Health |
| *ERP* | Enterprise Resource Planning |
| *FDA* | (U.S) Food and Drug Administration |
| *GMP* | Good Manufacturing Practice |
| *IOM* | Instructions and Operations Manual |
| *IOS* | Inter-Organisational System |
| *IoT* | Internet of Things |
| *ITP* | Inspection and Test Plan |
| *KPI* | Key Performance Indicators |
| *MDR* | Manufacturing Data Record |
| *MRB* | Manufacturing Record Book |
| MSDS | Material Safety Data Sheet |
| *MTR* | Material Test Report |
| *NDT* | Non-Destructive Test |
| *OEE* | Overall Equipment Effectiveness |
| *OLA* | Operational Level Agreement |
| *PDMA* | Product Development and Management Association |
| *PQP* | Project Quality Plan |
| QMS | Quality Management System |
| *QP* | Quality Plan |
| *RTD* | Real Time Data |
| *SaaS* | *Service as a Software* |
| *SME* | Small and/or Medium-sized Enterprise |
| *WIP* | Work in Progress |

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# 1 Introduction

This chapter aims to give the reader a brief introduction to the subject of industrial document management. It begins with a presentation of the background and the problem description and continues with presenting the project delimitations, the goal and project objectives as well as the research questions that the Master Thesis aims to answer. Lastly, an overview of the report structure is illustrated.

## 1.1 Background

Technological advancements over the last decades have resulted in an increased degree of digitalisation within as well as in between companies around the world. By the year 2020 a complete generation, so called *Generation C* (C for Connected), will have grown up in a highly digitised environment where Internet, smartphones and communication through social media is a part of everyday life[1]. Consequently, a gradually increasing degree of digitalisation within companies will result in streamlining of activities, new ways of meeting customer needs and demands as well as the ability to reach new markets. The worldwide increase of digitalisation will also result in that higher requirements are put on companies of the future. In order to stay competitive in our increasingly digitalised environment, all companies (no matter size or industry) will have to adapt to the digital development sooner or later. This might in some cases result in that companies are forced to invest in certain technologies, even though they might deem them unnecessary at the time[2].

One area for which this is relevant and where there is still a lot of potential for improvement is industrial document management (i.e. the processes for creating and managing documents and records within companies). A company's document management system (DMS) defines its ability to create, store and manage documentation. A well-functioning DMS consequently facilitates the process of quickly finding and accessing desired information within a company database. If utilised properly the system also enables companies to assure a certain level of quality in their operations and to improve traceability (a requirement that is becoming increasingly important for companies all over the world). In some industries (for example in the airline, aircraft as well as the oil and gas industry) there are legislations, regulations and standards regarding traceability that companies are required to follow. Furthermore, in many industries it is also more or less a mandatory requirement for companies to keep transparent and comprehensive in-depth documentation regarding specific processes or operations. As a result, companies within these industries have to be able to both generate and process huge volumes of documents and to be able to fully comply with the existing requirements, companies need functioning DMSs. Moreover, as documentation is an essential part of a company's quality management system (QMS)[3], the activities

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[1] Strategy& PwC, 'Digitization: The Digitization megatrend', *Strategy& PwC* [Website], 2016, <http://www.strategyand.pwc.com/global/home/what-wethink/digitization/megatrend>, accessed 18 Jan. 2016.

[2] G. Westerman, D. Bonnet & A. McAfee, *Leading Digital: Turning technology into business transformation*, Harvard Business Review Press, Boston Massachusetts, 2014, pp. 22-23.

[3] K.T. Patel & N.P. Chotai, 'Documentation and Records: Harmonized GMP Requirements', *Journal of Young Pharmacists*, vol. 3, no. 2, 2011, p. 142.

related to quality control and assurance are also greatly affected by the level of its DMS. This implies that a well-functioning DMS also enables improvements in a company's QMS, which in turn increases its chances of obtaining certain forms of certification related to quality management, for example ISO 9000 (a standard series concerning documentation and quality management[4]).

In conclusion, the need for proper document management should not be overlooked as a well-functioning DMS helps companies to increase both effectiveness and efficiency of document management-related processes. This consequently enables improved financial as well as operational results, and thus also improves a company's performance in general. However, in order for companies to survive in an environment in which competition is steadily escalating, optimisation is crucial. In spite of this, many companies still utilise paper-based (i.e. manual) systems and aging technologies for managing company documentation, which consequently inhibits them from optimising operational and financial results. Hence, in order to achieve optimal results, increased digitalisation (i.e. the implementation of a digital DMS solution) is inevitable.

## 1.2 Problem Description

The Master Thesis project addresses mainly two problem areas. The first concerns the effects of document management in general, and the second concerns the process of implementing a digital DMS solution. Each problem area is described in further detail in the following sections.

First of all, it can be concluded that a company's DMS may have great affects on its financial and operational results. This is especially true for companies dealing with complex products, as their documentation needs are generally high. Establishing structures and routines for handling document management may lead to financial and operational improvements but in order to optimise results, digitisation of these activities is more or less necessary. However, in spite of the potential gains that effective and efficient DMSs may generate, many companies today are still turning a blind eye to this. Hence, there seems to be a common misconception regarding the effects of document management. Therefore, the first problem area addressed by the Master Thesis is the general lack of knowledge regarding DMSs, their effects as well as why companies should strive for developing digital DMS solutions.

Secondly, the process of implementing a digital DMS ultimately affects the performance results of the system. In other words, if the implementation process is not performed properly, there is a chance that the desired results will not be met. Today there does not exist any comprehensive digital solutions for document management, and for this reason, there does not either exist any general guidelines that facilitate the process of effectively and efficiently digitalising document management related activities. This is the second problem addressed by the Master Thesis.

[4] International Organisation of Standardisation, 'ISO 9000 Introduction and Support Package: Guidance on the Documentation Requirements of ISO 9001:2008', *International Organisation of Standardisation*, Document: ISO/TC 176/SC 2/N 525R2, 2008, p. 1.

## 1.3 Delimitations

This Master Thesis project was limited to investigate and analyse document management processes within manufacturing and service providing companies. The effects of implementing a digital system for document management, i.e. a digital DMS, were studied and focus was set on investigating how companies can achieve a successful implementation. Moreover, the thesis was conducted with a generic approach and does therefore not aim to improve nor develop any of the existing systems or solutions for document management. Due to the generic nature of the study, the Master Thesis does not either go into detail or provide complete descriptions regarding the technical features of the existing digital solutions for document management.

During the Master Thesis project was limited to a series of interviews were conducted with Bjørnar Torsnes, the CEO and founder of CodeIT AS (CodeIT). Furthermore, any areas that are not covered by the report are suggested for future research.

## 1.4 Goal and Project Objective

The objective of the Master Thesis project was to develop a generic framework supporting the implementation of a digital DMS. The aim of the framework was to provide guidelines that facilitate the process of effectively and efficiently implementing such a system, and in turn enable companies to fully obtain the potential benefits related to a digital DMS.

## 1.5 Research Questions

In order to better understand the concept of document management and to be able to better address the task at hand, a set of research questions were formed. Consequently, the research questions that the thesis aimed to answer were:

RQ1: *What are the main issues related to manual DMSs?*

RQ2: *How does document management influence quality assurance and quality control activities?*

RQ3: *What are the incentives for companies to develop effective and efficient DMSs?*

RQ4: *What are the potential benefits of implementing a digital DMS?*

RQ5: *What aspects should be considered when implementing a digital DMS?*

## 1.6 Deliverables

The project generated the following deliverables:

- Framework supporting the implementation of a digital DMS.
- Master Thesis report for public presentation.
- Public seminar at Lund Faculty of Engineering.
- Scientific paper.

## 1.7 Structure of the Thesis

The structure of the Master Thesis report is presented in the following sections.

### Chapter 1 - Introduction
This chapter aims to give the reader a brief introduction to the subject of industrial document management. It begins with a presentation of the background and the problem description and continues with presenting the project delimitations, the goal and project objectives as well as the research questions that the Master Thesis aims to answer. Lastly, an overview of the report structure is illustrated.

### Chapter 2 - Methodology
This chapter describes the methodology that has been chosen for the project and begins with a presentation of the research approach and research purpose of the project. The chapter continues with describing the research strategy, the data collection methods as well as the data analysis technique used throughout the project. Further on, the chapter presents an illustration of the work process and finally the chapter is concluded with a general discussion regarding how to attain validity and reliability in a study.

### Chapter 3 - Literature Review: Document Management
In this chapter, the literary background of document management and related concepts is presented. The chapter covers general requirements as well as ideas about current systems for document management and provides the reader with an understanding of essential concepts within the area. The chapter aims to give the reader a general understanding of the subject and its scope, which in turn is necessary in order to understand the upcoming analysis, discussion and conclusions. The information presented in this chapter is collected through literature studies and qualitative content analysis of books, journals and other general publications within the studied area. Consequently, this chapter may be disregarded if the reader possesses previous knowledge of the subject.

### Chapter 4 - Literature Review: ISO Standardisation and Certification
This chapter consists of a literary review of the concept of ISO standardisation. The chapter focuses on the ISO 9000 standard series (primarily the ISO 9001 and ISO 9004 standards), which is considered to be one of the world standards for quality management. General requirements, benefits as well as ideas about the ISO 9000 standard series are covered and the chapter aims to provide the reader with an understanding of essential concepts related to the area. The information presented in this chapter is mainly collected through literature studies and qualitative content analysis of books, journals and other general publications within the studied area. Furthermore, if the reader possesses prior knowledge of the subject, this chapter may be skipped.

### Chapter 5 - Literature Review: Digitisation Trends
This chapter aims to provide the reader with an understanding of current digitalisation trends. Concepts such as *Industry 4.0*, *Internet of Things (IoT)* and *Connected Manufacturing* are introduced, and general explanations of current digitalisation trends within the manufacturing industry are presented.

### Chapter 6 - Generic Description of a Digital Document Management System
Chapter 6 presents a generic description of a potential digital DMS solution. The chapter begins with a brief summary of the product realisation process (PRP) as well a general description of the flow of documents throughout this process. This is followed by a presentation of the major issues related to non-digital DMS solutions. Lastly a

requirement set-up for the digital DMS solution is formed, and to each requirement a corresponding feature that aims to fulfil it is presented. However, since the description of the digital DMS is generic in nature, it does not take factors such as size, industry or specific operational goals of individual companies into account. Instead, the theoretical description of the digital DMS aims to provide the reader with a generic definition of the digital DMS concept.

### Chapter 7 - Framework 1.0

In this chapter a first version of the generic model for implementation of a digital DMS is presented. The chapter begins with a introducing a general implementation-model and continues with a stepwise description of the preliminary framework for implementation of a digital DMS i.e. *Framework 1.0*. The framework is divided into four different phases (*Pre-Installation, Installation, Post-Installation* and *Evaluation and Corrective Action)*, which are presented in chronological order. Lastly, the chapter is concluded with a summary of *Framework 1.0*.

### Chapter 8 - Case Study: CodeIT and the eMRB

In this chapter data from an empirical case study at the case company (CodeIT) is presented. The main part of the empirical data presented in this chapter has been collected through a series of open and semi-structured interviews as well as conversations with the CEO and founder of CodeIT, Bjørnar Torsnes. The remaining part has been collected through archival data analysis, based on a set of business documents received from the company. During the case study, a new software solution for digital document management, the *CodeIT eMRB* (eMRB) software, has been investigated. The purpose of the case study was to analyse the eMRB in order to identify features that might affect its implementation process.

### Chapter 9 - Framework 1.1

In this chapter the updated version of the framework described in Chapter 7, *Framework 1.0*, is presented. Findings from the empirical case study have been compared to *Framework 1.0*, and accordingly new features have been added to the framework design in order to create a more comprehensive model. The chapter begins with an analysis of the findings from the empirical study, and is concluded with a presentation of the final model of the framework for implementation of a digital DMS, i.e. *Framework 1.1.*

### Chapter 10 - Discussion and Conclusions

The tenth and final chapter of this Master Thesis report begins with presenting answers to the research questions listed in *chapter 1.5 – Research Questions*. This is followed by a concluding discussion regarding the validity and reliability of the project results and further on, the academic as well as de general contribution of the Master Thesis project is presented. Lastly, the chapter is concluded with a presentation of recommendations for further studies.

# 2 Methodology

This chapter describes the methodology that has been chosen for the project and begins with a presentation of the research approach and research purpose of the project. The chapter continues with describing the research strategy, the data collection methods as well as the data analysis technique used throughout the project. Further on, the chapter presents an illustration of the work process and finally the chapter is concluded with a general discussion regarding how to attain validity and reliability in a study.

## 2.1 Research Approach

Data can either be qualitative or quantitative. Quantitative data is classified as data that can be counted or categorised, i.e. numbers, shares, weight, colour and so on. Qualitative data on the other hand consists of words and descriptions and contains a high level of detail and nuances. When analysing quantitative data one uses statistics while qualitative data is analysed by categorisation and sorting[5]. Studies can be either quantitative, qualitative or a combination of both. The latter can be referred to as "mixed methods" and often provides a better understanding of the studied phenomenon[6]. Furthermore, a research process may be either fixed or flexible[7]. In a research process with a fixed design, all parameters are defined at the start of the project. In a research process with a flexible design on the other hand, the key parameters can be changed throughout the project[8].

For this thesis, a qualitative approach was chosen since in-depth knowledge and understanding of the problem had to be obtained. Moreover, the research questions and sources of data were not fixed in advance and therefore a flexible research process has been used throughout the project.

## 2.2 Research Purpose

The choice of research methodology or strategy depends on the research purpose, i.e. one type of methodology does not serve all purposes. There are mainly four different types of research purposes:

- *Exploratory* – aims to find out what is happening, seeks new insights and gathers ideas and hypotheses for new research.
- *Descriptive* – portrays or describes a situation or phenomenon.
- *Explanatory* – seeks explanations of situations or problems.
- *Improving* – tries to improve a certain aspect of the studied phenomenon[9].

In general, the area of industrial document management man is still fairly unexplored. Large amounts of data has therefore been collected, examined and analysed in order to get a better understanding of the systems for document management that are currently

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[5] M. Höst, B. Regnell & P. Runeson, *Att genomföra examensarbete*, Studentlitteratur, Lund, 2006, p. 30.
[6] P. Runeson & M. Höst, 'Guidelines for conducting and reporting case study research in software engineering', *Empirical Software Engineering*, vol. 14, 2008, p. 136, doi:10.1007/s10664-008-9102-8.
[7] C. Robson, *Real World Research*, 2nd ed., Blackwell, Oxford, 2002, cited in Runeson & Höst, 2008, p. 136.
[8] Runeson & Höst, 2008, p. 136.
[9] Ibid.

being used and to create a deeper understanding of the subject. For this reason, the research purpose is primarily descriptive and exploratory. However, as the information gathered during the Master Thesis project has been used to develop a framework that aims to facilitate (i.e. improve) the process of implementing a digital DMS within companies, the research purpose is also partially improving.

## 2.3 Research Strategy

Depending on what type of study that is being conducted, different methodological strategies may be used. Within applied science there are mainly four different approaches, namely *action research, surveys, case studies and experiments*[10].

### *2.3.1* Action Research

The action research strategy is a carefully monitored and documented study of an activity that aims to solve a problem[11]. An action research study starts by observing a situation or a phenomenon within an entity. In action research observing is generally done closer to the phenomenon than in for example case studies, and these studies often also aim to affect the phenomenon being studied. The aim is to identify or clarify a problem that needs solving by the use of e.g. questionnaires, interviews, observations and archival data analysis. The next step of action research is to develop a primary solution to the identified problem. When a primary solution has been developed it should then be evaluated, e.g. by observing the implementation as well as analysing and reflecting over the result. The action research approach is an iterative process. In other words, if the created solution does not solve the identified problem or if new problems occur after implementing the solution, the process is repeated until acceptable results are achieved [12].

Action research is suitable when conducting a study with an improving research purpose[13]. For studies that apply the action research strategy, a flexible research process is most commonly used.

### 2.3.2 Survey Studies

Survey studies are conducted by sample-based questioning, e.g. by the use of questionnaires. This type of study includes summaries and descriptions of the current situation of the object or phenomenon that is studied[14]. Furthermore, survey studies often aim to answer broadly formulated research questions[15] and can be used to describe for example how many people that use a certain computer program, or to identify what the most urgent problems within a company are[16]. The survey study strategy is a suitable when the research purpose is descriptive or exploratory[17].

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[10] Höst, Regnell & Runeson, 2006, pp. 30-31.
[11] Ibid.
[12] Ibid, p. 39.
[13] Ibid.
[14] Ibid, pp. 30-31.
[15] Ibid.
[16] Ibid p. 31.
[17] Ibid.

### 2.3.3 Case Studies

As the name implies a case study describes a specific case, using a system approach with defined interfaces and limitations. The case is often chosen with a specific purpose in mind and it should not always be assumed that the results of one single case study could be generally applied to other situations[18]. Case studies aim to make in-depth descriptions of a phenomenon or an object[19] and are therefore suitable for studies with descriptive purposes. The case study methodology can for example be used within an organisation to better be able to understand internal processes[20]. Observations, interviews and archive analysis are examples of techniques that are commonly used when conducting a case study[21].

### 2.3.4 Experiments

Experiments are used to identify causality and to explain what causes a certain phenomenon[22]. This strategy can be used to compare different technical solutions during specific circumstances, but may also involve people and human behaviour. The research process for experiments has a fixed design i.e. nothing in the design can be changed when the experiment has started[23]. The data collected during an experiment is mainly quantitative[24] but this data may also be complemented with qualitative evaluations of for example how the experiment was performed.

### 2.3.5 Applied Strategy: Single-Case Study

Since the parameters of the study were not defined from the start of the project, a flexible research process was deemed suitable. Furthermore, as the research purpose was exploratory, descriptive and partially improving, both the action research and the case study strategy were considered viable options. However, studies applying the action research strategy aim to affect the phenomenon being studied, which was not the goal in this project. Therefore, the strategy chosen for this Master Thesis project was the case study strategy, and more precisely the single-case study strategy. This was partially due to the extensive literature review that had to be conducted in combination with the project time limit. The case study was been performed at a fast growing Norwegian software company that provides a digital solution for document creation and management. The purpose of the case study was mainly to gather information about and analyse a new and innovative system for digital document management, in order to identify characteristics that might affect its implementation process. Furthermore, in order to collect relevant data, case study methodology was applied.

## 2.4 Data Collection Methods

There are many different sources that can be used for data collection when conducting a study and in order to increase credibility, it is important to utilise multiple sources. If the same conclusion can be drawn from multiple information sources, the conclusion will be stronger than a conclusion based solely on one source of information[25]. This is

[18] Höst, Regnell & Runeson, 2006, p. 34.
[19] Ibid, p. 33.
[20] Ibid.
[21] Ibid, p. 34.
[22] Ibid, p. 36.
[23] Ibid, p. 35.
[24] Ibid, p. 37.
[25] Runeson & Höst, 2008, p. 144.

referred to as triangulation and is discussed in *chapter 2.7 – Validity, Reliability and Representativeness.*

In this study, primarily a combination of literature reviews, archival data analysis and interviews has been used for collecting data.

### 2.4.1 Literature Review

Reviews of literature within relevant areas have been conducted in order to collect large amounts of information and to map the already existing knowledge within the field of the study. For this study, several books and articles regarding the area of industrial document management has been studied. In order to find trustworthy literature relevant to the study, mainly the library catalogue of Lund University (Lovisa) as well as the search engine LUBsearch have been used.

### 2.4.2 Interviews

Interview-based data collection is a method in which the researcher (the interviewer) asks a series of questions to a group of subjects (respondents or interviewees) regarding the area of interest of the study. This leads to a dialogue between the researcher and the subject, which is guided by a set of interview questions[26].

The respondents that participate in the interviews are selected through stratification, meaning that different categories are defined and then the respondents are selected from these categories. These categories can be based on for example gender, roll at a company, level of experience and so on. One issue with selecting respondents through stratification is that the selection is not random, which means that general conclusions of the population cannot be drawn. However, this selection method allows for qualitative in-depth studies of the area[27].

An interview can be structured in different ways depending on its goal. In general, there are three different interview structures: structured, semi-structured and open interviews[28]. A structured interview is basically an orally performed questionnaire, i.e. an interview that strictly follows the guidelines of the interview guide and has fixed questions[29]. In an openly structured interview on the other hand, the researcher follows an interview guide that only contains different question areas. Depending on the respondent, the questions can be formulated in different ways and they do not either have to be asked in any particular order. In other words, an open interview is focused on the areas that the respondent is most willing to answer questions about[30]. Lastly, a semi-structured interview is a mixture between a structured and an open interview. In a semi-structured interview the researcher combines open and fixed questions.

An advantage with using interviews as a method for data collection is its flexibility. During an interview, it is possible to modify the interview questions depending on the answers that are given by the respondent. It is also possible to pose follow-up questions and to go in deeper into motives and feelings, which opens up the possibility for a

[26] Runeson & Höst, 2008, p. 145.
[27] Höst, Regnell & Runeson, 2006, p. 90.
[28] Ibid.
[29] Ibid, p. 91.
[30] Ibid, p. 90.

deeper level of understanding of the research subject[31]. An issue with interview-based data collection however is that the process can be relatively time consuming. It is also a subjective method for data collection, which means that there is a risk for biased results[32].

During this Master Thesis project, a series of open and semi-structured interviews have been conducted with the CEO and founder of the Norwegian software company CodeIT. These interviews consequently created the foundation for the case presented in *chapter 8*. The initial interview was held in Oslo, Norway, at CodeIT's head office and throughout the Master Thesis project, the author has had regular correspondence with the case company. The completing interviews have been performed via web-based communication and telephone. The open interview structure was chosen in order to enable the respondent to talk freely about certain areas relevant to the subject at hand. Consequently, the flexibility of the open interview structure also enabled the author to naturally pose follow up questions, which allowed for more detailed answers. Shorter semi-structured interviews were mostly used as a complement to the open interviews, in order to fill information gaps.

Furthermore, a series of open interviews have also been conducted with the project supervisor, Bertil I Nilsson, who has several years of experience working with quality control and assurance. These interviews have been performed continuously throughout the project and their aim has mainly been to contribute to a better understanding of the studied area. Due to the unstructured nature of many of the interviews that have been conducted with Mr Nilsson, as well as the fact that they have been performed on a continuously throughout the writing of this thesis, the results from them are not presented together with the rest of the empirical data in *chapter 8*. Instead, the interviews have been used to complete information gaps in the literature review, and are hence presented on going throughout the report.

### 2.4.3 Archival Data Studies

Archival data studies are conducted by studying company documentation (for example documents from different development phases, organisational charts, financial records or previously collected measurements in an organisation)[33]. This data collection method can also involve the studying and analysing of protocols and correspondences[34] within a company or organisation.

It is important to keep in mind that archival data is not originally produced with the intention to provide data in a certain type of study. In some cases, this type of data might include parts that are mandatory according to an organisational template but that have no relevance for the study that is being conducted. It should also be mentioned that some information that is needed by the researched might be missing in this type of data. In turn, the analysis must be combined with other data collections methods in order to

[31] J. Bell, *Introduktion till forskningsmetodik*, 4th ed., tr. B. Nilsson, Studentlitteratur, Lund, 2006, p. 158.
[32] Ibid, p. 158.
[33] Runeson & Höst, 2008, p. 148.
[34] Höst, Regnell & Runeson, 2006, p. 90.

increase the chances of obtain the missing data[35]. The data collected by the use of this method can be both qualitative and quantitative[36].

Archival data, in the form or business documents, from the case company has been used in combination with the interviews (described in *chapter 2.4.2 – Interviews*) in order to create the foundation for the case presented in chapter 8. Hence, potential information gaps in the archival data have been filled by interviews with the case company and vice versa.

## 2.5 Data Analysis

For studies that apply a flexible research process, qualitative methods for data analysis are commonly used[37]. Therefore, qualitative data analysis methods are applied in this project as well.

The basic objective of qualitative data analysis is to develop conclusions from the data while keeping a clear chain of evidence. This means that the reader should be able to follow the development of the results and conclusions from the collected data[38]. Analysis of qualitative research is also characterised by that the analysis is performed in parallel with the data collection and the use of systematic analysis techniques[39].

The data analysis technique chosen for this project is Grounded Theory. The main methodological focus of the analysis technique is to develop a theory without relying on any specific category of data, research focus or theoretical interest[40]. In other words, theory is not defined in advance but emerges and develops as the research proceeds[41]. This data analysis technique is based on an iterative process where theoretical insights arise and develop from data, after which the insights are tested with regard to other data that has been collected in order to determine whether it has any significance. This consequently generates and develops new theoretical insights, which are then tested in the same way[42]. In general, theories created by the use of the Grounded Theory principals can in some cases become context specific, which in turn means that they can only be applied to a relatively small amount of situations. On the other hand, since the theory is grounded in data that has been gathered from reality, it can be used as a solid

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[35] Flynn et al., 'Empirical research methods in operations management', *Journal of Operations Management*, vol. 9, no. 2, 1990, pp. 250–284, cited in Runeson & Höst, 2008, p. 148.
[36] Höst, Regnell & Runeson, 2006, p. 35.
[37] C. Seaman, 'Qualitative methods in empirical studies of software engineering', *IEEE Transactions on Software Engineering*, vol 25, no. 4, 1999, pp. 557-572, cited in Runeson & Höst, 2008, p. 150.
[38] R.K. Yin, *Case study research: design and methods*, 3rd ed., Sage Publications, Thousand Oaks, 2003 cited in Runeson & Höst, 2008, pp. 150-151.
[39] Runeson & Höst, 2008, p. 151.
[40] A.L. Strauss, *Qualitative analysis for social* scientists, Camebridge University Press, Camebridge, 1987, p. 5, cited in Bell, 2006, pp. 27-28.
[41] Bell, 2006, p. 28.
[42] N. Hayes, *Doing psychological research: gathering and analysing* data, Open University Press, Buckingham, 2000, p. 184, cited in Bell, 2006, p. 28.

base for further investigation and research and the generated theory still has significant meaning as a result of research[43].

A common approach when working with Grounded Theory is to begin with developing research questions and generally, one does not begin with formulating hypotheses or doing a complete review of literature relevant to the subject. Instead, a theory is built by analysing the data continuously throughout the data collection process. The results are reviewed at the same time as data collection is in progress and the data is then analysed before additional information is collected. This process goes on until 'theoretical saturation' is reached. Theoretical saturation refers to the point when the collected data begins to confirm what has already been concluded, rather than results in new theoretical elements that help develop the theory[44]. However, one thing to keep in mind is that knowledge and understanding of a situation or process is obtained gradually during the time it is studied. The longer it is studied, the more layers of knowledge and understanding seem to appear. In turn, this makes it hard to determine when the analysis can be concluded. In other words, if time or economic resources do not limit the project, research and analysis might go on for a long time[45]. Since this project has had a limited timeframe, the latter was not an issue.

## 2.6 Work Process

The Shewart-cycle is a model that illustrates a general method for working with development. It includes the following steps:

1. *Plan* – identify the problem and what causes it.
2. *Do* – suggest and implement improvements that solve the problem.
3. *Study* – control that the implemented solutions have led to improvement.
4. *Learn* - if the implemented changes have been successful they shall be made permanent[46].

With the Shewart-cycle in mind, a work process model for the Master Thesis project was developed.

[43] N. Hayes, *Doing psychological research: gathering and analysing* data, Open University Press, Buckingham, 2000, p. 184, cited in Bell, 2006, p. 29.
[44] Ibid.
[45] M.B. Miles & A.M. Huberman, *Qualitative data analysis: an expanded sourcebook*, 2nd ed., Sage, Thousand Oaks, p. 62, cited in Bell, 2006, p. 29.
[46] Höst, Regnell & Runeson, 2006, p. 39.

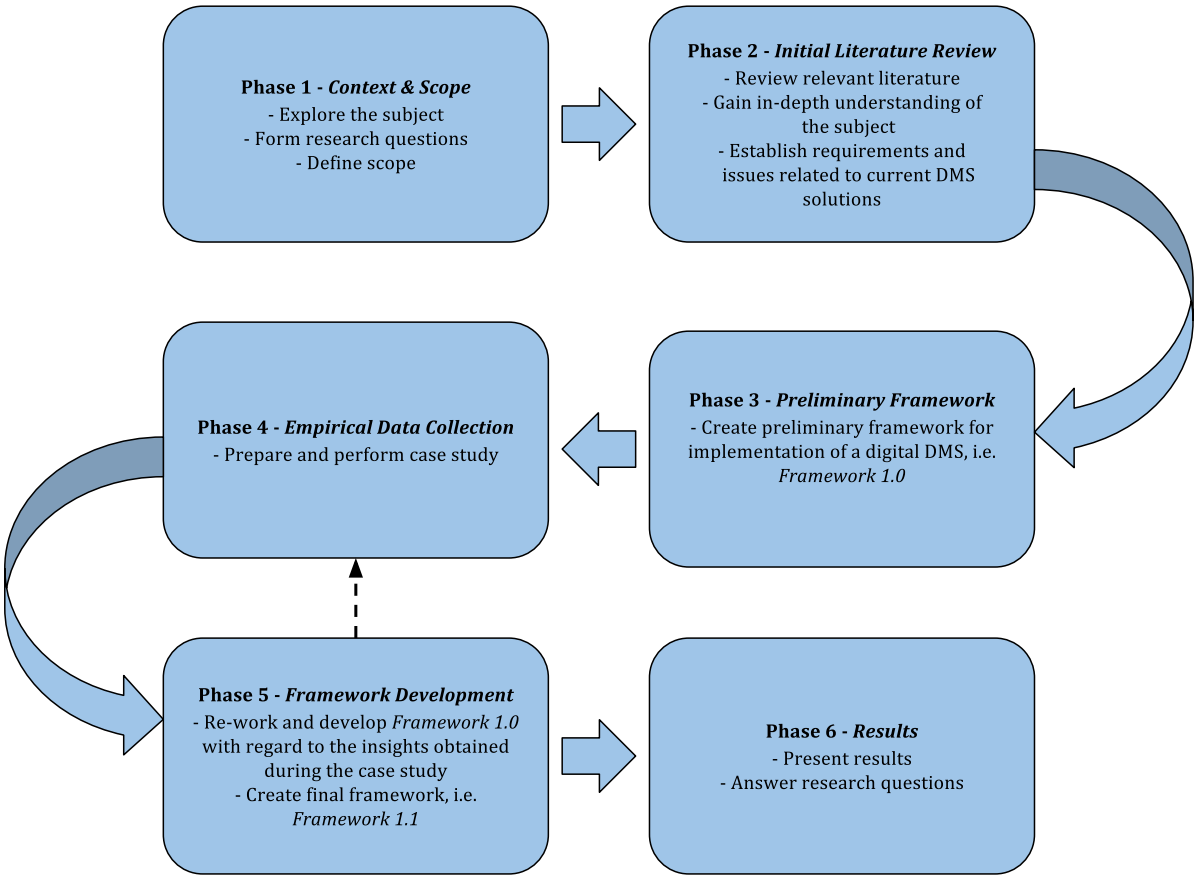


*Figure 1: Work Process Overview*

As illustrated by *Figure 1*, the process has been divided into six phases, namely:

- *Context & Scope*
- *Initial Literature Review*
- *Preliminary Framework*
- *Empirical Data Collection*
- *Framework Development*
- *Results*

During the first phase, *Context & Scope*, the subject of industrial document management as well as quality assurance and control was explored in order to form relevant research questions and to define the scope of the project (i.e. the delimitations). During the second phase, *Initial Literature Review,* an initial review of relevant literature was performed in order to gain in-depth understanding of the subject and to establish requirements and issues for current DMS solutions. Based on the literature review and the research questions, a preliminary framework (i.e. *Framework 1.0)* like the one mentioned in chapter *1.4 - Goal and Project Objective*, was then created in Phase 3. In the fourth phase empirical data was collected from a case study performed at the case company (CodeIT). The goal was to gain insights on how to revise and improve *Framework 1.0*. Empirical data collected during the case study was used for validation and inspiration purposes, and the insights obtained during the case study were then used in the fifth phase to create *Framework 1.1* (i.e. the final version of the framework). Lastly, in the sixth and final phase of the work process, the results were concluded and the research questions formed in Phase two were answered.

The section above presents a linear description of the work process, while in reality the process was more iterative. More precisely, the framework was not finalised after a single interview session. Instead, the framework was 'tested' and reworked after the first interview sessions and then 'tested' again with regard to new empirical data collected through additional interviews (all according to the principles of Grounded Theory). This is illustrated by the dotted line between Phase 4 and Phase 5 in *Figure 1.* However, in order to facilitate for the reader, the results are presented in a linear fashion, i.e. in sequence with the case study findings. Furthermore, data collection and the data analysis were performed simultaneously and continuously throughout the project until the results were finalised. The literature review described in Phase 2 was thereby not concluded at the end of this phase. Moreover, the writing of the thesis was performed continuously throughout the project.

## 2.7 Validity, Reliability and Representativeness

The trustworthiness of a study is denoted by its validity, i.e. to what extent the results are true. To assure validity of a study, it must be considered from the start of the process[47]. The trustworthiness is also affected by the reliability of a study. The reliability depends on to what extent results are dependent on the researcher conducting the study. The reliability is considered high if another researcher conducts the same study later on and obtains the same results. If it is unclear how collected data is coded or how questionnaires and interview guides have been designed, the reliability of the study might be compromised[48]. Another way of judging the results of a study is by evaluating the representativeness, i.e. if the results and conclusions are generally applicable[49]. The results of studies that apply the case study or action research strategy do not usually have a high degree of representativeness[50]. Although, the representativeness increases if the context that the researcher wishes to draw general conclusions about is similar to the context in which the research is conducted. A detailed description of the studied context will also lead to a higher degree of representativeness[51].

One way of increasing the validity of a study is by the use of triangulation, meaning that different angles towards the studied object are taken in order to provide a broader picture of it. This is of great importance when relying primarily on qualitative data, which on the one hand is broader and richer than quantitative data but at the same time less precise[52]. In general, there are four different types of triangulation that can be used:

- *Data source triangulation* – uses more than one data source or collects data at different occasions.
- *Observer triangulation* – uses multiple observers in the study.
- *Methodological triangulation* – combines different types of data collection methods.
- *Theory triangulation* – uses alternative theories or viewpoints[53].

[47] Runeson & Höst, 2008, p. 153.
[48] Ibid, p. 164.
[49] Höst, Regnell & Runeson, 2006, p. 41.
[50] Ibid, p. 42.
[51] Ibid.
[52] Runeson & Höst, 2008, p. 136.
[53] Ibid.

The main methods of triangulation that have been used throughout this project were data source triangulation and methodological triangulation. Since there was only one person conducting the study, observer triangulation was not possible.

Furthermore, analysis often benefits from having multiple researchers since it reduces the risk of biased results[54]. In this project however, there was only one researcher conducting the study. In order to reduce the risk of bias and to increase the credibility of the study, the project supervisor has closely monitored the analysis continuously throughout the project.

[54] Runeson & Höst, 2008, p. 151.

# 3 Literature Review: Document Management

In this chapter, the literary background of document management and related concepts is presented. The chapter covers general requirements as well as ideas about current systems for document management and provides the reader with an understanding of essential concepts within the area. The chapter aims to give the reader a general understanding of the subject and its scope, which in turn is necessary in order to understand the upcoming analysis, discussion and conclusions. The information presented in this chapter is collected through literature studies and qualitative content analysis of books, journals and other general publications within the studied area. Consequently, this chapter may be disregarded if the reader possesses previous knowledge of the subject.

## 3.1 Good Manufacturing Practice

Good manufacturing practice (GMP) is a part of quality assurance. It ensures that products are consistently produced and controlled to the quality standards appropriate to the intended use[55]. According to Patel & Chotai (2011) there are *10 golden rules* for complying with GMP and two of them, rule number 3 and 5, directly emphasise the importance of effective and efficient documentation. The *10 golden rules* are:

1. Get the facility design right from the beginning.
2. Validate processes.
3. Write good procedures and follow them.
4. Identify who does what.
5. Keep good records.
6. Train and develop staff.
7. Practice good hygiene.
8. Maintain facilities and equipment.
9. Build quality into the whole product life cycle.
10. Perform regular audits[56].

According to the basic rules in any GMP, manufacturers should maintain proper documentation and records regarding their products. As a matter of fact, documentation is crucial in order for a company to be able to comply with GMP since it helps ensure traceability of all development, manufacturing and testing activities. Documentation also provides guidelines for auditors to assess a company's quality operations and the produced products[57]. One way to put it is: "if it's not written down, then it didn't happen"[58]. Documentation helps create detailed descriptions of what a manufacturing function has done in the past as well as what it is doing at the moment and thus creates a foundation for planning what is to be done in the future. Effective documentation also enhances the visibility of the quality assurance system. This reduces inspection times since the reviewing and examining of documents is facilitated[59]. It should however be pointed out that there are different regulatory systems and guidelines for GMP around the world[60], some more detailed than others.

[55] Patel & Chotai, 2011, p. 139.
[56] Ibid.
[57] Ibid.
[58] Ibid, p. 138.
[59] Ibid.
[60] Ibid, p. 139.

### 3.1.1 General Documentation Requirements

Effective and efficient documentation is an essential part of the quality assurance system. Procedures that are clearly documented prevent errors resulting from verbal communication and it also permits tracing of activities that have been and are being performed[61]. Preventing errors from occurring is also more effective than finding deviations or rejects within a process, since in many cases it is not possible to detect all of the deviations that occur. Preventive action therefore increases effectiveness within a company's processes[62]. In order to obtain these benefits, documents must be designed, prepared, reviewed and distributed with care. Documents must also be approved, signed and dated by appropriate, competent and authorised personnel. Any correction made to a document or record must be signed and dated[63].

The content of documents must be unambiguous, i.e. the title, nature and purpose should be clearly stated. Documents must be kept up-to-date and be regularly reviewed and therefore, when a document is revised, systems must be updated to prevent unintentional use of the out-dated document[64]. When reproduction of working documents from master documents is necessary, errors have to be counteracted. Changes made to documents should therefore be signed and dated and the alteration should also allow for reading of the original unaltered information. When it is appropriate, the reason for the alteration should also be recorded. If documentation is handled electronically, only authorised personnel should be able to enter or modify data in the computer. Records or changes and deletions should also be kept[65].

Procedures for retaining specific documents (e.g. development history reports, process validation reports, training records, production records and distribution records) must be established in order to facilitate the retention process and the retention periods for these documents should also be specified. During the retention period, originals or copies of records should be available at the establishment where the activities described in the records occurred. If this is not possible, the records should be swiftly and easily retrievable either electronically or from another location[66].

Documents should preferably not be handwritten since this increases the risk of misinterpretation. However, when manual entry of data is required, the entries should be made in clear and legible handwriting and sufficient space must be provided[67].

Records should be kept in such a way that activities and produced products are traceable. Important records must be stored in a secure place with access limited to authorised personnel. The storage location must ensure adequate protection from loss, destruction or falsification and damage (e.g. water damage). Records that are critical to

[61] Patel & Chotai, 2011, p. 140.
[62] Ibid, pp. 138-139.
[63] Ibid, p. 140.
[64] Ibid.
[65] Ibid, p. 143.
[66] Ibid.
[67] Ibid, p. 140.

regulatory compliance or to support business activities must be duplicated (e.g. on paper, micro film or electronically) and stored in a separate, secure location[68].

If documentation is handled by electronic data processing methods, only authorized personnel should be allowed and able to enter or change data in the computer. Access must therefore be restricted by passwords or other means and entry of critical data must be independently checked[69].

### 3.1.2 Hierarchical Documentation – The Document Hierarchy Pyramid

In order to facilitate GMP compliance, it has been suggested that organisations should apply hierarchical documentation. The following sub-chapter presents the *Document Hierarchy Pyramid* (DHP), which is a system that can be used when applying hierarchical documentation within an organisation. Furthermore, the following sub-chapter also provides a brief summary of the most commonly used documents and records.

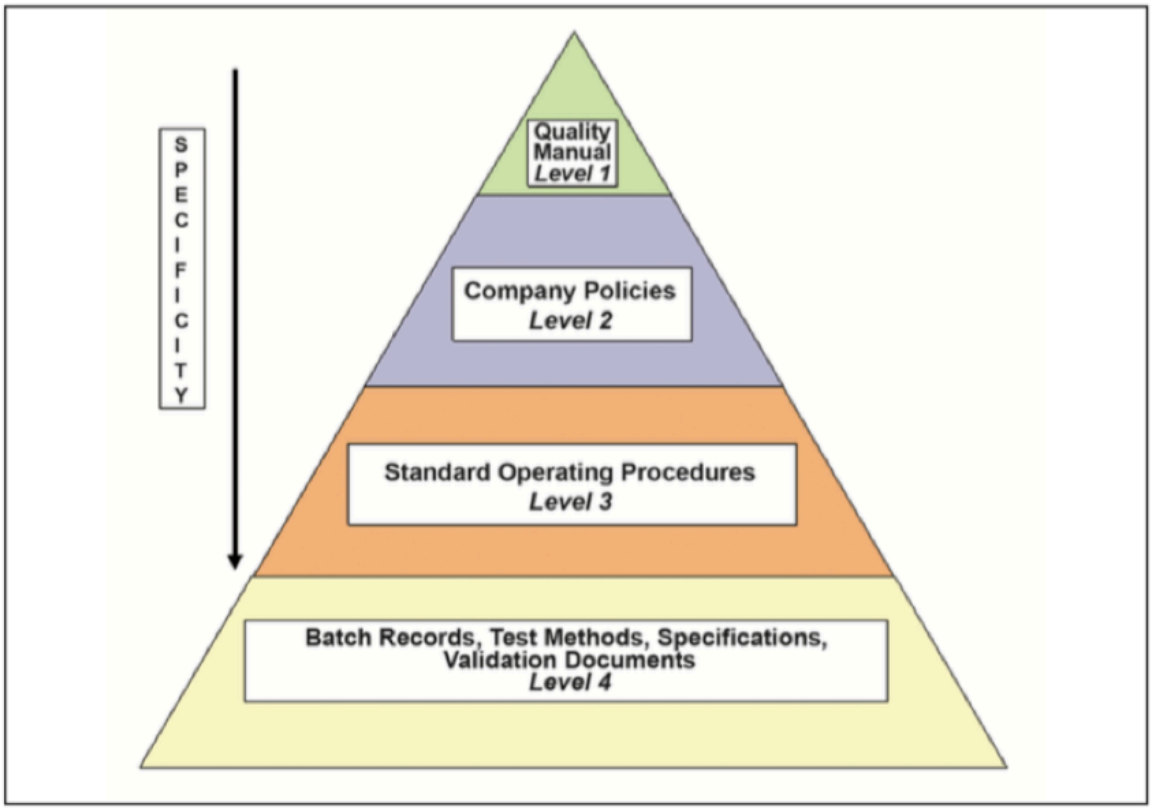


*Figure 2: The Document Hierarchy Pyramid*[70]

The DHP, illustrated in *Figure 2*, creates a hierarchical order for documentation by dividing it into 'levels'. This is done in order to create a comprehensible overview of organisational documentation. As shown in *Figure 2*, the governing documents (for example the quality manual and organisational policies) are placed on top of the DHP whereas more detailed documentation (for example documentation related to specific activities or procedures) is placed at the bottom. The term specificity refers to the amount of detail in the different documentation levels and as the figure implies, the

[68] Patel & Chotai, 2011, p. 140.
[69] Ibid.
[70] Ibid, p. 141.

amount of detail increases downwards in the DHP (i.e. the amount of detail for documentation in *level 4* is higher than in *level 3*).

The DHP is one way of organising a company's documents, although it is possible to add or subtract levels to the pyramid in order to meet the needs of a specific company[71]. The following sections present the different levels of documentation in a basic DHP-model.

### Regulations

First of all, every organisation is responsible for following certain regulations that apply to their specific business or industry (e.g. FDA, GMP, ASME and DOSH). Even though the regulations are not included in the DHP-model, it was deemed important to mention them as they govern the directives of all activities (i.e. all levels of documentation) within an organisation[72].

### Level 1 Documentation: The Quality Manual

The organisation's quality manual is placed at the top of the DHP. The quality manual documents break down and describe the regulations into parts that are specific to those that the company is required to follow [73]. In turn, these documents establish overall principals and guidelines for how the company plans to develop, document and implement a quality system that complies with GMP. In the DHP, the quality manual is referred to as *level 1-documentation*[74].

### Level 2 Documentation: Policies

Policy documents are placed beneath the quality manual in the DHP and are therefore referred to as *level 2-documentation*. Policies are documents that in general terms describe how specific GMP aspects (for example security, documentation, health and responsibilities) will be implemented. These descriptions are not in detail or with step-by-step instructions[75] but provide the overall intentions and guidelines that govern critical programs and systems within the company. They also provide explanations for the rationale and program designs. These documents should apply to all departments within a company that complies with GMP in order to ensure consistency across departments [76].

### Level 3 Documentation: Standard Operating Procedures

The *level 3-documentation* consists of Standard Operating Procedures (SOPs). These documents should provide specific step-by-step instructions for performing operational tasks or activities[77]. An SOP could for example provide instructions for the process of writing, revising, numbering, and distributing controlled documents. SOP documents should be either department specific or function specific[78].

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[71] Patel & Chotai, 2011, p. 141.
[72] Ibid.
[73] Ibid, pp. 140-141.
[74] Ibid, p. 141.
[75] Ibid, p. 140.
[76] Ibid, p. 141.
[77] Ibid, p. 140.
[78] Ibid, p. 141.

### Level 4 Documentation: Batch Records, Test Methods, Specifications, Validation Documents

*Level 4-documentation* consists of batch records, test methods, specifications, and validation documents. *Level 4 documentation* is the most specific in nature within the hierarchical documentation system and applies to a specific department, product or piece of equipment or process. These documents provide step-by-step instructions for activities related to production and also provide the means for documenting such activities, e.g. by using data sheets or forms.

*Batch records*, which constitute one form of *level 4 documents*, are most commonly used and completed by the manufacturing department. They provide step-by-step instructions for activities related to production and also contain space on the record itself for documenting such procedures[79]. Batch records should include complete information relating to the production and control of each batch. They should be containing the unique batch numbers for different batches and be signed when they are issued. This information in combination with the date and time for issuance later serves as an identifier for the different batches. Examples of additional information that should be included in the batch records are:

- Identity of major equipment used for production.
- Product identity and size of batches.
- Weights and measures of products in the batch.
- Results of release testing.
- Decision for release or rejection of the batch including date and signature of the person responsible for the decision.
- Actual results recorded for critical process parameters.
- Any sampling performed.
- Signatures of the persons performing and directly supervising or checking each critical step in the operation.
- Description of packaging and label.
- Any deviation noted, its evaluation, and the investigation conducted (or reference to that investigation).[80]

Another type of *level 4 documents* is called *test methods*. These are documents that are typically used and completed by the quality control department. They provide step-by-step instructions for testing supplies, materials, products and other production-related tasks, e.g. environmental monitoring of the GMP facility. These documents usually contain forms that have to be filled in at the end of each procedure in order to documents the testing and testing results[81].

A third kind of *level 4 documents* lists the requirements that a supply, material or product must meet before being used or sold. These documents are called *specifications*. The quality control department use the specifications to compare their test results in order to determine it they comply with the pre-determined requirements.[82]

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[79] Patel & Chotai, 2011, p. 140.
[80] Ibid, p. 145.
[81] Ibid, p. 140.
[82] Ibid.

The details that are defined in the *level 4-documentation* may disregard directions given in lower level documentation. A company's SOP might state that numbers should be rounded off to three significant figures while the batch record might state that all numbers should be expressed in scientific notation. In this case, the instructions in the *level 4-documentation* can overrule the instruction described in the *level 3-documentation* since the *level 4-documentation* is specific to a particular process and thus more detailed in nature[83].

### 3.1.3 Systems and Specifications Related to Good Manufacturing Practice

Since documentation is an important part of the quality assurance system, it should be related to all aspects of GMP. The aim of documentation is to define specifications for all materials used within the manufacturing processes as well as the method for manufacturing and control. This is done in order to assure that well-informed decisions regarding, for example whether or not to release a produced batch for sale or to provide an audit trail that allows for investigation of defective products or bathes. In turn, these specifications serve as a basis for quality evaluation since they aim to give detailed descriptions of the requirements that produced products or materials used during manufacturing have to fulfil[84].

Instructions for processing and packaging should specify all materials that are used and also describe all operations within these processes. Documentation containing specified directions for performing certain operations such as cleaning, testing and how to handle specific equipment should be available and records containing information regarding the history of produced products, including its distribution, as well as all other information regarding circumstances that are pertinent to the quality of the final product should be kept[85].

In order to ensure uniformity between produced products, *master production instructions* should be prepared. These instructions could include:

- The name of the components being manufactured.
- A complete list of raw materials and intermediates (entitled by names or codes that are sufficiently specific to identify any special quality characteristics).
- An accurate statement of the quantity or ratio of each raw material or intermediate used.
- The production location and major production equipment to be used.
- Detailed production instructions (including sequences to be followed, ranges of process parameters to be used, methods to be used for preparing critical equipment, sampling instructions and in-process controls with their acceptance criteria, time limits for completion of individual processing as well as steps and/or the entire process).
- Special notions and precautions to be followed.
- Instructions for storage of the components being manufactured to assure its suitability for use[86].

[83] Patel & Chotai, 2011, p. 141.
[84] Ibid, p. 142.
[85] Ibid, pp. 142-143.
[86] Ibid, p. 145.

Furthermore, the master production instructions should be dated and signed by one person for each finished product, and the instructions should be independently checked, dated and signed by a second person in the quality department or quality unit. Competent personnel with experience of production and quality control should be responsible for the content and distribution of the master production instructions within the company[87].

### 3.1.4 Policy for Compliance to Good Manufacturing Practice

In order to help pharmaceutical manufacturers meet the requirements of different regulatory agencies and comply with GMP, a set of recommendations or policies has been formulated by Patel & Chotai (2011). These recommendations are:

- Write good procedures
- Follow the written procedures
- Keep good records[88]

Since pharmaceuticals are complex, these policies are deemed applicable to manufacturers of complex products in general and also to manufacturers of less complex products as well[89]. The policies for GMP compliance are described further in the following sections.

#### Write Good Procedures

It is critical that good procedures are written down in order to ensure a controlled and consistent performance. Written procedures should be clear, concise and logical and it is recommended to hire a professional technical writer to help formulate these procedures. It could also be favourable and help improve the process to have the written procedures reviewed by an objective party[90].

Tasks should also be outlined before procedures are written. It could be helpful to break down the task, divide it into steps and to identify key points related to the task by using for example flowcharts. It is also important to keep in mind that people do not usually read procedures and instructions from start to finish, instead people tend to scan the document for key words. Therefore it is important to make the information in the written procedures easy to digest and follow. This can be done by for example breaking down the procedure in modules by using clear headings, tables, bullet points and diagrams[91].

#### Follow Written Procedures

Having well written procedures in place enables controlled and consistent performance within a company, but it does not guarantee it. In order to guarantee that the goals for control and consistency are met, the procedures also need to be followed. Following procedures is also considered a requirement for GMP compliance.

The steps described in written procedures might not always appear to be the most efficient way of working. In these cases it can be tempting for workers to take shortcuts

[87] Patel & Chotai, 2011, p. 145.
[88] Ibid, p. 147.
[89] Ibid.
[90] Ibid.
[91] Ibid.

in order to save time or to make the task easier. Even though the rationale of a particular step may not be immediately apparent to the worker, it is probably added to the procedure for a specific reason. Certain steps might be put in the procedure as a check for other stages further along in the process. It is therefore of great importance that deviation from the written procedures is avoided. To ensure that the written procedures are followed correctly, deviation should not be allowed without the approval of a supervisor from the quality department. Ideas for improvement should however always be encouraged, but changes to procedures should not be done before a proper impact assessment has been conducted[92].

#### Keep Good Records

Keeping good records is an essential part of GMP and enables the tracking of all activities performed during manufacturing. Good records cover all of the processes from the receipt of raw material to the final product release and they provide a history of produced products, their batches and the distribution. Accurate records also convey the message that procedures are being followed and demonstrates that the processes are known and under control. This can be helpful, especially during audits[93].

## 3.2 Risks Related to Simplification of Document Quality Standard

Creating accurate and well-written documents can be both time and effort consuming. In order to either save money or simply speed up the implementation process, companies sometimes choose to simplify their documentation processes. However, there are a number of risks related to simplification of document content or structure that should not be disregarded. The following sub-chapters describe some of these risks.

### 3.2.1 Simplification of Process Design and Work Instructions

If process designs or work instructions are not as detailed as necessary, the following negative effects could arise:

- Misinterpretation of activities.
- Process mutations over time.
- Workarounds in violation of the process design.
- Key performance indicators (KPIs) and Operational Level Agreements (OLAs) breaches[94].

#### Simplification of CSFs, KPIs and OLAs

If the details of Critical Success Factors (CSFs), KPIs and OLAs are not defined, there is a risk for report inaccuracies since different parties might use different interpretations. This might also lead to untrustworthy report results leading to inappropriate process management[95].

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[92] Patel & Chotai, 2011, p. 147.
[93] Ibid.
[94] L. Lukac & M. Kyncl, 'Quality Standard for ITIL Process Implementation', *itSMF International Whitepaper Submission Competition*, 2012, p. 11.
[95] Ibid.

### Simplification of Countermeasures

If the risks and countermeasures are not defined for the different process steps, there is a significant risk for lengthened recovery times as a result of unclear responsibilities for risk mitigation and low quality of mitigation strategies[96].

### Simplification of Functional Specifications for Supporting Tools

Inadequate definitions and descriptions regarding functional specifications for supporting tools might lead to difficulties related to tool usage, which in turn affects processes related to them. It could also make it difficult to perform KPI and OLA measurements, which in turn affects process management negatively. Finally, inadequacies within this area can lead to vague, incomplete and inaccurate reporting[97].

### Simplification of Reports

If definitions concerning reports are insufficient, more time and effort will be spend on report creation and inconsistencies will become more frequent[98].

### Simplification of Communication Channel Definitions

Inaccurate or incomplete definitions regarding communication channels with customers can result in insufficient process integration within the organisation. In turn, undefined rules of interaction may also cause process delays[99].

## 3.3 Quality Management Systems

Companies use quality management as a strategy to improve organisational efficiency and effectiveness with the aim of meeting customer expectations[100]. A Quality Management System (QMS) can be regarded as the set of policies, processes and procedures required to reach this goal. Some refer to the QMS as merely a group of documents, but more correctly it refers to the entire system for quality management. The documents regarding the QMS are merely used to describe the system[101].

There are many ways of carrying out and implementing a QMS but standards (for example the ISO 9000 series) require organisations to document the processes that make the company successful[102]. Another requirement is that objective methods should to be used to assess the efficiency of the processes. In other words, at certain stages the compliance and conformance of the established processes have to be verified objectively[103].

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[96] L. Lukac & M. Kyncl, 2012, p. 11.
[97] Ibid.
[98] Ibid.
[99] Ibid, p. 12.
[100] Chee Ming Ong, Kathawala, Yunus & Sawalha, Nabeel, 'A Model for ISO 9000 Quality Management System', *Quality Management Journal*, vol. 22, no. 2, 2015, p.11.
[101] The 9000 Store, 'ISO 9001 Quality management System', *The 9000 Store* [Website], <http://the9000store.com/what-is-iso-9001-quality-management-system.aspx>, accessed 26 Sept. 2016.
[102] H. Hernandez, 'Quality Audit as a Driver for Compliance to ISO 9001:2008 standards', *TQM Journal*, vol. 22, no. 4, 2010, p. 455.
[103] Ibid.

### 3.3.1 Quality Assurance vs. Quality Control

Quality assurance and quality control are two concepts that are closely related. Both concepts evaluate actual quality by comparing it to predetermined quality goals, and each concept also stimulates corrective action as needed. The difference between quality assurance and control is the prime purpose to be served. During quality control, the main purpose is to serve those who are directly responsible for conducting operations in order to help them regulate current operations. During quality assurance on the other hand, the main purpose is to serve those who are not directly responsible for conducting operations but who have a need to know that everything is going according to plan. In a sense quality assurance activities function as a kind of 'insurance', as it involves spending a small sum to secure protection against a large loss. In other words, quality assurance activities serve as a kind of insurance system as they can provide early warnings that in turn may avoid large losses[104].

### 3.3.2 Requirements for Implementing a Quality Management System

The following sub-chapter presents the requirements according to the ISO 9001:2008 standards for establishing a QMS.

#### *3.3.2.1 General Requirements*

First of all, in order to establish, document, implement and maintain a QMS, an organisation shall:

- Determine the processes necessary for the QMS and their application throughout the organisation (this includes processes for management activities, provision of resources, product realisation, measurement, analysis and improvement).
- Determine the sequence and the interaction of the processes mentioned above.
- Determine criteria and methods necessary to assure that operation and control of the QMS processes are effective.
- Assure availability of resources and information needed to support operation and monitoring of the QMS processes.
- Monitor, measure and analyse the QMS processes.
- Implement necessary actions to attain intended results and continual improvement of the QMS processes[105].

If the company implementing the QMS outsources any processes that affect their product's ability to conform to requirements, the company shall guarantee control over these processes. Even though control has been guaranteed, the company implementing the QMS is still responsible for conformity to all customers, statutory and regulatory requirements. The type and extent of control that is to be applied to the outsourced processes shall also be defined in the QMS documents[106].

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[104] J.M. Juran & A.B., Godfrey, *Juran's Quality Handbook*, 5th ed., McGraw-Hill, New York, 1999, p. 2.13.
[105] ISO 9001:2008, 'Quality management systems – Requirements', *International Organisation for Standardisation*, 2008, p. 2.
[106] Ibid.

Documentation of the QMS can be in any form or type of medium and shall contain the following:

- Statements of quality policy and objectives.
- A quality manual.
- Procedures and records required by the ISO 9001 international standard.
- Records determined by the organisation to be necessary to ensure the effective, planning, operation and control of its processes[107].

The extent of the QMS documentation differs between companies and depends on:

- Size of the company.
- Type of activities.
- Complexity of processes and their interactions.
- Competence of personnel[108].

#### *3.3.2.2 The Quality Manual*

A company implementing a QMS shall establish and maintain a quality manual, which should include:

- The scope of the QMS, including details of and justification for potential exclusions.
- The documents that have been established for the QMS, or references to them.
- A description of the interactions between processes of the QMS[109].

#### *3.3.2.3 Control of Documents and Records*

The documents that are required by the QMS shall be controlled. Documented procedures shall also be established to define the control needed in order to:

- Approve documents for suitability prior to issue.
- Review, update and re-approve documents as necessary.
- Ensure that changes and the current review status of documents are identified.
- Ensure that up-to-date versions of applicable documents are available.
- Ensure that documents remain comprehensive and identifiable.
- Ensure that documents of external origin, that are determined by the company to be necessary for the planning and operation of the QMS, are identified and their distribution controlled.
- Counteract unintentional use of obsolete documents and to apply appropriate identification to them if they for any reason are retained[110].

Records are considered to be a special type of document and the requirements for control therefore differ slightly from the requirements described in the section above[111]. Therefore, specific documented procedures that define the control needed for the identification, storage, protection, retrieval, retention and disposition of records shall also be established.[112].

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[107] ISO 9001:2008, pp. 2-3.
[108] Ibid, p. 3.
[109] Ibid.
[110] Ibid.
[111] Ibid.
[112] Ibid.

## 3.4 The Manufacturing Record Book

Manufacturers must collect and check all relevant documents in order to ensure their accuracy and validity. The documents are then to be collated in order to produce a single, unique and comprehensive document for each product (for high value, low volume products) or batch (for low value high volume products). This document is commonly referred to as the *Manufacturing Record Book* (MRB). The MRB can be described as a collection of all verifying documents and drawings that are required in order to assure that a company's equipment, material and products comply with company, customer and authoritative regulations. May also be referred to as a *Manufacturing Data Record* (MDR). A list of examples of the contents of the MRB is presented in alphabetical order in *Table 1*.

*Table 1: Contents of the MRB*[113]

| Contents of the MRB |
|---|
| *Introduction and MRB index* |
| *List of certificates* |
| *Analysis, tests, calculations, curves and tables* |
| *Balancing certificates* |
| *Calibration certificates on test instruments and supplied instruments* |
| *Certificates needed for re-certification of equipment* |
| *Certificates of conformance* |
| *Final inspection results* |
| *Final test/acceptance with customer representative* |
| *Instrument calculations* |
| *Lifting certificates* |
| *Manufacturing reports* |
| *Material certificates* |
| *Material testing and control* |
| *Material traceability list* |
| *Mechanical and structural calculations* |
| *Non-conformance reports* |
| *Painting reports* |
| *Performance/functional test reports* |
| *Photos of equipment/inspections* |
| *Pressure test certificates* |
| *Testing/acceptance after installation* |
| *Third party verification reports* |
| *Weight certificates* |
| *Welding reports* |
| *Welding procedure qualification records* |

[113] NORSOK Z-018, 'Supplier's documentation of equipment', *Norsk Sokkels Konkuranseposisjon*, 1st ed., May 2013, p. 15.

# 4 Literature Review: ISO Standardisation and Certification

This chapter consists of a literary review of the concept of ISO standardisation. The chapter focuses on the ISO 9000 standard series (primarily the ISO 9001 and ISO 9004 standards), which is considered to be one of the world standards for quality management. General requirements, benefits as well as ideas about the ISO 9000 standard series are covered and the chapter aims to provide the reader with an understanding of essential concepts related to the area. The information presented in this chapter is mainly collected through literature studies and qualitative content analysis of books, journals and other general publications within the studied area. If the reader possesses prior knowledge of the subject, this chapter may be skipped.

## 4.1 ISO 9000 Standardisation

The International Organisation for Standardisation (ISO), in an independent and non-governmental organisation that brings together experts in order to share knowledge and develop voluntary, consensus-based, market relevant international standards[114]. ISO has published more than 21 000 international standards and related documents within industries such as technology, food safety, agriculture and healthcare[115].

The ISO 9000 family deals with different aspects of quality management. The standard series provide guidance for organisations that want to ensure that their products fulfil certain pre-set requirements and that the quality is continuously improved. Furthermore the ISO 9000 quality standards (including ISO 9001 and ISO 9004) also provide a framework for a functional and certified QMS. For some companies, this has more or less become a commercial necessity since the ISO standards specify the minimum requirements for establishing and maintaining a sustainable and trustworthy QMS[116]. Moreover, within certain industries quality certification to international standards has become an obligatory requirement for suppliers[117].

## 4.2 General Guidance on Documentation Requirements of ISO 9001

The ISO 9001:2008 standard provides guidelines that help companies develop flexible ways for creating and managing documentation regarding their QMSs. The standard provides guidelines on how to handle documentation in order to demonstrate effective planning, operation and control of processes as well as QMS implementation and effectiveness. It also helps companies increase documentation efficiency (i.e. to develop the minimum amount of documentation necessary) [118]. Over the years the ISO 9001 standard has been developed, however many companies today still use the 2008-version.

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[114] International Organisation for Standardisation, 'About us', *ISO* [Website], About ISO, <http://www.iso.org/iso/home/about.htm>, accessed 27 Sept. 2016.
[115] Ibid.
[116] Chee Ming Ong, Kathawala, Yunus & Sawalha, Nabeel, 2015, p. 11.
[117] Hernandez, 2010, p. 454.
[118] International Organisation for Standardisation, 2008, p. 1.

### 4.2.1 ISO 9001:2008

For organisations that are in the process of implementing a QMS, the ISO 9001:2008 standard emphasises that companies should:

- Identify the processes that are needed for an effective implementation of the QMS.
- Determine the interactions between these processes.
- Document these processes to the extent that is needed in order to assure effective operation and control[119].

The processes mentioned above include management, resources, product realisation and measurement processes that are relevant to the QMS operation. Furthermore, process analysis should be the key driving force when determining the amount of documentation needed for the QMS. Hence, the documentation should not drive the processes[120].

Moreover, in order to obtain ISO 9001 certification it is necessary for an organisation to provide objective evidence of the effective implementation of its QMS as well as the effectiveness of its processes. According to clause 3.8.1 in the ISO 9001:2008 standard, objective evidence is defined as "data supporting the existence or verity of something". It also notes that objective evidence can be obtained through observation, measurement, tests or other means[121]. In other words, objective evidence does not have to depend on the existence of documented procedures, records or documents except for when it is specifically mentioned in the ISO 9001:2008 standard. Instead, it is up to the organisation to determine what records are necessary in order to provide objective evidence[122]. Furthermore, according to clause 4.2 in the ISO 9001:2008 standard, documents may be kept in any kind of form or medium (for example on paper, electronic or optical computer discs or photographs)[123].

### 4.2.2 Documents Required by ISO 9001:2008

Clause 4.1 in the ISO 9001:2008 standard states that a company or organisation is required to establish, document, implement and maintain a QMS and continuously improve its effectiveness. This system shall therefore include the following:

- Documented statements of the quality policy and quality objectives.
- The quality manual.
- Documented procedures specified by the ISO 9001:2008 standard.
- Documents necessary for the organisation in order to ensure effective planning, operation and control of its processes.
- Records specified by the ISO 9001:2008 standard[124].

[119] International Organisation for Standardisation, 2008, p. 4.
[120] Ibid.
[121] Ibid.
[122] Ibid, p. 5.
[123] Ibid, pp. 1-2.
[124] Ibid, p. 2.

In addition, the standard also requires companies and organisations to maintain documented procedures for the following activities:

- Control of documents.
- Control of records.
- Internal audit.
- Control of non-conforming products.
- Corrective action.
- Preventive action[125].

For some activities (for example corrective and preventive action) it is convenient to combine the procedures for more than one activity into a single documented procedure, while for others (for example internal audits) it is more convenient to document the specific activity by using more than one documented procedure. It is up to the company to decide what suits them best, as both alternatives are acceptable[126]. In addition to the documented procedures mentioned in the ISO 9001:2008 standard, larger organisations or companies with complex processes may require additional procedures (especially for the PRP) in order to implement a functional QMS. Depending on the size and culture of the organisation, these additional procedures could be effectively implemented without the company having to document them. Although, in order to completely prove compliance with the ISO 9001:2008 standard, documentation of all additional procedures is favourable. Nevertheless, the only documents that are specifically required by the ISO 9001:2008 standard are:

- The quality policy.
- The quality objectives.
- The quality manual[127].

### 4.2.3 Value Adding Documentation

Some examples of documents that are not specifically required by the ISO 9001:2008 standard, but that may help organisations to add value to their QMSs, are listed below:

- Process maps, process flow charts and process descriptions.
- Organisation charts.
- Specifications.
- Work and test instructions.
- Documents containing internal communications.
- Production schedules.
- Approved supplier lists.
- Inspection and test plans (ITPs)
- Quality plans[128].

### 4.2.4 Records Required by ISO 9001:2008

Examples of records that are specifically required by the ISO 9001:2008 standard are presented in *Table 2*. Other records that may be necessary in order to demonstrate conformity of their products, processes and QMS can however also be developed[129].

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[125] International Organisation for Standardisation, 2008, p. 3.
[126] Ibid.
[127] Ibid.
[128] Ibid.
[129] Ibid, p. 4.

*Table 2: Records Required By ISO 9001:2008*[130]

| Records required by ISO 9001:2008 |
|---|
| *Management reviews* |
| *Education, training, skills and experience* |
| *Evidence that the realisation processes and resulting product fulfil pre-set requirements* |
| *Design and development inputs relating to product requirements* |
| *Results of design and development reviews and any necessary actions* |
| *Results of design and development verification and any necessary actions* |
| *Results of design and development validation and any necessary actions* |
| *Results of the review of design and development changes and any necessary actions* |
| *Results of supplier evaluations and any necessary actions arising from the evaluation* |
| *The unique identification of the product (when traceability is a requirement)* |
| *Customer property that is lost, damaged or otherwise found to be unsuitable for use* |
| *Basis used for calibration or verification of measuring equipment where no international or national measurement standards exist* |
| *Results of calibration and verification of measuring equipment* |
| *Internal audit results and follow-up actions* |
| *Results of corrective action* |
| *Results of preventive action* |

## 4.3 Capitalising on ISO 9001 Benefits

Many companies chose to become ISO certified because they are more or less forced to do so by business partners, customers or in some cases governments. However many of these companies also seek economic benefits of the ISO systems that they implement[131]. In order to obtain ISO certification, companies have to fulfil certain requirements specified by the specific ISO standard but if properly understood and implemented, these requirements also provide a foundation for innovative ways of developing and exploiting the QMS to attain higher quality and improvements in business performance[132].

Previous research states that if ISO 9000 standards are well applied, i.e. if all standard criteria and principles are followed, they are expected to significantly increase a company's performance. Although, other research concludes that the benefits of QMS implementation can vary among companies and that implementing the ISO 9000 standards does not automatically bring benefits to a company. Hence, for a company to be able reap the benefits of ISO standardisation, certain pre-conditions have to be met[133].

It should be pointed out that the ISO 9000 standard series is under continuous development and because of this, it changes slightly every few years. In turn, this could

[130] International Organisation for Standardisation, 2008, p. 7.
[131] B. Rusjan & M. Alič, 'Capitalising on ISO 9001 benefits for strategic results', *International Journal of Quality & Reliability* Management, vol. 27, no. 7, 2010, p. 757.
[132] Ibid.
[133] Ibid, p. 758.

affect the benefits related to its implementation. However, it is assumed that the newer releases of the ISO 9000 standard series contribute with the same potential benefits as the older ones. However since less research has been conducted on the later releases of the standard, it should be emphasised that there might also exist new potential benefits related to these releases that have not yet been identified[134].

### 4.3.1 Pre-Conditions for Successful ISO 9001 Implementation

Motivation (especially internal motivation) and management support are two pre-conditions that have a significant effect on the results of implementing the ISO 9001 standard[135]. Quality improvement, as an internal factor for motivation, is significantly correlated with overall performance improvement within companies. However, if the implementation of the ISO 9001 standard is forced upon a company due to external pressure (for example from customers), the impact on company performance is smaller[136]. In other words, quality improvement as an external factor for motivation is not as effective as internal motivation for quality improvement. In addition, companies that are internally motivated to implement the ISO 9001 standard actively work towards developing and maintaining an effective and efficient system instead of simply working towards obtaining a certificate of standardisation. Furthermore, the goal for these companies is not only to formally meet the requirements of the ISO 9001 standard but also to follow the recommendations on continuous improvement set by for example the ISO 9004 standard[137].

Aligning the company's quality policy and quality objectives with the company's strategic objectives is also important for successful implementation of the ISO 9001 standard[138]. This will result in an effective QMS, which in turn enables organisational, and business improvement as well as an increase in company incomes and product quality[139]. Furthermore, it is important for companies to define clear business goals in order to achieve specific objectives linked to them. Therefore, appropriate integration of the QMS into the strategic planning of the company is of crucial[140].

### 4.3.2 Benefits of ISO 9001 Implementation

Business objectives can be divided into four different groups or perspectives, which are all affected differently by ISO standard implementation:

1. The customer perspective
2. The process perspective
3. The learning and development perspective
4. The financial perspective[141]

Benefits related to ISO 9001 certification can also be of either internal or external nature. Internal benefits are related to organisational improvements whereas external

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[134] Rusjan & Alič, 2010, p. 774.
[135] Ibid, p. 758.
[136] Ibid, p. 759.
[137] Ibid.
[138] Ibid.
[139] Ibid, p. 760.
[140] Ibid, p. 773.
[141] Ibid, p. 760.

benefits affect marketing and promotional aspects[142]. In the following sections, benefits related to the different groups mentioned above are presented. It should however be pointed out that even though all of these benefits are related to ISO 9001 certification, all of them are not proven to be direct results of it[143].

#### 4.3.2.1 Customer-Related Benefits

From the customer perspective there are several potential benefits, related to proper implementation of the ISO 9001 standard. Some examples are presented in *Table 3*.

*Table 3: Customer-Related Benefits of ISO 9001 Implementation*[144]

| **Customer-related benefits of ISO 9001 implementation** |
|---|
| *Better applicability of products and services* |
| *Saving of time due to reduced need for control* |
| *Higher reliability due to increased and consistent product quality* |
| *Less time spent on searching for and choosing new suppliers* |
| *Enhanced company image and reputation as well as increased confidence from customers* |
| *Increased customer loyalty* |
| *Simplified negotiations with customers due to attained ISO certificate* |
| *Increased sales through new customers and longer contracts with existing customers* |
| *Expanding market shares due to improvements in product quality* |
| *Stronger reputation in the eyes of company stakeholders* |
| *Improved communication with customers and suppliers* |
| *Improved documentation of customer needs* |
| *Increased chance of meeting customer expectations* |
| *Increased competitiveness due to increased product quality and managerial capacity (the QMS is used as a managerial tool)* |
| *Increased customer satisfaction overall resulting in fewer customer complaints* |
| *Shorter time for delivery due to reduced lead times* |
| *Improved response time to customer complaints* |
| *Faster response to customer demands due to improvements in customer-related processes and more effective co-operation with clients* |
| *No need for costly customer audits because it is assumed that requirements are met* |

The list of customer-related benefits above can be divided into two main groups, basic and consequential benefits[145]. The basic benefits are presented in *Table 4* and the consequential benefits in *Table 5*.

[142] P. Sampaio, P. Saraiva & A.G. Rodrigues, 'ISO 9001 certification research: questions, answers and approaches', *International Journal of Quality & Reliability Management*, vol. 26, no. 1, 2009, p. 45.
[143] Ibid, p. 46.
[144] Rusjan & Alič, 2010, pp. 761-762.
[145] Ibid, p. 762.

*Table 4: Basic Customer-Related Benefits of ISO 9001 Implementation*[146]

| Basic customer-related benefits of ISO 9001 implementation |
|---|
| *Improved supplier selection* |
| *Enhanced product quality* |
| *Fewer non-conformances in delivered goods resulting in fewer customer complaints* |
| *Improved communication and relationships with customers and suppliers* |

*Table 5: Consequential Customer-Related Benefits of ISO 9001 Implementation*[147]

| Consequential customer-related benefits of ISO 9001 implementation |
|---|
| *Increased customer satisfaction* |
| *Enhanced company image* |
| *Increased sales through new customers and longer contracts with existing customers* |

#### 4.3.2.2 Process-Related Benefits

In addition to the customer-related benefits mentioned in the previous section, there are a number of potential benefits related to the processes within a company as well. Some of examples of these benefits are presented in *Table 6.*

*Table 6: Process-Related Benefits of ISO 9001 Implementation*[148]

| Process-related benefits of ISO 9001 implementation |
|---|
| *Clear, standardised and simplified work procedures due to improved and developed documentation* |
| *Improved administration between functional departments, a reduced amount of paperwork and bureaucracy as well as elimination of non-value adding bureaucratic routines due to better control of documentation* |
| *Increased leadership, improved planning and prioritisation of activities as well as optimisation of use of resources* |
| *Clear definition of jobs and roles, clear a distribution of responsibilities and a reduced need for management attention for routine matters and supervision* |
| *Improved operational and management control, improved supervisory mechanisms (including both internal and external audits), increased control of subcontractors, systematic and objective monitoring of product quality as well as an increased ability to detect, prevent and correct in process failures* |
| *Improved design processes* |
| *Reduced inventory (both raw materials and finished products) due to more stable and predictable production processes* |
| *Increased delivery accuracy* |
| *Reduced number of deficiencies, scrap and waste as well as decreased need for rework* |
| *No need for repeated control by customers and multiple second-party audits that are costly for the company* |
| *Increased productivity and effectiveness (for example shorter lead-times and improved accuracy of delivery)* |

[146] Rusjan & Alič, 2010, p. 762.
[147] Ibid.
[148] Ibid, pp. 763-766.

The process-related benefits can also be divided into basic and consequential benefits. The basic benefits are presented in *Table 7* and the consequential benefits are presented in *Table 8*.

*Table 7: Basic Process-Related Benefits of ISO 9001 Implementation*[149]

| **Basic process-related benefits of ISO 9001 implementation** |
|---|
| *Improved clarity of procedures due to clearly identified and documented processes, well defined responsibilities and recorded results* |
| *Enhanced quality planning, control and decision making* |
| *Improvements in processes overall* |
| *Decreased amount of rework and scrap as well as an improvement in handling these activities* |

*Table 8: Consequential Process-Related Benefits of ISO 9001 Implementation*[150]

| **Consequential process-related benefits of ISO 9001 implementation** |
|---|
| *Decreased amount of external audits and reduced need for customer control over processes* |
| *Increased productivity* |
| *Improvement in process effectiveness* |

#### 4.3.2.3 Learning and Development-Related Benefits

Related to the learning and development perspective, there are a number of benefits of implementing an ISO 9000 QMS. Some of these benefits are presented in *Table 9*:

*Table 9: Learning and Development-Related Benefits of ISO 9001 Implementation*[151]

| **Learning and development-related benefits of ISO 9001 implementation** |
|---|
| *Improved training of personnel as well as improved transfer of know-how and experience internally* |
| *Increased involvement of employees and improved communication between different departments within the company* |
| *Improved development of quality management* |
| *Improved motivation and morale of employees as a result of more effective processes and better results* |
| *Increased personnel loyalty and less fluctuation of man-power due to the use of standardised systems for identifying and satisfying training requirements* |
| *Reduced stress among workers due to clear descriptions of jobs, roles and expectations* |
| *Establishment of an organisational culture of continuous improvement* |
| *A competitive advantage through continuous improvement of processes and increased product quality* |

As for the benefits in the previous sub-chapters, the benefits mentioned above can also be divided into a basic and a consequential group. The basic benefits are presented in *Table 10* and the consequential benefits are presented in *Table 11*.

[149] Rusjan & Alič, 2010, p. 766.
[150] Ibid.
[151] Ibid, p. 769.

*Table 10: Basic Learning and Development-Related Benefits of ISO 9001 Implementation*[152]

| **Basic learning and development-related benefits of ISO 9001 implementation** |
|---|
| *Increased qualification of employees for work tasks* |
| *Increased transfer and distribution of knowledge, know-how and personal experience within the company and improved communication between employees* |
| *Improved morale among employees* |
| *Continual improvement in quality management* |

*Table 11: Consequential Learning and Development-Related Benefits of ISO 9001 Implementation*[153]

| **Consequential learning and development-related benefits of ISO 9001 implementation** |
|---|
| *Increased motivation and satisfaction of employees due to clearer descriptions of jobs, roles and expectations* |
| *A competitive advantage through continuous development of processes and increased product quality* |
| *Increased ability to innovate* |

#### *4.3.2.4 Financially Related Benefits*

Research has shown that companies implementing high customer focus in their business have better chances of gaining a competitive edge and to improve financial results (i.e. revenue, yield etc.) compared to their competitors. In turn, this is something that could be facilitated through ISO standardisation. Other financial benefits of implementing a ISO 9000 QMS presented in *Table 12*:

*Table 12: Finance-Related Benefits of ISO 9001 Implementation*[154]

| **Finance-related benefits of ISO 9001 implementation** |
|---|
| *Reduced costs for operation by decreasing design failures and the need for rework* |
| *Better organisation of work which in turn increases efficiency and reduces operational costs* |
| *Added value leading to higher profit margins and sales per employee since high quality products are easier to sell* |
| *Improved financial planning and control* |
| *Increased control of costs and expenses as well as decreased costs of rework and waste* |

The financially related basic and consequential benefits are presented in *Table 13* and *Table 14*.

[152] Rusjan & Alič, 2010, pp. 769-770.
[153] Ibid, p. 770.
[154] Ibid.

*Table 13: Basic Finance-Related Benefits of ISO 9001 Implementation*[155]

| Basic finance-related benefits of ISO 9001 implementation |
|---|
| *Decreased costs (both operational and material related costs) due to a reduced amount of scrap, material waste and customer complaints as well as improvements of processes effectiveness and product quality* |
| *Increased incomes as a result of improved product quality* |

*Table 14: Consequential Finance-Related Benefits of ISO 9001 Implementation*[156]

| Consequential finance-related benefits of ISO 9001 implementation |
|---|
| *Improved profitability* |
| *Increased owner satisfaction* |

### 4.3.3 Motives for Implementing a ISO 9001 QMS

Motives for ISO certification can be divided into the following categories:

- *Internal motives* – motives with the goal of achieving organisational improvement.
- *External motives* – motives related to promotional and marketing issues, pressure from customers and improvement of market share[157].

ISO 9001 certification may be used as a tool for marketing. However, depending on a company's purpose of achieving certification, two different types of organisations exist: *non-developmental companies* and *developmental companies*. Non-developmental companies are companies whose purpose for seeking certification is mainly driven by the mentality of achieving a certificate, i.e. companies with external motivations for certification. Developmental companies on the other hand are companies with internal motivations for achieving certification, i.e. companies whose purpose for seeking certification is driven by the potential internal benefits related to the certification[158].

As for the benefits of ISO standardisation mentioned previously, the motives can also be divided into different groups:

- Customer-related motives
- Process-related motives
- Learning and development-related motives
- Financially related motives

#### *4.3.3.1 Customer-Related Motives*

Several external customer-related motives for implementing an ISO 9001 QMS have been identified. Some of these are:

- Demands and requirements from customers, inspectors, legislations and regulations.
- Increased company reputation.
- Increased customer satisfaction.
- Better competitive position.

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[155] Rusjan & Alič, 2010, p. 772.
[156] Ibid.
[157] Sampaio, Saraiva & Rodrigues, 2009, p. 45.
[158] Ibid.

- Maintaining and increasing market share[159].

#### 4.3.3.2 Process-Related Motives

The internal process-related motives for implementing a QMS based on the ISO 9001 standard are connected to the expected benefits. These motives mainly concern improved organisation, control and effectiveness of work and activities due to simplified and standardised processes[160].

#### 4.3.3.3 Learning and Development-Related Motives

The motives related to learning and development for implementing an ISO 9001 QMS that have been identified are mainly internal. Some examples are presented below:

- Clearly assigned roles and well-defined job descriptions resulting in an improvement in employee morale as well as an increase in personal accountability for job performance.
- Enhanced communication within the company.
- Internal improvement of the products and processes[161].

#### 4.3.3.4 Financially Related Motives

There are two main financial motives related to implementing an ISO 9001 QMS. One of these motives concerns reducing the risk of liability and insurance costs. The second motive concerns improving the financial efficiency and performance of the company, mainly by lowering costs but also by increasing income and profitability. Altogether this results in company growth[162].

### 4.4 Impact on Organisational Performance of ISO 9001 Certification

Over the years numerous studies examining the impact that quality management has on organisational performance have been conducted. Most of these studies state that there exists a positive relationship between the implementation of a structured QMS and organisational performance improvement. Some results also show that ISO 9001 certified companies exhibit better results related to for example technological management and quality management control[163]. There is however literature stating the opposite, i.e. that there does not exist sufficient evidence that supports a positive relationship between quality management and organisational performance. As a matter of fact, some literature states that ISO 9001 certification is a poor predictor of organisational performance and quality. There does on the other hand appear to exist a clear relationship between the motives for certification and the corresponding results obtained through this. For example, companies with mainly external motives for getting certified often adopt a minimalistic approach for achieving certification. The reason is that these companies generally see certification is the actual goal itself, instead of focusing on the possibility to make organisational improvements. In turn, this limits their ability to make internal performance improvements and thus also the potential benefits related to the certification[164].

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[159] Rusjan & Alič, 2010, pp. 760-761.
[160] Ibid, p. 763.
[161] Rusjan & Alič, 2010, p. 769.
[162] Ibid, p. 770.
[163] Sampaio, Saraiva & Rodrigues, 2009, p. 48.
[164] Ibid.

## 4.5 ISO 9001 Certification Obstacles

During the literature study, a number of obstacles on the path towards ISO 9001 certification were identified. The certification obstacles included the lack of involvement from top-level management during the implementation or certification process, high investment and maintenance costs (in spite of its predicted decrease over time) as well as different interpretations of standards among auditors. Furthermore, small and medium-sized enterprises (SMEs) also face restrictions related to human and material resources[165].

[165] Sampaio, Saraiva & Rodrigues, 2009, p. 48.

# 5 Literature Review: Digitalisation Trends

This chapter aims to provide the reader with an understanding of current digitalisation trends. Concepts such as *Industry 4.0*, *IoT* and *Connected Manufacturing* are introduced, and general explanations of current digitalisation trends within the manufacturing industry are presented.

## 5.1 Industry 4.0

The manufacturing industry today is moving at a fast pace and is characterised by constant changes driven by increased globalisation, tough competition and increasing customer demand. The industry is going through a deep transformation, which puts high pressure on manufactures to simplify operations, reduce costs and to speed up product development. The reduction of custom taxes and fees has also influenced global competition and the ability to convert concepts into value quicker than competitors will determine who survives and who does not. In other words, manufacturing is no longer simply about making and selling products but about connecting end-to-end operations across the entire supply chain in order to determine what customers want quicker and more cost efficiently than competitors.

The increased degree of digitalisation has led to the birth of a new international trend called *Industry 4.0*. It is a concept that refers to a new era for producing industries, i.e. the fourth industrial revolution[166]. Simply put, the concept is based on a new way of organising and managing supply chains. A higher focus is put on that customer requirements are taken into account and that r*eal time data* (RTD) is collected, assessed and made available to all actors involved in the processing operations, throughout the production process[167]. Companies adapting to Industry 4.0 also utilise smart production lines, in which all active components are connected. The goal is to make production lines and factories autonomous and to let each individual product carry information about itself throughout the production line and since everything is connected, the product will be able to 'communicate' with the manufacturing equipment. By carrying information about how, why and for whom it is to be manufactured, the product will for example be able to communicate which steps in the production process it will have to go through. This will in turn enable the product to create its own individual supply chain route[168].

[166] M. Alpman, 'Här är Tysklands Industri 4.0', *Ny teknik* [Web article], 17 Sept. 2014, <http://www.nyteknik.se/nyheter/automation/verkstadsautomation/article3846291.ece>, accessed 28 Sept. 2016.
[167] H. Abrahamson, 'Definierar Industri 4.0', *Ny Teknik* [Web article], 15 April 2014, <http://www.nyteknik.se/nyheter/automation/verkstadsautomation/article3821153.ece>, accessed 28 Sept. 2016.
[168] Alpman, 2014.

However, in order for Industry 4.0 to become reality, major changes in organisational practices will have to be made. These changes involve new forms of IT architecture and data management as well as new organisational structures. Most importantly, the transition to industry 4.0 will require a new digitally orientated culture with a strong focus on data analytics[169]. The reason why data analytics is of such importance for the transition into Industry 4.0 is best understood by studying what led to the last major industrial revolution, i.e. the *lean production approach*. Exercises such as the "five whys" and statistical analysis lead to an increased degree of awareness in production, which in turn resulted in never before seen levels of quality and reliability. However, in Industry 4.0 the machines and the production equipment possess and utilise this degree of awareness themselves. For example, they can be programmed to detect when material is being used inefficiently (i.e. detect waste) or when inefficient supply chain routes are being used. This implies that the machines can bring relevant information to the attention of top-level management and company leaders themselves, and thus cut out the middleman. This can be compared to with how a GPS navigator communicates information about traffic congestions in order to help the driver change route before being affected by it[170].

Moreover, Industry 4.0 processes will generate enormous amounts of data regarding both customer demands and supply chain logistics. If performed properly, data analytics can be used to help companies boost supply chain efficiency, grow closer to supply chain partners as well as develop products and services better adapted to customer demands. However, if not enough care is taken, much of the effort may be wasted. According to a study conducted by PwC, some of the most common issues related to building capabilities for data analytics are:

- Lack of people with analytical expertise.
- Poor data quality.
- Lack of access to relevant data.
- Lack of support from top-level management[171].

Furthermore, data analytics can help companies improve their ecological footprint by for example the identifying wasted materials and finding new ways to reclaim or reuse them. Analytical processes can in some cases also reveal new markets or even opportunities for growth in existing markets[172]. For example the availability of as well as the ability to analyse RTD allows companies to create more personalised products and customised solutions better suited for their customers. This in turn enables higher profit margins compared to mass-produced offerings and increases the chances for revenue gain[173].

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[169] R. Geissbauer, J. Vedsø & S. Schrauf, 'A Strategist's Guide to Industry 4.0', *strategy+business magazine* [Online journal], no. 83, 9 May 2016, p. 5, <http://www.strategy-business.com/article/A-Strategists-Guide-to-Industry-4.0?gko=7c4cf>, accessed 12 May 2016.
[170] Geissbauer, Vedsø & Schrauf, 2016, p. 6.
[171] Ibid.
[172] Ibid.
[173] Ibid, p. 4.

### 5.1.1 Industry 4.0 Obstacles and Challenges

There are nonetheless a few obstacles standing in the way of development towards Industry 4.0. The main obstacles are described in the following sections:

#### Lack of common standards for communication

First of all, there is the lack of common standards for communication within and between companies[174]. This complicates both internal communication (for example between different departments within a company) and external communication (for example between supply chain actors) and consequently obscures both internal as well as external collaboration.

#### New ways of organising production and managing supply chains

The transition into Industry 4.0 will require new and unfamiliar ways of organising production and thus managing supply chains in order for the development to keep moving forward. The uncertainty regarding the reorganisation of current systems and the potential results are holding back the development[175] [176].

#### Openness with data

Industry 4.0 will require that certain information is made available to all actors involved in for example manufacturing processes[177]. However many companies today are not comfortable with sharing specific information with others[178], even though it should theoretically help to improve and facilitate collaboration between supply chain actors. Therefore, openness with data is another obstacle standing in the way of Industry 4.0-development.

#### 'Leap of faith'

Due to the inherent conservatism existing within the manufacturing industry today, there is a general concern over investment costs among manufacturers. Consequently, investments in Industry 4.0-technology could be seen as a 'leap of faith'. The reason is that many of these investments must be made today, even though a lot of the products and processes involved in the approach are still unknown[179]. In other words, companies do not yet know if, how or when they will be able to earn back their investments.

### 5.1.2 First movers

Companies that hold back, waiting to see what happens before they invest will fall behind and thus miss out on the advantages of being a 'first mover'[180]. For example, companies that are able to realise their expected cost savings and revenue gains will be able to generate more capital that later can be reinvested in new Industry 4.0-strategies. Consequently, this enables them to improve performance and further increase their lead over competitors. Furthermore, the adoption of Industry 4.0-technology might even be seen as a qualifier for funding by investors[181].

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[174] Alpman, 2014.
[175] Geissbauer, Vedsø & Schrauf, 2016, p. 6.
[176] Abrahamson, 2014.
[177] Ibid.
[178] Geissbauer, Vedsø & Schrauf, 2016, p. 6.
[179] Ibid.
[180] Ibid.
[181] Ibid, p. 7.

## 5.2 Internet of Things and Connected Manufacturing

IoT is a new trend within manufacturing that has evolved over the last few years. It is a collective term that is used for describing the inter-connection of machines, vehicles, goods, household appliances and other 'devices' (including human operators). IoT technology enables otherwise unaware units (such as machines), to perceive their environment through integrated sensors and microprocessors and through them, adapt their actions to different situations[182].

IoT technology enables a phenomenon called *connected manufacturing*. It is a term that is used to describe the technology that enables integration of processes, products and people within the manufacturing industry[183]. The power of the Web is expanded to link machines, sensors, computers and humans in order to enable new levels and ways of monitoring, collecting, processing and analysing information. The concept aims to provide increased precision within manufacturing and enables translation of collected data into insights, which can be used to understand how certain aspects impact manufacturing performance. Black & Decker has implemented this technique in one of its plants in Mexico to monitor the status of production lines in real time through mobile devices and smart RFID tags. This has led to an increase in overall equipment effectiveness by 24% and an increase in labour utilisation by 10%[184].

Especially industrial manufacturing companies have great potential when it comes to utilising IoT technology. However, before investing in IoT, it should be determined exactly what type of data that is valuable to collect and the efficiency of the analytical structures that will be used to assess the data should be estimated. Another important aspect to consider is that next generation equipment will require a mix of workers, which should include employees who can design and build IoT products as well as data experts who can analyse the outputs[185]. Also, considering that manufacturing technology is evolving faster than ever, many technologies that are introduced today will become commonplace, or maybe even industry standards, within the next five or ten years[186].

By standardising global processes and complex supply chains, manufacturing companies can increase effectiveness and thereby also reduce costs. It can also help increase efficiency of back-office activities and raise profits. Providing employees with cost effective digital tools also encourages and facilitates cooperation within the company, which in turn speeds up product development and has positive effects on quality. Increased cooperation and communication between suppliers, engineers, manufacturers

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[182] Internet of Things Sverige, 'Om IoT', *Internet of Things Sverige* [Website], <http://iotsverige.se/internet-things-2/>, accessed 28 Sept. 2016.
[183] Veckans Affärer, 'Så hänger ditt företag med i den digitala utvecklingen', *Veckans Affärer* [Web article], 14 March 2016, <http://www.va.se/nyheter/2016/03/14/connected-manufacturing--sa-producerar-du-varde-i-alla-led-av-produktionen/>, accessed 28 Sept. 2016.
[184] R. Bono & S. Pillsbury, '2016 industrial manufacturing trends: Manufacturers must weather the risk that comes with embracing new technologies', *Strategy&* [Online Report], 2016, p. 5, <http://www.strategyand.pwc.com/perspectives/2016-manufacturing-trends>, accessed 29 March 2016.
[185] Ibid, p. 6.
[186] Ibid, p. 9.

and customers also increases innovation and also reduces the risk for downtime. All together, this generates better possibilities for manufacturing companies to gain insights on customer needs and to increase the quality of their service, which in turn raises customer satisfaction[187].

## 5.3 Digitalisation within Complex Discrete Manufacturing

In order for discrete manufacturing companies to stay competitive, the need for comprehensive visibility and transparency of production processes has become increasingly important. Hence, complex discrete manufacturers today have had to start relying more on digitised processes and less on manual interaction in order to effectively be able to manage their operations and to optimise their supply chains[188]. Moreover, there are a number of challenges and trends that affect these manufacturers and their ability to compete. Some of these are listed below:

- Shorter development times.
- Global price pressure.
- Increased demand for customisation and high quality.
- Pressure to manage costs.

### Shorter development times

Demand for new products and changes in engineering change swiftly, i.e. manufacturers today generally have less time for development and introduction of new products than before. Consequently, this trend force manufacturers to produce products rapidly and only leaves a limited timeframe for recouping the investments and turning them into new offerings[189].

### Global price pressure

As globalisation increases, many discrete manufacturers face competitive global price pressures and at the same time struggle with rising costs for raw materials, labour and energy. This means that manufactures must learn 'how to do more with less' in order to protect their profitability margins without raising prices[190].

### Increased demand for customisation and high quality

The need for flexibility, agility and responsiveness without compromising quality to meet customer demands has today become more important than ever[191].

### Pressure to manage costs

Increasing competition from emerging economies such as China and India has created an urgency to lower costs. This includes everything from costs for labour and warranties to operational overhead costs. Furthermore, as globalisation increases, discrete

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[187] Veckans Affärer, 2016.
[188] GE Intelligent Platforms, 'Digitizing Complex Discrete Manufacturing Processes: Driving lowe costs, higher quality and faster production to stay competitive today and ensure success tomorrow', *GE Intelligent Platforms* [Online white paper], Document: 11.12 GFT-851, 2012, p. 2, <http://www.geautomation.com/products/connected-manufacturing>, accessed 30 March 2016.
[189] Ibid, p. 3.
[190] Ibid.
[191] Ibid.

manufacturers will have to continuously keep working on minimising costs while increasing productivity in order to stay competitive[192].

### 5.3.1 Digitisation Through Manufacturing Execution Systems

The definition of a manufacturing execution system (MES) varies depending on who is asked. However, simply put, a MES could be described as a computerised system used for documenting, controlling and managing manufacturing processes[193]. Consequently, MES digitisation refers to digitisation that is enabled thorough the latest MES software capabilities. Through MES digitisation, complex discrete manufacturers are able to:

- Record and collect production data in real time (i.e. leverage RTD).
- Automate processes.
- Easily monitor production through increased process visibility.
- Consistently produce products of high quality.
- Analyse production data and thus identify for example the drivers behind waste and inefficiencies[194].
- Easily produce comprehensible product records by eliminating the need for paper-based systems and manual processes that are known to be prone to error.
- Reduce errors by eliminating manual tracking and updating of non-conformances, quality data measurements, quality approvals and so on[195].

Consequently MES digitisation enables companies to leverage more advanced manufacturing capabilities. Moreover, the ability to leverage advanced manufacturing capabilities is becoming increasingly important for manufacturers as their needs grow (due to rising expectations from customers, increasing competition and new IT capabilities and so on)[196]. For example collaboration through the utilisation of RTD, cloud-based technologies and mobile capabilities enables a person at one location to overlook a manufacturing site in another part of the world. Consequently this enables troubleshooting of problems without being physically present. It also enables executives, situated anywhere in the world, to access RTD that is vital for optimising supply chain operations[197], which in turn facilitates the process of making well-informed decisions. However to fully obtain the benefits mentioned above companies must strive for full MES digitisation. In order to attain this goal, the following activities should be considered:

- Digitisation of processes
- 'Enabling personnel'
- Quality control
- Enabling collaboration with suppliers
- Creating comprehensible product records

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[192] GE Intelligent Platforms, 2012, p. 2.
[193] Business Dictionary, 'manufacturing execution system (MES)', *Business Dictionary* [Website], 2016, <http://www.businessdictionary.com/definition/manufacturing-execution-system-MES.html>, accessed 1 Dec. 2016.
[194] GE Intelligent Platforms, 2012, p. 3.
[195] Ibid.
[196] Ibid.
[197] Ibid, p. 4.

### Digitise processes

The first step towards full MES digitisation is to eliminate paper-based travellers that are released with production orders to the floor[198]. A traveller refers to a list or record of instructions that follows a component, part or product throughout a manufacturing process. Depending on the degree of complexity of the final product, there can be tens of thousands of orders and thus also travellers released every year[199]. It is also important to identify what certifications are required for e.g. people and equipment in order to perform the different manufacturing operations defined within the supply chain route. In complex manufacturing the routes and instructions usually need to be approved by people from the quality control department, product engineering or manufacturing supervision. By digitising workflows, these approvals can be facilitated[200].

### 'Enable personnel'

The next step towards full MES digitisation is about providing digitised information to the operators on the floor and in the production lines as orders are released and executed. The idea is to implement a digital system that provides a list of jobs for the operators to select and then execute. When a job from the list is selected, the instructions are digitally provided, which in turn helps eliminate potential errors associated with paper-based instructions. When the job is completed, the order is then digitally routed to the next operation automatically[201]. Furthermore, the digitised information facilitates the process of managing and supervising operations and also increases visibility of WIP. This reason is that supervisors do not actually have to be present at each station that they are supervising and they do not either have to manually transport themselves across the manufacturing facility in order to identify locations and statuses of the orders within the plant. Instead, flexible displays that show WIP can be used to identify all in-process material throughout the entire plant or in specific areas[202].

### Perform quality control

Another important step in the process towards obtaining full MES digitisation is to gain better control of quality. One way to make this possible is to clearly define and digitise all key variables needed to be able to assess the quality of produced products. These key variables could then instantly be compared to quality data from associated equipment (such as tools and production machinery) that is either collected automatically or manually entered by plant-floor personnel. In turn, this increases the company's ability to monitor and control quality[203].

### Enable collaboration with suppliers

This step has to do with expanding the digitised MES beyond the plant to the suppliers in order to enable collaboration. Collaboration with suppliers by the use of a digitised system would mean that outsourced operations could be digitally routed to the suppliers and at the same time provide the suppliers with a digitised display, containing a queue of their orders to work from. Furthermore, certificates of analysis could be digitally delivered from the suppliers to the main manufacturer, meaning that hundreds

198 GE Intelligent Platforms, 2012, p. 4.
199 Ibid.
200 Ibid.
201 Ibid.
202 Ibid.
203 Ibid.

of suppliers could be included at the same time as WIP is being managed from a central point in the MES[204].

#### Create comprehensible product records

The fifth and final step on the journey towards full digitisation is about enabling realisation of complete, comprehensible digital product records of the end products. This is obtained through implementation of the previously mentioned steps and the record should include all associated components as well as sub-assemblies. Digitised product records eliminate the need for managing and keeping paper-based product records in boxes at secure storage facilities. It also eliminates the need for personnel to manually retrieve and pursue stacks of paper in order to find the appropriate information for example if a warranty issue occurs. In order words, an online digitised database for product records enables quick and easy retrieval of any information that could be required[205].

### 5.3.2 Benefits of Digitising Complex Discrete Manufacturing Processes

In general, digitalisation of complex discrete manufacturing processes helps to eliminate non-value adding production time, which in turn directly affects cycle times within production. In turn digitalisation enables manufacturers to produce products faster and thus contributes to a significant competitive edge (especially since lead times within complex discrete manufacturing cycles are typically long). As an example, General Electric (GE) claims that manufacturing businesses within GE have reduced their cycle times by approximately 20% through MES digitisation[206]. GE also claims that the real time visibility of WIP (which is available through MES digitisation) can reduce inventory levels by at least 10% and by as much as 30%[207].

Implementing digitised instructions can also help increase the level of quality control by monitoring and validating quality data against the expected specifications. In turn, this helps prevent irreversible errors and enables products to be produced correctly the first time. According to GE, it could reduce the amount of rework and scrap by as much as 25%. Furthermore, GE also claims that by keeping digital records, warranty investigation time can be reduced by as much as 70%[208].

Complex manufacturing is characterised by long cycle times and that significant labour is required for all manufacturing and assembly operations. Any reduction in cycle time therefore directly affects the labour costs associated with the product being produced. Eliminating costs directly associated with paper and related items (printers, ink etc.) along with hidden costs associated with the paper-based system (for example handling, storage and retrieval of paper) enables further cost savings[209].

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[204] GE Intelligent Platforms, 2012, p. 5.
[205] Ibid.
[206] Ibid.
[207] Ibid.
[208] Ibid, p. 6.
[209] Ibid.


*Figure 3: Benefits of Digitisation within Complex Discrete Manufacturing*[210]

In conclusion, as competition escalates it is getting more difficult for complex discrete manufacturers to overlook the need for digitised processes. MES digitisation is therefore a critical enabler when it comes to achieving effective operations and optimising supply chain activities. Full digitisation enables manufacturers to draw benefits that can help them leapfrog competition by the use of RTD and elimination of non-value adding production time. These benefits include:

- Higher accuracy within production
- Faster approval routing
- Reduced WIP
- Tighter quality and quality controls
- Better integration and collaboration with suppliers.

Consequently, the result enables manufacturers to produce a complete digitised product records and to create a foundation for making well-informed decisions, which in turn helps improve operational and financial results. Lastly, digitisation also provides manufacturers with the ability to leverage more advanced technological capabilities as their needs extend in the future[211].

## 5.4 Voice of the Customer

Voice of the customer (VOC) is a term used to describe the complete set of customer wants and needs regarding the product. It is expressed in the customer's own language and organised to reflect how the customer thinks about, uses and interacts with the product. These needs and wants are also prioritised on the grounds of what the customer believes to be important and how performance is viewed in the context of the of the customers current level of satisfaction with already existing alternatives[212].

### 5.4.1 Identifying VOC

Identifying VOC is a critical phase in any product development process and according to the international research company AMR (Advanced Market Research), more than 50% of product-introductions fail because they do not meet customer requirements[213]. Furthermore, the Product Development and Management Association (PDMA) has determined (through analysis of the variables that separate the best performing product

[210] GE Intelligent Platforms, 2012, p. 6.
[211] Ibid.
[212] Siemens PLM Software, 'Outlining the voice of the customer', *Siemens PLM Software* [Online white paper], p. 1, <https://www.plm.automation.siemens.com/ru_ru/Images/7561_tcm802-4604.pdf>, accessed 2 Dec. 2016.
[213] Ibid.

development companies from their competitors) that VOC activities are among the strongest differentiators when it comes for achieving success in the marketplace[214].

VOC can either be gathered continuously in order to serve as feedback to a generation of products, or it can be collected prior to the introduction of a new product that has not yet been introduced to the market. In both cases, the collected VOC data should be used as basis for determining a products ultimate success, as well as measuring its progress throughout the product development process. When analysing VOC, companies must make sure that customer needs and wants are captured and communicated in a systematic and repeatable way. If the customer is not satisfied with a product and does not buy it, other requirements related to development, such as budget and time-to-market become debatable[215].

### 5.4.2 The Importance of VOC

Business interests of multiple actors in the supply chain are affected by VOC initiatives. For executive management, VOC requirements can be used as a framework for monitoring project success and it can also be helpful in decision-making processes, where conflicts have to be escalated and resolved[216]. For product management, VOC helps outline a product's requirements. It also helps assure that the product fulfils these requirements and that it meets the pre-set goals[217]. The marketing department can use VOC as the framework for value messaging, i.e. VOC can help the marketing department communicate that the entire development organisation is working toward satisfying the needs of potential customers[218]. For research and development processes as well as for design and engineering departments, VOC provides visibility into the project's requirement dependencies and in turn facilitates decision-making. Finally, sales departments can also leverage VOC requirements as a part of the product's value proposition, which in turn can be presented to potential customers[219].

### 5.4.3 Translating VOC into Functional Requirements

Functional requirements are requirements that can be used to guide individual development teams. For example, a requirement such as *form factor* could be described by several other factors, such as *overall dimensions, packaging dimensions* and *shipping weight*. In addition, each of these factors could be broken down to cover targets for several different functional requirements, for example *enclosure dimensions* and *circuit board dimensions.* In turn, this enables different development teams to focus on specific functional requirements throughout the development process[220]. By translating VOC into functional requirements, they also become tangible and thus easier to handle[221].

Translating VOC into functional requirements can however be tricky since it is usually expressed in 'fuzzy' or diffuse terms that customers use. An example of a VOC-statement could for example be 'easy to use'. Hence, important details might get lost in the

[214] Siemens PLM Software, p. 1.
[215] Ibid.
[216] Ibid, p. 2.
[217] Ibid.
[218] Ibid.
[219] Ibid.
[220] Ibid, p. 3.
[221] Ibid, p. 4.

translation when trying to describe the requirements using finite engineering terms. In order to reduce the risk of losing vital information during translation, VOC-statements are first of all prioritized and then quickly translated into specific functional requirements that can be used as guidance for specific development teams[222].

A common mistake when translating VOC requirements into functional requirements is that the overall relationship back to the original customer want or need is not completely understood before development starts. The reason for this is that VOC data is usually difficult to analyse and measure quantitatively. In turn this increases the risk of that pragmatic teams (such as engineering teams) will ignore the original VOC and instead focus on more tangible data. Another problem occurs when companies lack proper systems for managing requirements and thus fail to communicate changes in an effectively on time[223].

### 5.4.4 Conflicting Requirements

Different VOC requirements will sometimes conflict with one another, and in turn this often results in the need for trade-offs. A VOC requirement regarding a product's package size might for example determine the effort to fit necessary electronic components into a relatively small space, and thus define the choice of electronic technologies. Consequently, this might result in the need for smaller and more expensive electronic components, which in turn might conflict with budgetary requirements[224]. This example illustrates the significance of VOC prioritisation and the importance of determining which customer wants and needs are vital for project success. For example making the package bigger could help meet the project's material budget but the decision might at the same time endanger a critical customer want[225], which in turn would have a negative effect on sales.

In order to avoid decisions that could potentially affect the entire requirement prioritisation, the original VOC requirements must always be taken into account when making trade-off decisions. Otherwise there is a substantial risk for errors that in turn may lead to the need for re-engineering and manufacturing rework as well as misunderstood capabilities that impact the product's ability to succeed in the marketplace[226].

### 5.4.5 Establishing Requirement Hierarchy

One best practice method for prioritising, and thus defining a hierarchy of VOC requirements, is to categorise the original VOC requirements by the use of an *Affinity Diagram*. In an Affinity Diagram a hierarchy of requirements is defined simply by the title of each category representing a higher order requirement that is detailed by the requirements underneath[227]. An example of this is illustrated in *Figure 4* below.

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[222] Siemens PLM Software, p. 3.
[223] Ibid, p. 4.
[224] Ibid, p. 3.
[225] Ibid, p. 4.
[226] Ibid.
[227] Ibid, p. 5.

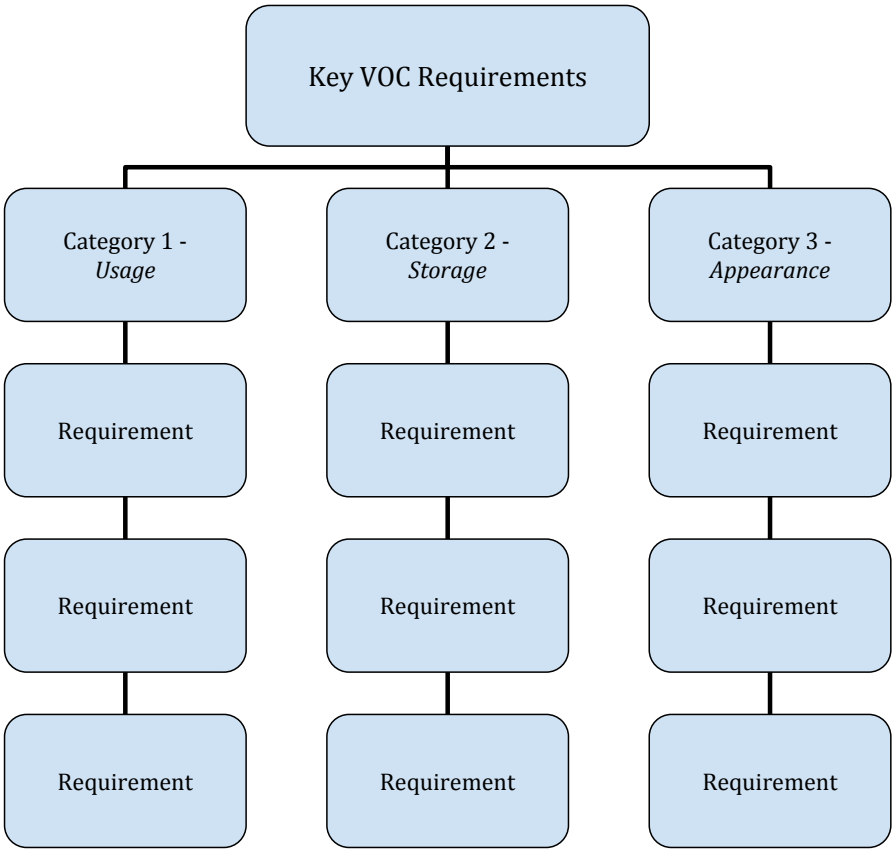


*Figure 4: Author's Illustration of the Affinity Diagram*

### 5.4.6 Inter-Organisational Communication of VOC

Companies often have different teams for defining VOC and functional requirements and in order to obtain successful results, these teams need to communicate with each other. However these teams seldom share the same IT systems and in turn, this often results in a communications breakdown[228].

Marketing and development teams often use tools such as Microsoft Office, Excel, and PowerPoint for conceptualising and brainstorming activities. Usually files and information is sent back and forth using email and in many cases the resulting files are not managed in any of the company's data silos. Instead, they rely on the VOC requirements being communicated downstream within the company[229]. Essentially, after the requirements or customer wants are defined, they are in many cases simply 'thrown over the wall' to a design team where engineers translate them into features. These features are then again thrown over the wall to the manufacturing team, which in turn continues with the over the wall-principle downstream in the organisation. This way of communicating and sharing information within the organisation often results in that the original VOC requirements are lost or forgotten before actual development has even begun. This often results in situations where development teams only rely on functional requirements without understanding the initial source, i.e. the original customer wants and needs that the resulting product should aim to satisfy[230].

[228] Siemens PLM Software, p. 4.
[229] Ibid.
[230] Ibid.

### 5.4.7 Enabling VOC Success

In order to enable VOC success, it is crucial to ensure that development teams carefully input VOC requirements as carefully as possible by articulating and prioritising them in customer terms. It is also important that not only the development teams' perspectives are taken into account. Furthermore, requirements should be prioritised by the use of customer participation when it is possible. Categorisation of the requirements into logical groups, by the use of for example Affinity Diagrams, should also be done in order to correctly map the relations between the different requirements. The hierarchy of the requirements (including both VOC and functional requirements) should also be effectively disseminated to all parts of the organisation that are part of the development process, and potential changes should be clearly communicated in time[231].

To meet the objectives mentioned above, organisations should make sure that they are capable of managing complex interrelations between requirements and handling requirement changes. It should be possible to trace requirements back to the original VOC requirement that address the needs and wants that they were designed to address. In order for this to work companies should implement systems that allow all teams that are participating in the development process to access the requirements throughout the entire project. This way of working enables multiple teams to resolve conflicts between requirements since it keeps track of the overriding goal of satisfying the customers[232].

[231] Siemens PLM Software, p. 6.
[232] Ibid, p. 7.

# 6 Generic Description of a Digital Document Management System

Chapter 6 presents a generic description of a potential digital DMS solution. The chapter begins with a brief summary of the PRP as well a general description of the flow of documents throughout this process. This is followed by a presentation of the major issues related to non-digital DMS solutions. Lastly a requirement set-up for the digital DMS solution is formed, and to each requirement a corresponding feature that aims to fulfil it is presented. Since the description of the digital DMS is generic in nature, it does not take factors such as size, industry or specific operational goals of individual companies into account. Instead, the theoretical description of the digital DMS aims to provide the reader with a generic definition of the digital DMS concept.

## 6.1 Flow of Documents Throughout the Product Realisation Process

According to the ISO 9001:2008 standard, the PRP describes activities that companies perform in order to develop, manufacture and deliver finished products to their customers. In order to assure a certain level of quality, or to obtain a specific form of certification, these activities have to be performed and documented in a specific manor. This is illustrated in *Figure 5.*

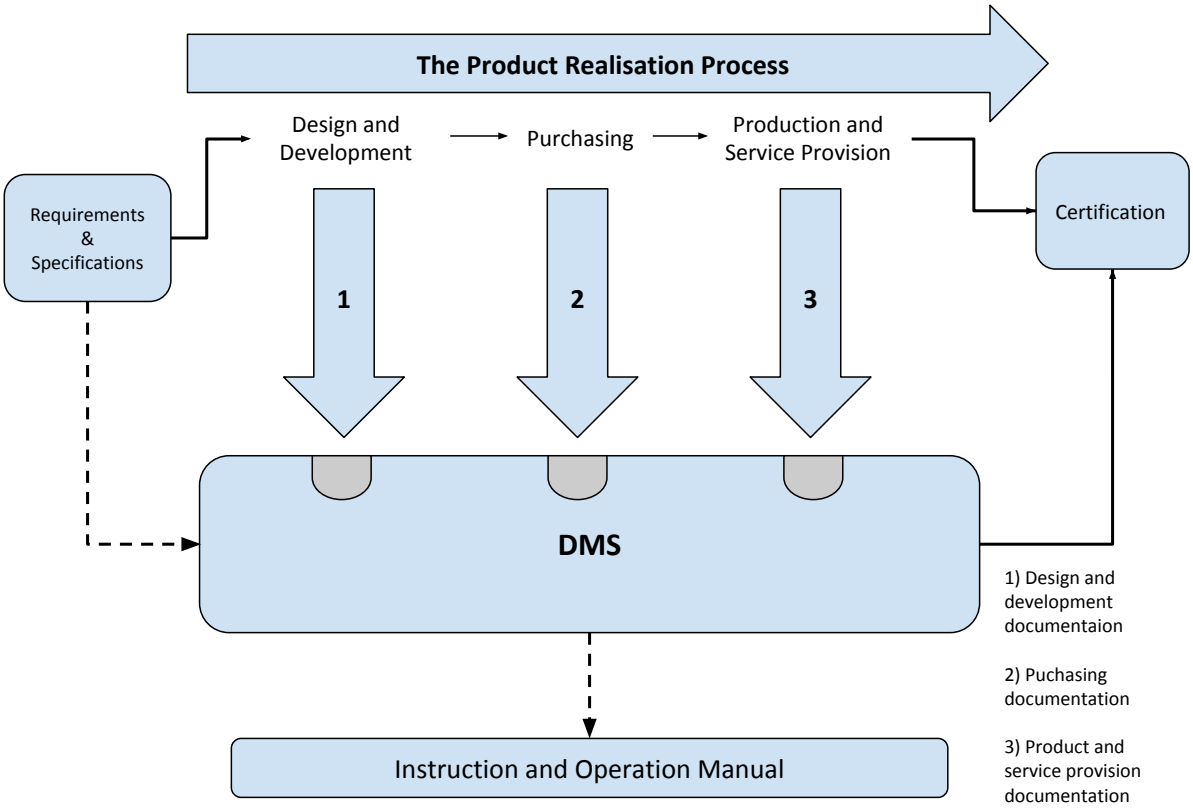


*Figure 5: Author's Illustration of the Flow of Documents Throughout the Product Realisation Process*

As illustrated by *Figure 5,* the PRP can be divided into three phases:

1. *Design and Development*
2. *Purchasing*
3. *Production and Service Provision*

*Figure 5* also demonstrates that each one of these phases is affected by a set of requirements and specifications, which can be more or less forced upon the company by customers and/or legislation. These requirements and specifications do not generate any official documentation. However, depending on the company's level of ambition, the requirements and specifications may be documented and maintained in the company's DMS. This is represented by the dotted line between the requirements and specifications and the DMS in the *Figure 5*. Furthermore, each phase in the PRP consists of a number of different activities, and each activity consequently generates specific forms of documentation. In order to qualify for certain forms of certification (for example ISO certification), this documentation has to be both documented and submitted to the company's DMS. The arrows in *Figure 5* marked '1', '2' and '3' illustrate this. Furthermore, the documentation generated during the PRP may also be used as basis for the creation of an *Instruction and Operating Manual* (IOM). This is illustrated by the dotted line between the IOM and the DMS in *Figure 5*. The IOM is used to describe activities regarding for example the handling of a produced product or certain pieces of equipment and may in turn be distributed to customers together with the produced products.

Specific processes and activities in the PRP may vary between companies. However, regardless of the design of PRP, the process generates a huge amount of documentation that has to be maintained. In order to enable proper collaboration within the supply chain, this documentation (or at least parts of it) has to be shared among the different supply chain actors. Furthermore, as the number of supply chain actors increases, so does the amount of documentation that has to be shared between them.

### Phase 1 - Design and Development

According to the ISO 9001:2008 standard, the *Design and Development* phase includes activities such as:

- Planning design and development
- Determining design and development inputs
- Determining design and development outputs
- Design and development review
- Design and development verification
- Design and development validation
- Control of design and development changes

Consequently documentation generated in this phase may regard:

- The different stages in the design and development process (including responsibilities and authorities).
- Review, verification and validation processes that are appropriate to each design and development stage.
- Functional requirements stating particular product behaviours or functions when certain preconditions are met (i.e. non-measurable requirements that describe what a product should be able to do[233]).

[233] U. Eriksson, 'The difference between functional and non-functional requirements', *ReQtest* [Blog], 2015-04-03, <http://reqtest.com/requirements-blog/understanding-the-difference-between-functional-and-non-functional-requirements/>, accessed 2016-09-28.

- Performance requirements stating quality attributes or characteristics of a product (i.e. measurable requirements that describe how a product should perform a certain function[234]).
- Information derived from similar product designs.
- Product acceptance criteria.
- Characteristics essential for proper and safe use of the product.
- Review results.
- Verification results that guarantee that the outputs from the design and development phase meet the input requirements.
- Validation results that ensure that the final product is able to meet the requirements for intended use.
- Corrective action.

### Phase 2 - Purchasing

The second phase in the PRP-process is *Purchasing* and according to the ISO 9001:2008 standard, this phase involves activities such as:

- Establishing criteria for how to evaluate and choose suppliers.
- Determining the type and extent of control of suppliers.
- Inspection or other activities necessary to verify that the purchased products meet the specified requirements.

The documentation generated during this phase consequently includes:

- Results of supplier evaluations.
- Requirements for approval of product, procedures, processes and equipment of suppliers.
- Qualification requirements of suppliers' personnel.
- Inspection/verification results.
- Material and test reports (MTRs)

### Phase 3 - Production and Service Provision

The third and final phase of the PRP-process is *Production and Service Provision*. According to ISO 9001:2008, the activities in this phase include:

- Planning production and service provision.
- Performing Production and service provision.
- Assuring availability of the information necessary in order to plan and perform the above-mentioned activities in a controlled manor.
- Validation of processes for production and service provision.
- Establishment of processes for identifying and tracing products throughout the supply chain.
- Identification, verification and protection of customer property provided for use or incorporation into the product.
- Preservation of produced products during internal processing and delivery to the intended destination, in order to maintain conformity to the product requirements.
- Control of monitoring and measurement equipment

[234] Eriksson, 2015.

In turn, the documentation generated in the third phase of the PRP includes:

- Information regarding product characteristics.
- Work instructions.
- Monitoring and measuring data.
- Criteria for product release.
- Criteria for review and approval of production and service provision processes.
- Criteria for approval of production equipment.
- Qualification and competence of personnel.
- Specific methods and procedures used for production and service provision.
- Information used for identification as well as tracking and tracing of products throughout the supply chain.
- Information regarding customer property for use or incorporation into the product.
- Results from calibration and validation of manufacturing equipment.

## 6.2 Issues Related to Non-Digital Document Management Systems

Manufacturers of complex and discrete products as well as their suppliers are today still restricted by the use of paper-based processes and aging systems for managing plant floor production. In other words, there are a number of issues related to manual handling and management of documents within companies. Manufacturers in the engineering, medical and food sectors today are for example required to document all stages in the production of a product throughout the supply chain, and in some projects copies of the same document might even exist in many different binders. This includes everything from the supply of raw material to the final testing and delivery of the completed product to the customer. Consequently this forces manufacturers to be able to both generate and process huge volumes of documents, and when performed manually these activities become highly time and resource consuming.

Manual or paper-based DMSs often lack well-established systems for sharing information, both internally (within the company) and externally (with for example supply chain partners). As a result documentation is often sent back and forth between different supply chain actors, and in turn many copies of the same document in different versions may be 'active' within the supply chain at the same time. Consequently, this implies that some supply chain actors might acquire out-dated versions of certain documentation, which in turn increases the risk for substantial error. Moreover, assuring full traceability throughout the supply chain consequently becomes more complicated when using a non-digital DMS.

Another major issue related to non-digital DMSs is that processes for checking and validating document content are performed manually, which means that the documents that are to be controlled have to be identified, retrieved and then read by personnel. Due to the time-consuming and monotonous nature of this task it is difficult to ensure consistency as well as accuracy and the risk of errors due to the human factor is high. In turn, this may lead to that products are produced with faulty features or that they are delivered with incorrect documentation.

Aside from fact that many document management-related processes today are still performed manually, manufacturers often lack the infrastructure to quickly access specific information within company documentation. In turn, this inhibits them from

making well-informed decisions. Furthermore, paper-based systems make it difficult for manufacturers to both find and deliver relevant quality information that is demanded by customers, and in some cases even necessary in order to address for example warranty claims. Paper-based processes also reduce visibility of manufacturing operations, which in turn complicates the mapping of manufacturing costs as well as the tracking and tracing of produced products throughout the supply chain[235].

The issues mentioned in this sub-chapter conclude that manual documentation is an obstacle for companies that wish to optimise their operational and financial results. Apart from the fact that non-digital systems slow down production and are prone to errors[236], they also affect the process of controlling and assuring quality of produced products negatively. Consequently, this often results in negative effects on product quality as well as increased production costs. To better illustrate how companies can improve from their non-digital DMSs, the main issues related to these systems are listed in *Table 15.*

*Table 15: Issues Related to Non-Digital Document Management Systems*

| **Issues related to non-digital DMSs** |
|---|
| *Difficulties with generating and processing large volumes of documents* |
| *Difficulties regarding processes for checking and validating document content* |
| *Manual systems are prone to error* |
| *Inability to create, find, access and deliver relevant information on time* |
| *Complicated tracking and tracing of produced products* |
| *Complicated backward tracing of manufacturing equipment* |

## 6.3 Requirement Set-Up For a Generic Digital Document Management System

In order for companies to be able to reach their desired goals regarding operational and financial results, the issues mentioned in the previous sub-chapter need to be resolved. For companies that are still utilising manual systems for document management the solution is digitalisation, i.e. the implementation of a digital DMS solution. Consequently, the previously discussed issues helped generate a set of requirements that the digital DMS should fulfil in order to help companies achieve their goals. These requirements are listed in *Table 16*.

*Table 16: Requirement Set-Up For a Generic Digital DMS*

| **Requirement Set-Up For a Generic Digital DMS** | |
|---|---|
| **Requirement 1** | *Facilitate the process of generating and handling large volumes of documents* |
| **Requirement 2** | *Simplify the processes for checking and validating document content* |
| **Requirement 3** | *Minimise the amount of errors caused by the human factor* |
| **Requirement 4** | *Reduce the amount of time needed to find, access and deliver desired information in company documentation* |
| **Requirement 5** | *Simplify tracking and tracing of produced products* |
| **Requirement 6** | *Simplify backward tracing of manufacturing equipment* |

[235] GE Intelligent Platforms, 2012, p. 3.
[236] Ibid.

## 6.4 Features of the Digital Document Management System

For each of the requirements mentioned in the previous sub-chapter, a corresponding feature that aims to solve the issue has been generated. The following sections present short explanations of the generated features.

### *Resolving feature 1 - Enable creation and storage of documents in a digital database*

Depending on factors such as business mission and policy, the need of documentation within companies as well as in large projects may vary. However, more and more companies today are starting to rely on the fact that their documentation is flawless. Even the companies that do not know it yet could in many ways improve their business through improving the effectiveness and efficiency of their document management. The main reason is that manual creation and handling of documents requires manpower. Consequently the more documents that have to be generated, the more manpower is needed.

The suggested solution is to digitise the process of creating, submitting and storing company documentation. Instead of creating documents by for example filling in forms by hand, one ide would be to let the people responsible for creating the documentation fill in the necessary information in a pre-created digital file, or standardised digital template. When all of the necessary information has been filled in, a digital document is then automatically and instantly created and stored in the right place of the company's digital database. In order to enable easy access to company documentation, a cloud-based solution to the company's database could be implemented.

Another idea is that manufacturing or metrology equipment itself is allowed to create certain documentation. In other words manufacturing equipment could be equipped with tools to measure and register the information necessary to complete specific documents or records (*Industry 4.0*). After registering all of the information needed to complete a specific document or records, a digital file could be created and stored instantly in the correct place of the company's digital database. This would in turn facilitate the use of RTD. However, in some situations it might not be possible for the machinery to complete the documentation by itself. In these cases, the documentation should be able to be completed digitally as described above.

Implementing a digital solution like the one discussed above would not only eliminate the need for physical handwritten documents but would also enable companies to handle a larger amount of documents in shorter period of time. It would eliminate the need for handwriting during the creation process, reduce the need for handling of physical documents (i.e. papers) extensively as well as minimise the need for physical storage space.

### *Resolving feature 2 - Enable the process of checking and validating document content to be performed digitally*

In non-digital DMSs, the process of checking and validating document content is usually done manually by opening and reading physical documents. Furthermore, since there does not exist any widespread systems or routines for performing these activities, this type of control usually has to be executed repeatedly throughout the supply chain. This implies that the risk for error within these processes is high, and consequently these processes would benefit greatly from digitisation and ultimately automation (or at least

by implementing clearly defined routines and or systems for how to perform the activities).

The checking and validating of document content could be simplified greatly through the utilisation of digital documentation, i.e. through the implementation of *Resolving feature 1*. One of the main reasons for this is that the digital documents could be downloaded from the company's document database from anywhere in the world. Hence digital documentation completely eliminates issues related to the physical location of company documentation. Additionally, since the document exists digitally the person responsible for controlling document content does not have to search through heaps of paper in order to find the relevant documentation before the process of checking and validating can start. In turn, digital documentation in itself can help reduce the manpower needed for checking and validating document content.

An even more effective solution would however be to automate the process of checking and validating document content (as far as possible), maybe through the installation of certain software-solutions that enable document content to be checked and compared digitally. Even though it might not be possible to automate the processes completely, every step that is automated leads to a reduction of the manpower needed to perform these operations. Furthermore, even partial automation of these monotonous and time consuming activities would increase the probability of detecting errors in documentation sooner than if the operations would have been performed manually.

#### *Resolving feature 3 - Establish clearly defined routines and systems for handling of company documentation and automate processes as far as possible*

As previously mentioned, the human factor is the reason for many of the issues related to document management. Some of these issues could be either partially or completely resolved through the implementation of *resolving features 1* and *2*. However in order to minimise the errors caused by the human factor, the amount of physical handling related to the document management should also be minimised.

One way to reduce the degree of physical handling within document management related processes is to establish clearly defined routines and systems for the processes that are not yet performed digitally. These routines and systems should cover all activities related to document management (for example creation, storage and retention, retrieval, processing and delivering of company documentation) and state who is responsible for each activity, how the activity is to be conducted and (if necessary) in what order the different operations are to be performed. Establishing these kinds of routines and systems consequently increases the possibility of optimising effectiveness and efficiency of processes related to document management. Furthermore since these routines should describe the most effective and efficient way of performing specific activities, they consequently eliminate unnecessary process steps and reduce the risk for confusion among workers. All together routines and systems like this reduce the probability of errors associated with the human factor. However in order to reduce the amount of human interaction within document management even further, processes should be automated as far as possible.

#### *Resolving feature 4 - Enable documentation to be 'searchable' and instantly retrievable*

In order to reduce the time spent on finding, accessing, processing and delivering specific information that can be found in company documentation, the company's digital

document database should be 'searchable'. That is, it should be possible to digitally search through parts of or even the entire digital database by using 'search words', or 'keywords', in the same way as one can do when searching for specific words in for example a PDF file. This feature would radically shorten the time spent on finding, accessing and delivering specific information within company documentation.

#### *Resolving feature 5 - Increase visibility of processes throughout the supply chain by creating a clear and comprehensible overview of company documentation*

As mentioned previously, one of the issues related to non-digital DMSs is complicated tracking and tracing of produced products. In order to resolve this issue, visibility of processes throughout the supply chain must be increased. This is partially facilitated through implementation of the previously mentioned *resolving features,* but in order to further increase the visibility a clear and comprehensible overview of company documentation should be established. This kind of overview could for example be obtained by organising company documentation according to a clear and consistent document hierarchy, and/or by implementing a consistent system for categorising and storing of documents and records. Furthermore, the process of mapping manufacturing costs can also be facilitated through the implementation of this feature as it helps keep track of information regarding for example:

- Product type
- Amount of products produced
- Production time
- Manufacturing operations

However in order to accurately track a specific product's current location in the supply chain, the ability to utilise RTD is also of great value.

#### *Resolving feature 6 – Increase visibility of processes throughout the supply chain by creating a clear and comprehensible overview of company documentation*

The requirement that *resolving feature 6* addresses (i.e. *requirement 6*) is similar to the requirement addressed by *resolving feature 5* (i.e. *requirement 5*) and consequently, the same type of solution is implemented for these requirements.

### 6.5 Generic Design of the Digital Document Management System

In conclusion, for a DMS to be classified as a 'digital DMS', it should resolve the issues presented in *Table 15* and consequently fulfil *requirements 1-6*. Moreover the *resolving features* presented in the previous sub-chapter are merely suggestions for how to tackle the issues and requirements, and are therefore not necessarily the only possible way to go about when implementing a digital DMS. A summary of the *requirements* and their corresponding *resolving feature* is presented in *Figure 6.*

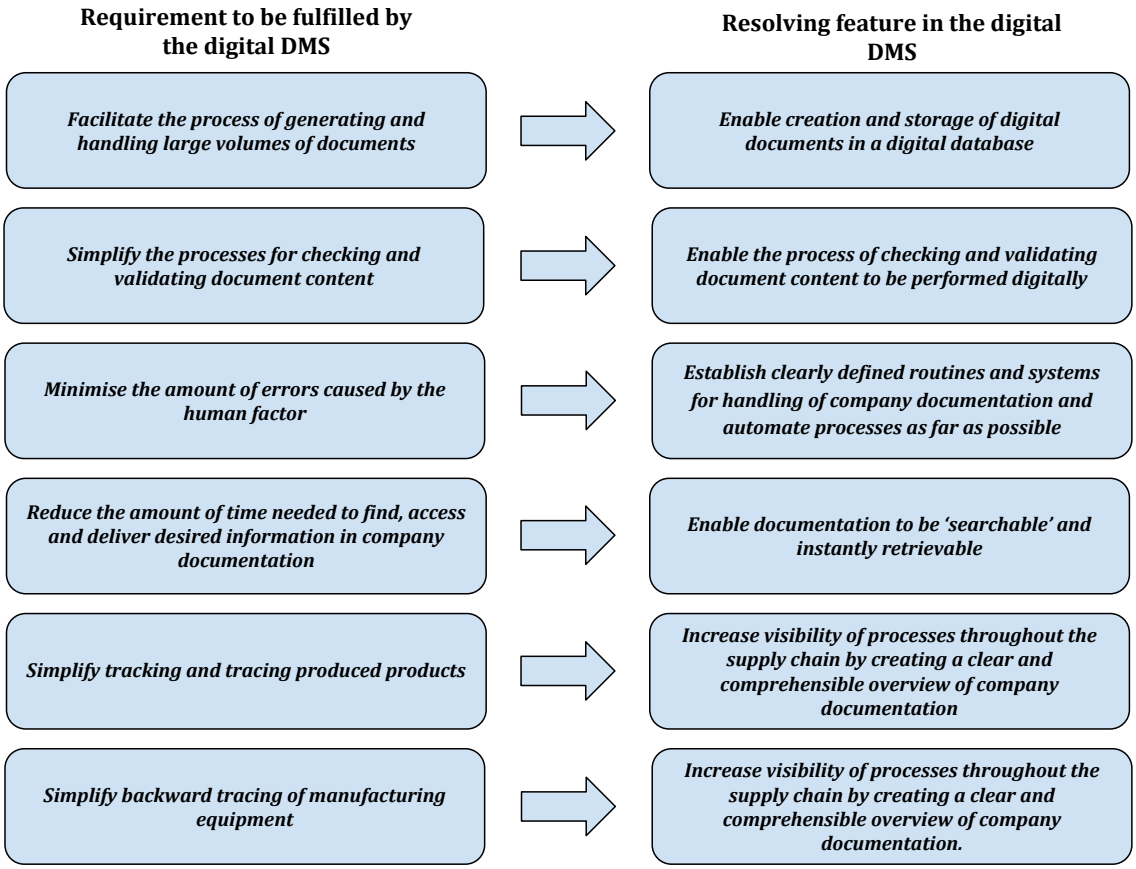


*Figure 6: Resolving Features in the Digital Document Management System*

As mentioned previously, the digital DMS described in this chapter is of generic nature. Hence, depending on factors such as the size, industry and operational goals of the company in question, its documentation needs may very. Therefore, in order to obtain the best possible results, the digital DMS should be adapted to suit the needs of the company in question and a thorough investigation on the company's specific documentation needs should be conducted before the implementation process begins. Furthermore, the process of implementing an efficient digital DMS requires both detailed as well as extensive work, and in order to be able to attain the potential benefits of a digital DMS solution, a properly thought through implementation process is key.

# 7 Framework 1.0

In this chapter a first version of the generic model for implementation of a digital DMS is presented. The chapter begins with a introducing a general implementation-model and continues with a stepwise description of the preliminary framework for implementation of a digital DMS i.e. *Framework 1.0*. The framework is divided into four different phases (*Pre-Installation, Installation, Post-Installation* and *Evaluation and Corrective Action)*, which are presented in chronological order. Lastly, the chapter is concluded with a summary of *Framework 1.0*.

## 7.1 General Model for a Successful Implementation Process

An implementation process can be divided into three obligatory phases that every company goes through when implementing a new technology or system. These phases represent work and activities related to the implementation process prior to, during and after the implementation process. In this Master Thesis, these phases are referred to as *Pre-Installation, Installation* and *Post-Installation*.

The first phase, *Pre-Installation,* refers to the work prior to the implementation and includes for example planning-activities. The *Installation* phase concerns the work that is performed by the company during the actual 'installation' or introduction of the new system or technology. This phase involves installation or introduction of the new technology or system. The third phase of the implementation process, *Post-Installation,* involves the work after the actual implementation of the new technology or system, i.e. primary use.

The three phases mentioned above give a general description of how to view work and activities related to an implementation process. However, in order to assure a successful implementation process, the implementation and its results should also be properly assessed. A fourth phase focusing on evaluation, assessment and corrective action should therefore be added to the process described above. In this Master Thesis, this phase is referred to as *Evaluation and Corrective Action,* and as the name implies the phase involves activities for assessing, measuring and evaluating the results from the implementation process. This phase is considered necessary in order to improve activities related to the implementation process, which in turn could both facilitate and improve future implementation processes the within the company. Hence the *Evaluation and Corrective Action* phase is deemed to have a substantial impact on the results from both current and future implementation processes.

With these four phases in mind, a general model for a successful implementation process has been developed (illustrated in *Figure 7*). This model can be applied to any implementation process, but in order to describe a specific implementation in detail it should be developed accordingly.

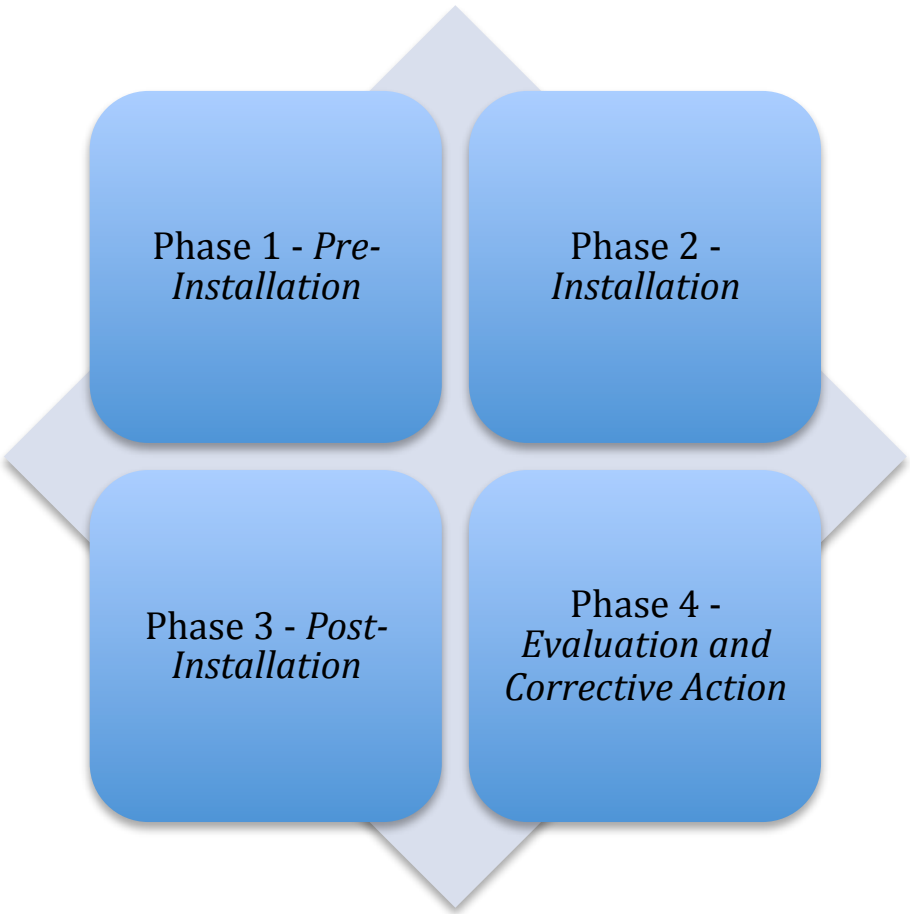


*Figure 7: General Model for a Successful Implementation Process*

In this Master Thesis project the implementation process in question is the implementation of a digital DMS. In order to enable effective implementation and fully gain the potential benefits related to such a system, a first draft of a supporting framework has been created.

## 7.2 Framework for Digitisation of Document Management System

The base of the framework for digitisation of document management consists of the four phases shown in *Figure 7*. Each phase is broken down into a set of critical steps, which companies implementing a digital DMS should follow in order to assure successful results.

Each phase in the framework has its own challenges as well as opportunities and depending on how each phase is handled, they all have different effects on the implementation process and its results. The critical steps in each phase are therefore identified through specification of challenges and opportunities in the different phases, as well as the potential effects of not taking them into account.

### 7.2.1 Phase 1 - Pre-Installation

The critical steps that have been identified for the *Pre-Installation* phase are focused on creating the required pre-conditions for a successful implementation process of a digital DMS. The critical steps are presented in *Figure 8*.


*Figure 8: Critical Steps in Digital DMS Phase 1 – Pre-Installation*

The following sub-chapters describe the critical steps in the *Pre-Installation* phase.

#### *7.2.1.1 Identify and Define Motives for Implementation*

Just like when defining the motives for ISO 9001 certification, defining clear motives before performing any form of implementation process is critical for its success. Therefore, one of the critical steps in the *Pre-Installation* phase is identifying and defining the motives for implementation. This could easily be perceived as a relatively simple activity, but still it must not be overlooked.

As mentioned earlier, motives can be divided into internal and external motives, which is also the case in this framework. Therefore the motives for the implementation of a digital DMS are also divided into internal and external motives. For this kind of implementation, examples of external motives include legislative requirements as well as pressure from customers and suppliers. Internal motives for implementation on the other hand could be to improve efficiency and effectiveness of document management related activities within the company, or to increase and improve collaboration and communication with actors both up- and down-stream in the supply chain. However, these motives may vary depending on the company in question. The degree of complexity of the digital DMS that is to be implemented within the company might also affect the implementation motives.

As it has been concluded in the literature study, internal motives are deemed to have a greater effect on an implementation process and tend to lead to overall better long-term results than external motives. The reason for this is that companies that are internally motivated generally work actively towards developing and maintaining effectiveness and efficiency of the implemented system, instead of simply working towards implementing the system. Consequently, internally motivated companies do not only strive to fulfil the minimum requirements because they realise that there can be more to implementing a certain system, than just obtaining the system for external motives.

However, even though the benefits related to external motives are generally not as great as the benefits related to the internal motives, external motives might still constitute enough reason for performing the implementation of a digital DMS. For example, a company might demand that their suppliers must fulfil certain requirements in order for them to do business together. In turn, a supplier that does not fulfil these requirements is more or less forced to make changes in their DMS in order to be able to do business with this company, even though they might not experience any troubles with it. In a situation like this, the external motives could actually be the main reason for implementing a digital DMS, which in turn generates the possibility of signing new deals and thus increasing revenue.

Some motives (internal and external) that are relevant for the implementation of a certain system today, were not perceived the same way a few years ago. As time passes, new requirements arise and companies are suddenly forced to respond to them. Major events and disasters similar to the BP oil spill in 2010 and the nuclear meltdown in Fukushima in 2011, are examples of incidents that could affect future requirements on for example traceability, which in turn also affects the requirements on companies' DMSs. Additionally, in order to keep up with the increasing global competition, companies can in some cases be pressured to invest in technologies they believe to be unnecessary at the time. This is not only the case for companies that are already ahead in technological development or companies that are lagging behind, this is true for all companies of all sizes in all industries. In order to stay competitive in our increasingly digitised environment, all companies have to adapt to the digital development sooner rather than later.

Even though a company might not find any motives for implementing a digital DMS at the time, it is an inevitable development either due to external requirements on document management from customers or government, or due to internal requirements on organisational efficiency and effectiveness. Since digitisation is increasing rapidly all over the world, it is vital for companies to acknowledge that potential requirements that might arise in the future could turn into both internal and external motives for implementation sooner than one might think. This is especially relevant for companies working with complex products, since external requirements (customer requirements as well as legislations and regulations) have drastically increased over the last decade.

The need for digital solutions for handling company documentation is increasing, and the development towards digital DMS solutions is inevitable. Rather than a question of 'if' the implementation of a digital DMS should be performed, it should be a question of 'when' to perform it. Generally it can be concluded that that is better to do it sooner rather than later in order to stay ahead of the competition and to be prepared for sudden changes in external requirements.

#### *7.2.1.2 Define Implementation Objectives and Translate Them into Comprehensible Metrics*

Defining implementation objectives is the second critical step in the *Pre-Installation* phase. One of the reasons for this is that the objectives help determine what has to be done during the actual implementation process. If the objectives can be translated into understandable metrics (i.e. quantifiable requirements), they also help facilitate the

planning of the implementation process. Clear and well-defined implementation-objectives simplify estimation of:

- Investment costs
- Timeframe of the implementation process
- Minimum requirements and degree of complexity of the implemented system
- Competence needed to perform the implementation
- Resources necessary in order to maintain the system

The objectives help define the implementation process and therefore also have a great impact on the results of the implementation. Clearly defined objectives increase the ability to properly define and plan the implementation process itself, and in turn increase the chances of achieving the desired results. Without clear objectives that can be translated into goals or requirements, it will become harder to assess whether the implementation actually achieved the expected results. Hence, having clearly defined objectives facilitates evaluation of the system-results and in turn also enables companies to set reasonable expectations for the implementation.

According to *Table 9 (chapter 4.3.2.3 – Learning and Development-Related Benefits)*, one of the benefits of ISO 9001 implementation is reduced stress among workers as it helps establish clear descriptions of jobs, roles and expectations. Furthermore, the results of the literature review indicate that clear descriptions of jobs, roles and expectations also increase motivation and satisfaction among the employees. This implies that clearly defined objectives can increase the satisfaction and motivation as well as reduce stress among employees involved in the implementation process of a digital DMS as well. In turn, well-defined objectives can also help reduce the risk of loosing valuable company assets, i.e. staff.

Evidently a company's implementation objectives are related to the specific system or technology that is about to be implemented and in this thesis, the system refers to a digital DMS. As stated previously, one of the effects of the digitisation of document management activities is an increased ability to both record and analyse data from processes within the company. In turn, a digital DMS increases the amount of data that can be collected and handled by a company, and thus also facilitates analysis of this data. There are a number of significant benefits related to the ability to collect and analyse large amounts data, for example to improve processes within the company and to create more personalised offerings to customers. However, simply collecting the data does not automatically benefit the company. Consequently the company has to assure that:

- The right type of data is collected.
- A sufficient amount of data is collected.
- The company possesses the required manpower, competence and tools for gathering and analysing the collected data.

Hence, the objectives related to the implementation of a digital DMS should clearly specify what type of data as well as the amount of data that the company aims to collect with the digital DMS. The company should also make sure that they possess sufficient resources to implement and maintain an efficient digital DMS. If the company does not possess the resources necessary for implementing and maintaining the system, the company should either put in sufficient effort to acquire these resources or redefine the implementation objectives. If neither of this is done there is a risk that the implemented

system does not function as planned, which in turn could result in additional work due to redesigning of the system.

#### 7.2.1.3 Align Motives and Goals for Implementation

The relationship between a company's quality policy and quality objectives (discussed in *chapter 4.3.1 – Pre-conditions for Successful ISO 9001 Implementation*), can be compared to the relationship between the motives and goals of implementing a digital DMS. In the same way as company quality policies affects the quality goals, the motives for implementation of a digital DMS affect the ability to clearly define and set reasonable and relevant implementation goals. In turn, the implementation goals are then translated into comprehensible objectives for the implementation, in the same way as the quality goals are used to create quality objectives. As stated in chapter *4.3.1 – Pre-Conditions for Successful ISO 9001 Implementation*, it is essential for a company to align its quality policy and their quality objectives in order to achieve positive results from the implementation of the ISO 9001 standard. Likewise, aligning the motives and goals of the implementation of a digital DMS should therefore be considered a critical step in the *Pre-Installation* phase in order to enable a successful implementation process.

#### 7.2.1.4 Obtain Sufficient Support from Top-Level Management

Based on the suggested pre-conditions for ISO 9001 certification, top-level management support is considered to have a significant impact on the results of the implementation. Obtaining support from top-level management is an important step when performing other major implementations as well, for example the implementation of a digital DMS. Since top-level management are responsible for distributing resources within the company, management support is a pre-condition for enabling and maintaining a successful implementation of the system. Hence, without support from management, there is a higher risk that the implemented system will generate poor results.

An investigation with the purpose of determining the extent of the resources needed, should therefore be conducted in order to assure that the company posses both the ability and the will to maintain the system. If this type of investigation is not performed, the level of commitment required to maintain the system properly might surprise the company resulting in the digital DMS getting insufficient resources to maintain it properly or, in a worst-case scenario, a complete shutdown of the digital DMS.

### 7.2.2 Phase 2 – Installation

During the *Installation* phase the actual 'installation' of the digital DMS is performed. Depending on the motives and objectives (i.e. the ambition) of the company in question, the scope and complexity of the digital DMS can vary. In general, high ambitions should result in a more complex system, which implies to a more complex implementation and installation process. Since this framework is developed with a generic approach, the critical steps for the *Installation* phase are also of generic nature. In other words, rather than describing specific functions that should be included in the digital DMS in detail, the critical steps in this phase describe what aspects should be considered during the installation in order to fully gain the potential benefits of the system. The critical steps of the *Installation* phase are presented in *Figure 9.*

A pre-condition for a successful implementation of a digital DMS is that all of the critical steps in the *Pre-Installation* phase have been performed before the *Installation* phase

commences. The main reason for this is to reduce the risk of design-flaws due to ill-defined motives, goals or other uncertainties.

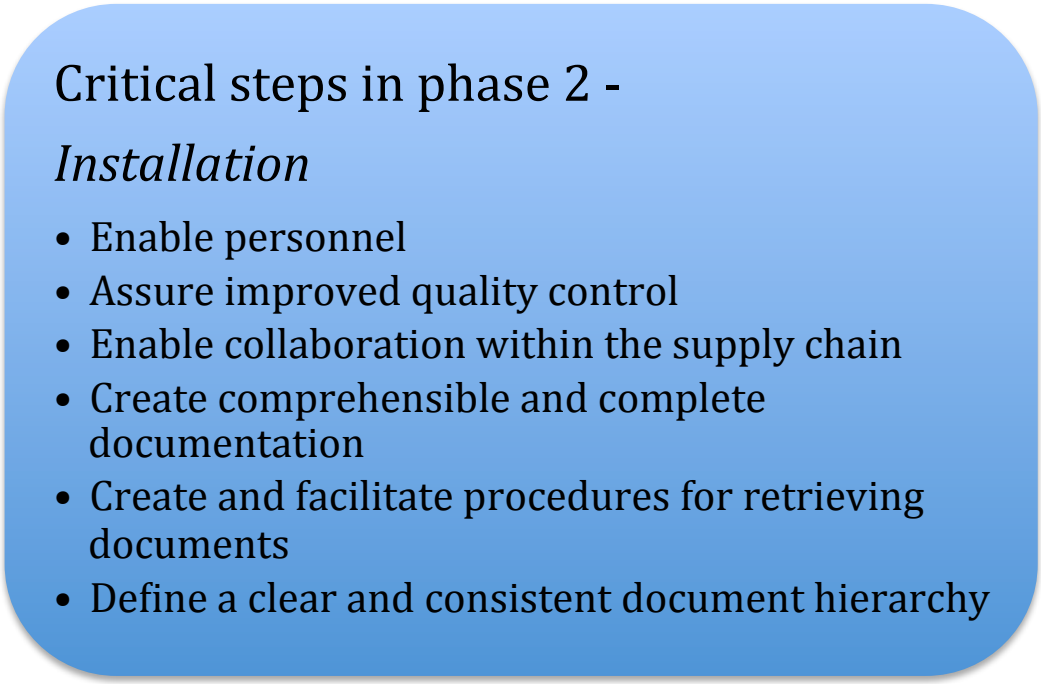


*Figure 9: Critical Steps in Digital DMS Phase 2 – Installation*

#### 7.2.2.1 Enable Personnel

In order to gain the full benefits from a digital DMS, it is vital to enable personnel to use the digital system properly. This might sound simple, but it is crucial the company implementing the digital DMS develops a set of activities that help provide the right people with the right information at the right time in order du enable success.

One thing standing in the way of enabling personnel is 'not having a uniform system for document management' within the company or organisation since it increases the risk for communication-issues. In other words, not having a uniform system for handling documents within a company increases the risk of information being "thrown over the wall", which in turn may lead to misinterpretations and unwanted results (this is discussed in chapter *5.4.6 - Inter-Organisational Communication of VOC*). Therefore, in order to fully obtain the potential benefits of a digital DMS, it is vital that the entire organisation is included in the implementation processes and given appropriate access to the system once it has been installed. More precisely, a digital DMS should not be implemented in only a part of the organisation as it could potentially cause communication-issues between divisions.

Another obstacle in this critical step concerns the updating as well as revising of documents, and throughout this Master Thesis project a number of issues related to this have been identified. These issues mainly arise when alterations of documents are not properly communicated to parties that might be affected by the changes. Not communicating document alterations clearly enough could have severe effects on activities within the organisation. For example, one potential risk is that products are produced according to out-dated specifications, which in turn will lead to the need for re-work and maybe even teardown. Furthermore, the effects of not disseminating

document-alterations throughout the organisation could even exceed organisational boundaries. For example, if the products do not fulfil the correct specifications, they will not be approved during the quality inspection. This will consequently affect customers that are expecting to buy the products, and depending on the gravity of the situation it might even affect the customers' willingness to do business in the future. Moreover, during quality inspection it is critical that the correct version of all relevant documentation is not only available, but also distributed to all parties involved. This might seem obvious, but if somebody (for example the quality inspector or surveyor) has 'the wrong version of the right document', it will not be possible to follow through with the quality inspection. This will cause both confusion and irritation among the parties involved and possibly lead to costly delays. In order to prevent the use of out-dated documents it is therefore critical that the digital DMS is updated when a document in the system is altered. As mentioned previously, this is also a GMP requirement (discussed in chapter *3.1.1 - General Documentation Requirements*).

#### *7.2.2.2 Assure Improved Quality Control*

A digital DMS improves a company's ability to instantly validate quality data (that is collected during for example manufacturing operations), which in turn increases a company's ability to monitor and control the quality of its products. Hence, an increased ability to monitor and control quality data increases the ability to detect unconformities in the early stages of production, which consequently decreases irreversible errors as well as the need for re-work and teardown.

However, as it has been discussed in chapter *7.2.1.2 - Define Implementation Objectives and Translate Them into Comprehensible Metrics*, simply collecting data does not automatically bring benefits to a company and does not automatically ensure improved quality control. In order to improve quality control, it is therefore important to make sure that the collected quality data is utilised properly. The company implementing the digital DMS should define all key variables or KPIs that are necessary to assess the quality of its products and include them in the digital DMS. Moreover it should be possible to instantly compare the KPIs to quality data (from for example manufacturing operations) that is continuously collected and inserted into the digital DMS. This would consequently increase the ability to monitor and thus control quality. In order to assure proper utilisation of quality data, it is also important to decide in advance what type of data that is to be collected as well as which KPIs the quality data should be compared to.

#### *7.2.2.3 Enable Collaboration Within the Supply Chain*

If implemented correctly, a digital DMS could help increase the visibility of operations within companies. Furthermore, the digital system could also help increase a company's ability to communicate and share information internally as well as externally. The increased visibility as well as the improved ability to communicate and share information can in turn be used to facilitate collaboration and communication with actors (suppliers, customers etc.) within the company's supply chain.

As discussed in chapter *5.2 – Internet of Things and Connected Manufacturing*, there are several benefits related to increased cooperation and communication between supply chain actors. These benefits include:

- Increased innovation
- Reduced risk of downtime
- Faster product development

- Increased product quality

Moreover, improved collaboration and communication with customers generate possibilities for companies to gather insights on customer needs, i.e. VOC, which in turn can be used to increase product quality and thus also customer satisfaction.

However, even though a digital DMS in many ways can both facilitate and improve communication between actors within the supply chain, it is vital that the communication channels are clearly defined. Inaccurate or incomplete definitions of the communication channels could otherwise result in insufficient process integration within the organisation and undefined rules of interaction. This could consequently have an opposite effect and instead cause costly delays. This is discussed in chapter *3.2.1 - Simplification of Process Design and Work Instructions*.

#### *7.2.2.4 Create Comprehensible and Complete Documentation*

In order to comply with GMP it is required that companies maintain accurate and proper documentation as it enables tracking and tracing of activities both within and outside the company. As mentioned in chapter *3.1 – Good Manufacturing Practice*, proper documentation and good records can also help enhance visibility and thus facilitate processes for reviewing and examining documents, which in turn reduces the inspection time during quality assurance and quality control. Moreover, proper and accurate (i.e. 'good') documents and records confirm that the company are following documented procedures and that processes are under control, which can also be helpful and save time during audits. This is discussed in chapter *3.1.4 - Policy for Compliance with Good Manufacturing Practice*. The definition of 'good' records can vary between companies (depending on their quality goals and objectives). However, good records should at least cover all of the processes from the purchase of raw material to the final product release. Furthermore, good records should provide a history of all produced products and their batches as well as their distribution.

The implementation of a digital DMS can facilitate the realisation of comprehensible documents and records as it eliminates the need for paper-based systems and manual processes, which are proven to be prone to error. Moreover, a digital DMS can also help to reduce errors and save time by eliminating manual tracking and updating of non-conformances in documentation (as discussed in chapter *5.3 – Digitalisation within Complex Discrete Manufacturing*). However, regardless of whether a company chooses to handle their documentation processes manually or digitally, all documents and records must be comprehensible. That is, in order to avoid confusion all documents and records should be clear, concise and logical. Documentation should also, whether handled digitally or not, be complete, meaning that documents and records should contain all relevant information with as few simplifications as possible in order to minimise the risk of misinterpretations. In spite of this, companies sometimes chose to simplify their documentation processes in order to save time or money, even though there are risks related to the simplification of document structure or content that could have severe effects on the companies' results.

One of the most obvious risks related to simplified documentation (discussed in *chapter 3.2.1 – Simplification of Process Design and Work Instructions*) is vague, incomplete and even inaccurate reporting, which in turn often leads to misinterpretations that can

result in process mutation. Another risk worth mentioning is that inadequate or incomplete descriptions or definitions regarding for example functional tool-specifications, might lead to difficulties or errors related to tool usage. Accordingly this also affects processes in which the tools are utilised. Incomplete definitions and descriptions might also make it harder to perform KPI measurements, which consequently complicates the validation of quality data and thus also impairs quality control and process management. Simplified documentation can also have direct effects on a company's activities. One example is that if definitions regarding reports are inadequate, the company will have to spend more time and effort on creating reports and inconsistencies will likely become more frequent. Furthermore, incomplete definitions regarding the company's communication channels will also negatively affect communication with actors in the supply chain due to undefined rules of interaction.

*Chapter 3.1 – Good Manufacturing Practice*, mentions the ten golden rules for complying with GMP. The third golden rule, 'write good procedures and follow them', implies that having well-written or 'good' procedures in place enables controlled and consistent performance of activities and operations within a company. However, in order to guarantee that the goals related to control and consistency are met, the procedures must also be followed. In spite of this, deviations from the written procedures occur time to time. In turn, deviations from the written procedures make it harder for companies to assure controlled and consistent performance and can also affect the end-results of the procedure.

During the writing of this thesis, two main reason for deviation from written procedures have been identified:

1. The worker misinterprets the instructions in the written procedure.
2. The purpose or rationale of certain steps in the written procedures is not apparent to the worker.

First of all, in order to be able to follow the steps in a written procedure it is crucial that the workers understand how to perform the different steps described in the written procedures. This is why comprehensible and complete descriptions of the written procedures are necessary. However, when the purpose or the effects of a particular step in the written procedure is not totally clear to the worker, the step might seem unnecessary or excessive. In turn, this could result in the worker taking shortcuts in order to save time or to simply make the task easier. As deviations from the written procedures might have severe effects on the end-results, it is of great importance that it is avoided. It should therefore be clearly communicated to all personnel that deviation from the written procedures is not allowed without the permission of a supervisor from the quality department. However ideas for improvement should always be encouraged. Moreover, as people usually tend to scan procedures and instructions for key words, it is crucial that the information in the written procedures is both easy to digest and follow. This could be done by for example breaking down the procedure by using clear headings, tables, bullet points and diagrams.

#### *7.2.2.5 Create and Facilitate Procedures for Retrieving Documents*

It has been concluded that the implementation of a digital DMS enables the creation of searchable documents and records, which in turn reduces the time for retrieval and facilitates the retrieval process significantly compared to paper-based systems. The reason for this is that the retrieval process in a paper-based DMS is handled manually,

i.e. people have to search through heaps of paper (often stored at different locations) in order to retrieve a specific document for a specific purpose. Consequently, searchable documents make it possible to reduce the time for the retrieval processes and thus also decrease labour costs related to this. Furthermore, shortened retrieval times can be especially helpful during situations when time is of the essence, for example when there is a warranty issue or during quality audits.

Even though the use of a digital DMS with digitally searchable documents enables a faster and simpler retrieval process, it might still be necessary to establish procedures for the retrieval process. Depending on the design of the digital DMS, the process for retrieving specific documents may differ from one company to another. Therefore, some systems might require strictly outlined and detailed procedures for how to retrieve specific documents, while other systems might only require the need for establishing rules regarding 'who is authorised to do what'. Establishing well-defined procedures for document retrieval could consequently facilitate the retrieval process further, which in turn would reduce the risk for misinterpretations and enable additional reductions in retrieval time.

#### *7.2.2.6 Define a Clear and Consistent Document Hierarchy*

As described by the DHP, company documentation (whether digitised or not) can be divided into different levels, which help create a comprehensible overview of the documentation within the company and in turn facilitate GMP compliance. However, the following extract from the *chapter 3.1.2 Hierarchical Documentation – The Document Hierarchy Pyramid* reveals an issue related to hierarchical documentation.

*"The details that are defined in the level 4-documentation may disregard directions given in lower level documentation. A company's SOP might state that numbers should be rounded off to three significant figures while the batch record might state that all numbers should be expressed in scientific notation. In this case, the instructions in the level 4-documentation can overrule the instruction described in the level 3-documentation since the level 4-documentation is specific to a particular process and thus more detailed in nature."*

Throughout this Master Thesis project it has become apparent that if a system for hierarchical documentation is applied incorrectly, misunderstandings regarding what instructions to follow might occur. The example above states that, even though lower level documentation should be governing, details that are defined in the higher levels may disregard directions given in lower levels. Unclear instructions like these might therefore result in misinterpretations and misunderstandings, which could for example result in the documented procedures not being followed correctly. In situations like the one in the example mentioned above, the consequences of a misinterpretation might not have any noteworthy effect on the overall results. However, depending on the situation, rounding off incorrectly might cause delays in standardised quality assurance activities and even corrective action. Generally stating that higher-level documentation sometimes may disregard directions given in lower level documentation, could consequently lead to unnecessary negative outcomes. This kind of general statement should therefore be avoided.

In order to avoid misinterpretations and misunderstandings, the final critical step in the *Installation phase* is to establish a clear and consistent document hierarchy within the

company. In other words, it should clearly be stated which directions and statements in the company documentation that are 'overriding' (i.e. which directions and statements that may never be disregarded), and which statements and directives that may be overlooked if more detailed specifications are available further down in the DHP. This could be done by for example adding symbols in connection to the overriding statements and directives in the digital documents. However, as the extent of documentation may vary drastically between companies, it is difficult to design a general system for hierarchical documentation. Each individual company must therefore design and implement individual system.

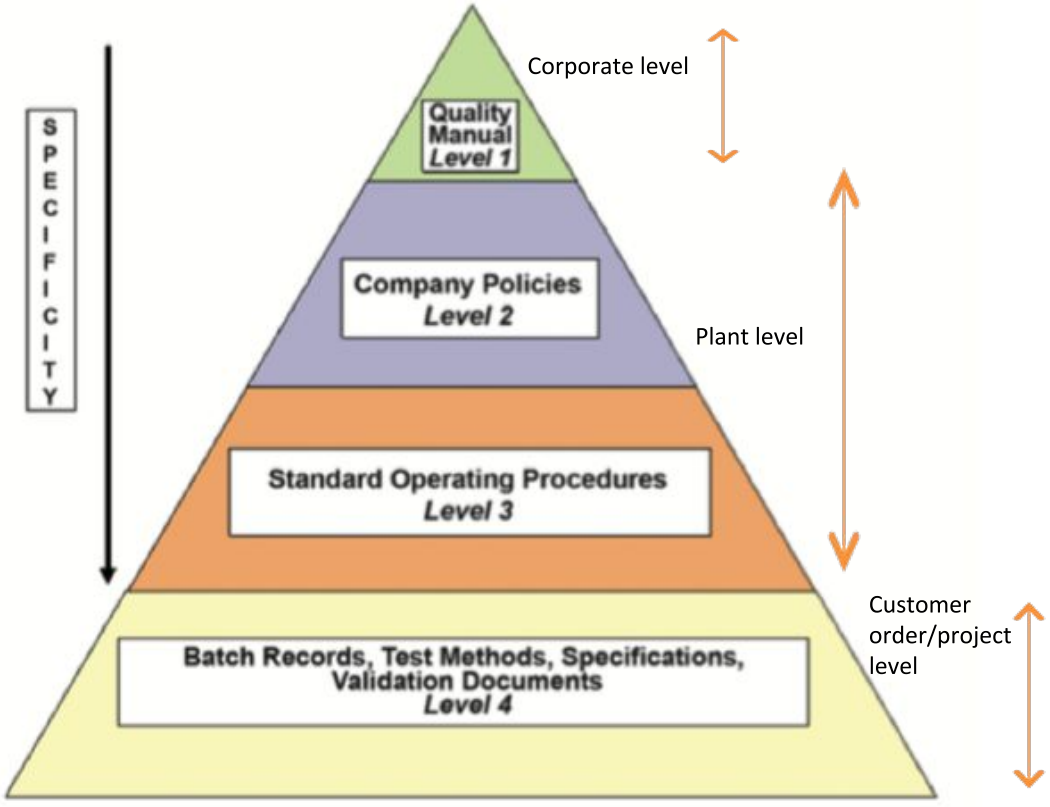


*Figure 10: Author's Illustration of the Document Hierarchy Pyramid*

Moreover, it should be emphasised that the documentation in level 1-3 (and parts of the documentation in level 4 as well) of the DHP is pre-loaded in the company's DMS. One could say that this documentation is 'fixed', since it is created beforehand and is not regularly modified or altered. Level 4-documentation on the other hand (for example batch records) is created, collected and submitted to the company's DMS continuously. Consequently, new submissions of different types of level 4-documentation are added to the company's DMS regularly and it is therefore important to have a clearly established document hierarchy within the different levels of the DHP as well.

### 7.2.3 Phase 3 - Post-Implementation

It has been concluded that manufacturers should not overlook the need for digitised processes as they function as critical enablers for achieving effective operations and optimising supply chain activities. Implementing a digital DMS is therefore an important step on the journey towards reaching Industry 4.0. However in order for this to become possible, certain measures have to be taken to assure that the digital DMS is utilised

correctly. Consequently, the purpose of the *Post-Installation* phase is to allow utilisation of the system in a way that enables development towards Industry 4.0.

In order to enable development towards Industry 4.0, companies must assure that the digital DMS keeps generating consistent and successful results even after the system installation is completed. It is therefore essential that companies continuously work towards maintaining an effective and efficient digital DMS. However, maintaining the system is not enough. As mentioned in *chapter 5.2 – Internet and Things and Connected Manufacturing*, technological development is escalating drastically and it is predicted that many technologies that are introduced today will become industry standards within the next five or ten years. Therefore, development of the digital DMS should be enabled in order to allow companies to adapt to future changes and consequently keep the competitive edge that is created by the digital DMS.

A set of critical steps that contribute to the development of Industry 4.0, are presented in *Figure 11*.

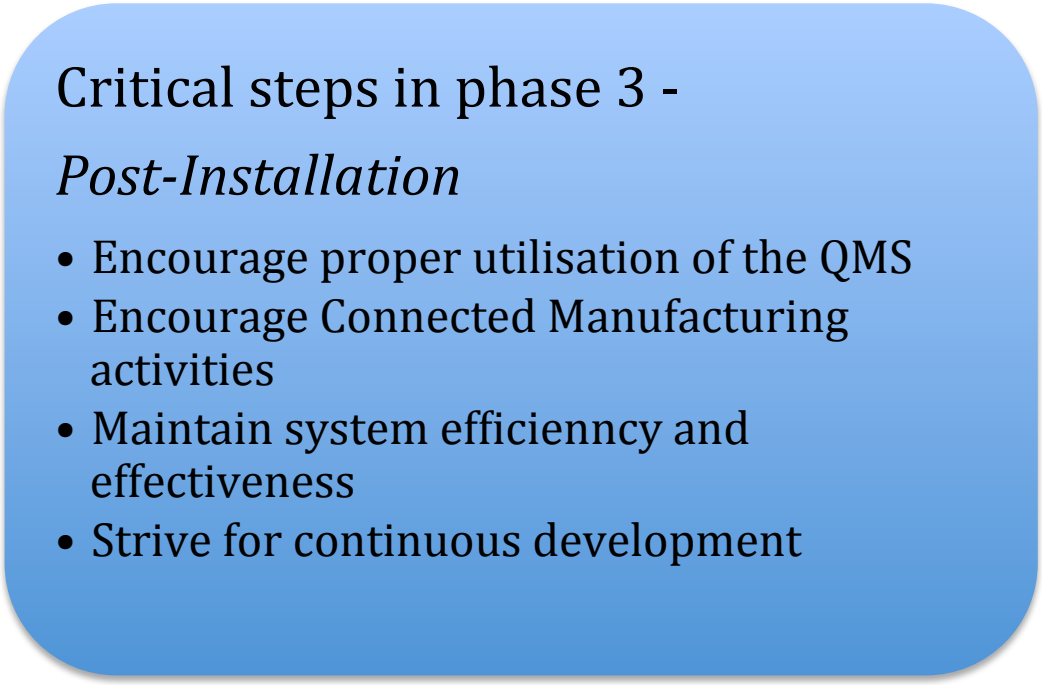


*Figure 11: Critical Steps in Digital DMS Phase 3 – Post-Installation*

In order for the *Post-Installation* phase to be successful, it is a precondition that all of the critical steps in the *Pre-Installation* phase as well as the *Installation* phase have been performed.

#### *7.2.3.1 Encourage Proper Utilisation of the QMS*

It has previously been stated that a properly implemented digital DMS can facilitate effective and efficient handling of documents. Consequently, this implies that a properly implemented DMS should help improve a company's QMS and thus facilitate ISO 9000 certification. Furthermore, a properly implemented QMS can be used to improve organisational efficiency and effectiveness and the implementation of a functional QMS is also an important milestone on the journey towards Industry 4.0. However a company implementing a QMS has to fulfil a number of requirements in order to assure successful

results. Furthermore some of the activities required to fulfil these requirements are related to the implementation of a digital DMS. Consequently, proper utilisation of a digital DMS could facilitate the implementation of a well-functioning QMS and thus help companies on their journey towards Industry 4.0.

Some of the requirements for implementing a QMS (from the ISO 9001:2008 standard) that could be facilitated through proper utilisation of a digital DMS are listed below:

- Monitor, measure and analyse data from the QMS processes.
- Guarantee control over outsourced processes.
- Ensure that up-to-date versions of applicable documents are available.
- Counteract unintentional use of obsolete documents.
- Ensure that documents remain comprehensible and identifiable.

### Monitor, measure and analyse data from the QMS processes and counteract unintentional use of obsolete documents

As stated in the literature review, one of the requirements for implementing and maintaining a functional QMS is to monitor, measure and analyse data from the QMS processes. All of these activities can be facilitated through digitisation as it enables the implementation of equipment for automatic data capture, which consequently simplifies the measuring processes. Digitisation also enables data to be instantly inserted in the right place in a 'digital library' or digital DMS, which in turn enables users (no matter where they are located physically) instant access to relevant data. This also enables users to easily search through heaps of documents in mere seconds, which in turn increases the visibility of processes within the company and in turn facilitates the monitoring. Finally, data analysis is simplified due to the increased visibility and ability to monitor data in general. The implementation of software solutions that allow for automation of data analysis processes (perhaps through add-ons to the digital DMS software) could further improve and facilitate these activities.

### Guarantee control over outsourced processes

Another requirement (from the ISO 9001:2008 standard) related to quality management is that if a company choses to outsource any of its processes, the company must guarantee control over them. Guaranteeing control over outsourced processes can in turn be facilitated through an inter-organisational system (IOS) for information sharing, i.e. a (preferably digital) system that allows companies to share information about specific processes or activities with each other.

As discussed in chapter *7.2.2.3 – Enable Collaboration within the Supply Chain,* a digital DMS can increase the visibility of operations within companies and thus increase their ability to communicate and share information (both internally and externally). Consequently, an increased collaboration and communication with actors within the supply chain increases the chances of creating an IOS for information sharing. Consequently, a digital DMS could help companies to guarantee control over their outsourced processes, provided that the companies performing the outsourced activities also utilise a digital DMS.

### Ensure that up-to-date versions of applicable documents are available

In order to implement a properly functioning QMS, companies have to make sure that up-to-date versions of all applicable documents are available (discussed in chapter *7.2.2.1 – Enable Personnel*). Through the utilisation of a properly implemented digital

DMS, companies can enable both constant and instant availability of the correct versions of all company documentation and records at all times. If the digital DMS is automatically updated when a document in the system is altered, the risk of out-dated documentation being used is also reduced significantly. Furthermore, if all company documentation is digitally available to all parties concerned at all times, there will be no need for sending out new documents to everybody as soon as a document is updated. Instead, the digital DMS allows for the correct versions of all relevant documentation to be available instantly to all concerned parties through the digital DMS. This consequently eliminates the risk for confusion and misunderstanding related to the use of out-dated documentation and thus simplifies the fulfilling of the above-mentioned QMS-requirement.

#### Ensure that documents remain comprehensible and identifiable

Another requirement for obtaining an effective and efficient QMS is the realisation of comprehensible and identifiable documentation. In other words, in order to establish a functional QMS information presented in the documentation has to both be easy to find and identify as well as easy to read and understand. Comprehensible and identifiable documentation saves companies both time and money, as it enables them to spend fewer resources (i.e. manpower) on searching for, identifying and interpreting specific documents and records.

A digital DMS enables realisation of comprehensible and identifiable documentation for mainly two reasons. First of all digitisation eliminates the need for handwritten documents. As the risk of misinterpreting handwriting is relatively high, digitisation increases the comprehensibility of documentation in general. Secondly, implementing a digital DMS allows companies to assign relevant identification marks or 'key words' to their documentation. These 'key words' enable companies to rapidly search through thousands of pages of company documentation in seconds, considerably facilitating the process of finding specific documents and the process of identifying relevant documentation.

### *7.2.3.2 Encourage Connected Manufacturing-Activities*

Throughout the writing of this Master Thesis, three typical Industry 4.0-characteristics have been identified:

- Increased focus on collecting and assessing customer requirements (i.e. VOC)
- Effective and efficient utilisation of RTD
- Improved communication and integration of functions within the supply chain

In other words, to reach an Industry *4.0* standard manufacturers will have to re-organise their current supply chain models in a way that enables increased collection and improved handling of VOC, effective and efficient utilisation of RTD as well as improved communication and integration of functions within the supply chain. Consequently, Connected Manufacturing is the key to fulfilling these requirements.

Connected Manufacturing is a term used to describe the technologies that enable integration of processes and products as well as people within the manufacturing industry. By using the power of the Web to link together machines, sensors, computers and humans, new ways of collecting, monitoring, processing and analysing data are enabled. The increased and improved integration between production equipment and

humans also enables instant collection and analysis of manufacturing data, which in turn can help increase the precision of manufacturing related activities overall.

A high degree of digitisation within the supply chain is necessary in order to enable Connected Manufacturing. Therefore, the utilisation of a digital DMS is an important step in order to enable Connected Manufacturing and Industry 4.0. However, the possession of digital tools (such as a digital DMS) does not guarantee that the Industry 4.0 requirements will be fulfilled. The following sections describe how the fulfilment of these requirements can be facilitated through proper use of a digital DMS.

### Increased focus on customer requirements

To be able to reach *Industry* 4.0, companies will have to increase their focus on collecting as well as assessing VOC. The insights obtained through VOC collection and assessment should also be properly disseminated throughout the organisation, so that everyone involved has access to the same information. However, to make this possible it is necessary to have effective and efficient communication internally (i.e. within and between the different functions in a company) as well as externally (i.e. between a company, its partners and its customers). Otherwise there is a risk of important information getting lost or distorted as it passes through the communication channel, like in a game of "Chinese Whispers".

A digital DMS can improve communication and collaboration both within an organisation and with its partners and customers. Since the digital DMS stores all relevant information in the same place, information does not have to be sent back and forth between parties. Furthermore, this consequently eliminates issues related to incompatible IT-systems. It also significantly reduces the risk of information getting lost or distorted as it is disseminated throughout the organisation. However, as mentioned in chapter *7.2.2.3 – Enable Collaboration within the Supply Chain,* companies have to establish clearly defined communication channels and stick to them in order to avoid delays in communication.

### Support proper use of real time data

Digitisation of documentation processes enables data to be instantly inserted 'in the right place' of a digital library. Furthermore, by utilising a cloud-based system, anyone with access to the digital DMS (regardless of their physical location) has the ability to access data more or less at the same time as it is entered into the system. In turn, this enables real time monitoring of processes from anywhere in the world, an activity that is vital in order to optimise supply chain operations. This is discussed in *chapter 5.3.1 – Digitisation Through Manufacturing Execution Systems*. However, in order to assure proper utilisation of RTD, it is important to enable access to the digital DMS for everyone in the organisation that requires it.

### Encourage integration of functions within the supply chain

Integration of functions within the supply chain refers to integration of both internal (within a company) and external functions (outside a company's boundaries). Hence, in order to obtain complete integration within the supply chain, companies should strive for both internal integration (for example integration of functions in different departments, teams and/or projects within a company) and external integration (e.g. integration with suppliers and customers).

Of many benefits associated to ISO 9001 certification (see *chapter 4.3.2 – Benefits of ISO 9001 Implementation*), some are related to the integration of supply chain functions. These benefits include:

- Improved communication as well as improved relationships with customers and suppliers (see *Table 4).*
- Increased transfer and distribution of knowledge, know-how and personal experience within the company and improved communication between employees (see *Table 10*).
- Increased sales through new customers and longer contracts with existing customers (see *Table 5*).

Through proper utilisation of a digital DMS, companies can gain additional value from the benefits mentioned above. For example, a digital DMS that allows users from all around the world to access information in a company's document database as soon as it is entered in the system facilitates the dissemination and sharing of information within as well as outside organisational boundaries. Consequently an increased ability to disseminate and share information enables further improvements in the overall ability to communicate and improve relationships with customers and suppliers. All together, this increases a company's ability to effectively integrate functions both within and outside of the organisation. Additionally, increased communication and collaboration between actors in the supply chain (for example between manufacturers and their customers) may result in even longer contracts and thus further increases in revenue.

There are however a few obstacles standing in the way of the development towards complete integration of supply chain functions and thus Industry 4.0. One of these obstacles is the lack of common standards for communication both within and between companies, which is discussed in *chapter 5.1.1 - Industry 4.0 Obstacles and Challenges*. A digital DMS could however help companies to overcome this obstacle, for example by granting limited access to specific parts of their digital DMS containing information relevant to their supply chain partners. This way, information could eaily be shared within the supply chain and across organisational boarders. However, when granting supply chain partners access to the digital DMS, companies must take into account what information they are willing to share as well as what information they want to keep for themselves. The issues related to openness of data are however not within the delimitations of this Master Thesis project.

#### *7.2.3.3 Maintain System Efficiency and Effectiveness*

In order to efficiently maintain the digital DMS, companies have to assure the following:

- Support from top-level management
- Sufficient resources and competence to secure system survival

As described in the *Pre-Installation* phase it is vital to have support from top-level management not only to implement a digital DMS, but also in order to properly maintain it. Without support from top-level management there is a risk that the system will not be assigned sufficient resources (i.e. manpower and monetary funds). Consequently this will affect a company's ability to utilise the system properly, which in turn will generate poor results and may lead to a complete shutdown of the system. However, by assuring support from top-level management these risks can be avoided. Proper utilisation of a digital DMS requires consequent and consistent monitoring and analysis of quality data.

Furthermore, a digital DMS will also require systematic service and updates to assure that it functions correctly. In turn, sufficient resources have to be assigned to the system in order to assure that it is updated regularly. This aspect is in turn also related to the degree of support from top-level management.

#### *7.2.3.4 Strive for Continuous Development*

The manufacturing industry of today is characterised by constant changes driven by increased globalisation, tough competition and increasing customer demands. It is no longer merely about making and selling products, but about connecting operations across the supply chain to efficiently be able to determine what customers want. The constantly changing industrial environment subsequently forces companies to continuously come up with new ways of maintaining their competitive edge, since a technological capability that grants a company a competitive edge today (such as a digital DMS) might become an industry standard in just a few years.

Even though the implementation of new technological capabilities such as a digital DMS enables manufacturers to leverage more advanced technological capabilities over time, it is vital that they strive for continuous development in order to stay competitive. Clause 4.1 in the ISO 9001:2008 standard states that an organisation is required to actively work towards continuously improving the effectiveness of its QMS in order to receive an ISO certificate. Therefore, in order to become ISO certified and enable future success, companies should not settle with implementing a digital DMS that is simply adapted to fulfilling their present needs. Instead, they should keep in mind that their needs might extend over time, which consequently may require them to update the system regularly. In conclusion, companies cannot rely on single investments in technological capabilities such as the digital DMS to help them thrive. Instead they must actively work towards continuously developing the technological capabilities that help improve their operational activities. It should also be emphasised that development of technological capabilities could generate new benefits that are difficult to predict and even comprehend in advance. Therefore, implementing new technologies within the company should be seen as long-term investments that have to be sought after, rather than solutions for short-term problems.

### 7.2.4 Phase 4 – Evaluation and Corrective Action

The fourth and final phase of the framework is called *Evaluation and Corrective Action*. The activities in this phase aim to evaluate and assess the results of the installation process, in order to identify areas of improvement. Through corrective action the areas of improvement can be developed in order to assure good results in the future.

As discussed in the previous phase (*Post-Installation*), maintaining the effectiveness and efficiency of the system is vital in order to assure good results. Furthermore, continuous development of the system is important in order for the company to be able to adapt to future changes. Thus, the activities in this phase should not be conducted exclusively after the implementation process is completed. Instead, it should be viewed as an iterative process in which the evaluation activities should be performed continuously throughout the implementation process and after its completion. Once an evaluation cycle has been conducted and areas of improvement have been identified, corrective action should be taken. This way a company is able to monitor and keep track of system performance, which in turn helps them secure good results.

In order to properly evaluate the implementation process and its results, the activities in this phase should focus on evaluating and assessing the results of use of the digital DMS. The activities in this phase should also focus on the handling of customer complaints regarding the company's newly implemented digital DMS and how to take corrective action. Consequently, these are the critical steps of the fourth and final phase of the implementation process. This is illustrated in *Figure 12*.

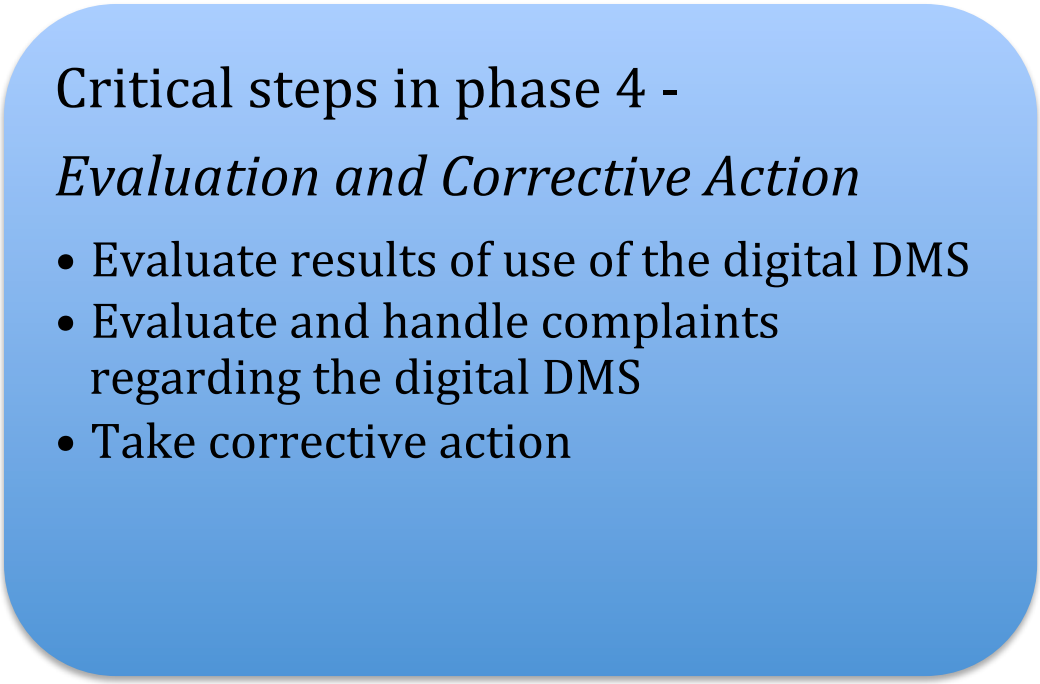


*Figure 12: Critical Steps in Digital DMS Phase 4 – Evaluation and Corrective Action*

#### 7.2.4.1 Evaluate Results of the Use of the Digital DMS

The evaluation of the results of use focuses on mainly two things:

- Company specific KPIs for document management
- Accuracy of the digital DMS

An example of company specific KPIs for document management is *the number of man-hours spent on retrieving or recovering documentation over a fixed period of time.* Depending on the company in question and its individual issues and challenges regarding document management, the relevance of these KPIs may vary. In order to perform a proper evaluation of the results of implementing a digital DMS, companies should first identify the minimum requirements for each or their document management KPIs.

The accuracy of a DMS is determined by the extent to which a finalised MRB/Manufacturing Data Record (MDR) consists of the correct versions of all relevant documentation. Consequently, the accuracy of a digital DMS must be high be in order to avoid risking costly delays caused by the need for correcting MRB documentation.

In order to perform a proper evaluation of the results of implementing a digital DMS, companies should also establish a uniform process for evaluating both their company-specific KPIs, and the accuracy of the digital DMS. This will allow them to compare the evaluation results over time and thus monitor the development of the system.

#### 7.2.4.2 Evaluate and Handle Complaints Regarding the Digital DMS

A company's handling of complaints is essential as it affects the way customers' view the company. For example inefficient handling of complaints may result in a low level of customer satisfaction, which consequently affects the customers' willingness to do business with the company in the future. Poor handling of complaints regarding for example a newly implemented digital DMS could therefore potentially lead to a decrease in revenues and thus affect the company's financial results negatively. Furthermore, ignoring complaints could result in that companies oversee the need for correcting certain issues that could potentially improve the performance of the digital DMS. It is therefore crucial that companies establish well-defined methods for evaluating and handling complaints regarding the digital DMS addressed by employees, customers as well as third party inspectors and surveyors.

In order to maintain an efficient and effective system for the handling of customer complaints, evaluations should be performed regularly. The evaluation process should analyse how the customer complaints are handled through assessment of for example:

- *Time to response* – time between a complaint being received and company's response.
- *Time to action* – time between a complaint being received and corrective action being taken.
- *Satisfaction* – general level of satisfaction among customers, users as well as third party inspectors and surveyors.

In conclusion, companies should establish a uniform process for evaluating and handling of complaints. This will enable them to compare results over time, and simplify the process of detecting deviations.

#### 7.2.4.3 Take Corrective Action

After having identified areas in need of improvement, a corrective action plan should be created. The corrective action plan should map out the activities that are required in order to correct the deficiencies that have been identified, and how to perform them. It is important that the procedures in the corrective action plan are followed through, in order to avoid simplifications that could affect the result of the corrective actions.

In some cases, certain risks related to the system (that have not yet caused any actual harm) may be identified. For these risks, it is important to establish well-defined countermeasures (including responsibilities). If not, there is a significant probability for lengthy recovery times.

### 7.3 Framework 1.0

A model of the final version of the preliminary framework, *Framework 1.0,* is presented in *Figure 13.* In the model, each phase is illustrated by a box in which the critical steps are presented. Each phase has been assigned with an equally large box in order to illustrate the fact that the different phases are of equal importance in order to obtain successful results. Moreover, to be able to assure successful results over time, it is crucial that measures to implement the changes suggested in evaluation phase are taken. In turn, this might lead to that the company has to 're-implement' certain features of the system in order to reach the desired results. Consequently, this implies that the implementation process is iterative. This is also the reason for why the different phases in the model for *Framework 1.0* are presented in a non-linear figure.


*Figure 13: Framework 1.0*

# 8 Case Study: CodeIT and the eMRB

In this chapter data from an empirical case study at the case company, CodeIT, is presented. The main part of the empirical data presented in this chapter has been collected through a series of open and semi-structured interviews as well as conversations with the CEO and founder of CodeIT, Bjørnar Torsnes. The remaining part has been collected through archival data analysis, based on a set of business documents received from the company. During the case study, a new software solution for digital document management, the *CodeIT eMRB* (eMRB) software, has been investigated. The purpose of the case study was to analyse the eMRB in order to identify features that might affect its implementation process.

## 8.1 Interviewee: Bjørnar Torsnes

Bjørnar Torsnes, CEO and founder of CodeIT, has over 30 years of experience of working with industrial marking, coding and automatic identification and data capture (AutoID/AIDC). In 1985 Mr Torsnes joined the UK based Willett International Group, which specialised in solutions for coding, labelling and product identification, where he started up new company divisions in Norway, Sweden, Denmark and Finland. Mr Torsnes possessed the title of Managing Director of Willett AS in Norway until 2004 when he joined Tiara-cml AS (later Goodtech AS). In 2011, the company spun off its division for AutoID, which Mr Torsnes acquired and renamed CodeIT. Today, Mr Torsnes is responsible for the day-to-day management of CodeIT.

During the writing of the Master Thesis, a large number of open and semi-structured interviews have been held with Mr Torsnes. Furthermore, the information gathered during these interviews has been completed with information from business documents received from CodeIT. However, these documents have only been used as 'working documents' and are thereby not included in the report.

Considering the amount of interviews that have been held as well as the fact that they have been conducted continuously throughout the writing of the thesis, it has been deemed inappropriate to transcribe and present each interview individually. Due to the unstructured nature of many of the interviews, it would not either be truthful to present the empirical data in such a manner. Moreover, as the data gathered from the interviews has been completed with information from business documents, it can be concluded that an extensive amount of information has been gathered during the empirical study. Therefore, in order to facilitate for the reader, a summary of the data gathered during the empirical study is presented in free flowing text in the following sub-chapters.

## 8.2 Company Background

CodeIT is a Norwegian SME founded in April 2011 consisting of a team of well-established and highly specialised employees possessing world-leading competences within software engineering, IT systems, AutoID as well as track and trace solutions for manufacturing and business. In 2015 CodeIT earned a place on the 'Gazelle list', a list of Norway's fastest growing and most successful companies by the Norwegian financial journal Dagens Næringsliv. The company's customers are primarily located in Norway, Sweden, Denmark and Finland and include companies such as Elkem Carbom, Marine Harvest, TINE, the Norwegian Technological Institute, Volvo Trucks, Boliden Zink and Kraft Foods.

CodeIT develops and delivers state-of-the-art fourth generation software and hardware solutions for industrial identification, marking, coding, labelling as well as tracing and integrates them into their customers' existing software solutions. The company's core business revolves around a software solution, named CodeIT Enterprise, for implementation of AutoID, labelling, marking and traceability of manufactured products and their components within a company. CodeIT also distributes a large range of hardware products (such as scanners, printers, label printers and RFID equipment) from leading global suppliers, which can be integrated into the customers' existing Enterprise Resource Planning (ERP) systems, MESs and Overall Equipment Effectiveness (OEE) systems through the utilisation of the CodeIT Enterprise software platform.

Recently the company identified an unfulfilled requirement in the manufacturing sector for an automated software solution that captures all data from manufacturing operations, and automatically creates and validates complete MRB documents for each individual produced product in real-time. This realisation led to the creation of the eMRB (electronic Manufacturing Record Book), an automated and customisable software solution for producing digital or electronic MRBs (eMRBs).

## 8.3 eMRB

The eMRB is a scalable software solution for industrial manufacturing that enables automation of processes for document collection, creation, validation as well as storage and compilation into comprehensive user specified documents (such as the MRB) across complete supply chains and geographical locations. The software is suitable for products that require stringent documentation from a product life cycle perspective and for which complete track and traceability is of the utmost importance. The development of the eMRB-system commenced when CodeIT (with the help of their customers) identified that there was an unfulfilled need for a way of structuring and simplifying the handling of large amounts of documents and the creation of necessary MRBs. In addition to this CodeIT also identified that the quality, i.e. accuracy and consistency, of company documentation was often compromised due to loss of information and errors in data entry through document creation processes. Hence, a need for increasing document quality was also identified.

### 8.3.1 What is a MRB?

The European manufacturing industry is currently facing increasing competition from both low labour cost economies (for example the Asian-Pacific region and the Indian sub-continent) and high-tech economies (for example USA and Japan). Meanwhile, it is becoming more and more important for companies to be able to demonstrate compliance with national regulations, standards as well as customer specifications and to be able to provide supply chain transparency. As a consequence, requirements regarding complete documentation as well as track and traceability of manufactured products and production equipment are also increasing. Today, many manufacturers must therefore be able to ensure that each part of their manufacturing equipment can be backward traced, for example if there is a need for replacement of any equipment or if an investigation concerning an in-service failure of a product has to be made. Furthermore, in order to help determine the quality, functionality and performance of a manufactured product, there are also specific documentation requirements regarding for example material composition, paint formulas, welding procedures, welders' certificates and non-destructive tests (NDTs). For producers of high-value and low-volume products (within for example the offshore, maritime, pharmaceutical, food and

beverage as well as the aerospace industries), this means that every stage in the supply chain must be documented. This includes every step from the supply of raw materials to final testing and delivery of a product to a customer. In many industries, in which safety and reliability of the final product is a matter of failure or success, companies must also document that the manufacturing activities have been performed by suitably certified employees and in compliance with specified procedures. All relevant documents and records must also be collected, checked (to ensure that all the necessary information is included and accurate), validated and then compiled in order to produce a single comprehensive document for each product (i.e. the MRB), which is then delivered to the customer together with the corresponding product or products. Furthermore, the MRB is can also be used as an efficient tool for documenting the product lifecycle management (LCM) process.

### 8.3.2 Issues Related to Current Solutions for Generating MRBs

One of the major problems with current solutions and procedures for generating MRBs, is that there are no common templates or document standards that fulfil the relevant requirements to generate an approved MRB. Hence, automation of the processes for checking document content is problematic. Currently, the process of checking document content is mostly done manually by first opening and then reading the original source documents (which can be both digital files and/or actual paper documents). In order to validate the content of these documents, they are then visually crosschecked against the content of the MRB. Moreover, there are no established systems or routines that can ensure the consistency and accuracy of documentation when a product moves through the manufacturing process. Instead, document control has to be done repeatedly and due to the tedious nature of this task, the risk for human error is high. Furthermore, the cost for correcting these kinds of errors increases substantially the later they are identified in the production process. There is also a significant risk that errors are not discovered at all and that products are delivered with faulty documentation.

### 8.3.3 How the eMRB Works

The eMRB is a Software as a Service (SaaS) solution is used for producing digital documents (mainly MRBs, but end users can also configure the system to create other documents as well) that can be customised to suit each customer's specific needs. The software automates collection and administration of existing documents through a process that enables automatic uploading and parsing of company documentation. It increases the quality of the final MRB by moving relevant data from the source documents (i.e. the original documents) into a single database (the eMRB database), where all data necessary for creating complete MRB documents is compiled. The system also enables information input directly from networked manufacturing and testing equipment into the eMRB database. Due to the automatic data collection and processing operations, the system also allows for automatic validation and consistency checks of the collected data. This consequently reduces the amount of human interaction in these processes and thus also the probability errors caused by the human factor. Furthermore, the system delegates data collection and registration to the personnel (i.e. the data owners) at the location where the information is created. Personnel at different end user facilities as well the end user's supply chain partners may also be given restricted access to the eMRB system. This enables them to directly upload the documentation required from them to the eMRB database, in order to facilitate creation of complete and comprehensible MRBs. Based on all of the information collected and handled by the eMRB system, complete electronic MRB (eMRB) documents specific to each product or

piece of equipment (or batch) can created. The eMRB documents may then be either printed or electronically delivered to the customer (depending on the needs and requirements of the eMRB users' individual customers) by simply pressing a button. Furthermore, the eMRB system also allows different types of status reports (based on for example current project data) as well as so called 'trace back reports' (based on historical data) to be generated. It makes use of the end user's existing technical infrastructure (for example networked equipment), can be integrated with the user's existing IT systems and enables lifecycle management (LCM) for both products and projects (including tracking and tracing capabilities). The eMRB solution can also be configured to handle any type of electronic document, and is designed to enable parsing of scanned versions of conventional paper copies.

The eMRB system can be accessed via a web-based interface and enables the manufacturing industry to produce MRBs faster and cheaper than what is currently possible with other solutions. It also enables users to digitally link data up and down the production processes, supply chain streams and across geographically dispersed manufacturing facilities, which in consequently supports implementation of Industry 4.0 initiatives that take advantage of industrial IoT technology.

The eMRB system can collect information (such as process parameters and machine configurations) directly from network-connected equipment and through the registration of all production events in a manufacturing process, the system enables tracking and tracing of all identifiable units. The system can present precise information (both current and historic) on location, material content and manufacturing operation performed (for example surface treatment, non-destructive testing, welding or calibration) and is able to interact with the users' existing 'back office' or IT systems. The system can also be configured to interact with the IT systems of the users' supply chain partners, which consequently facilitates and speeds up the process of collecting the information and documents necessary for creation of a complete MRB. Furthermore, by completely documenting every step in the supply chain, the eMRB offers supply chain transparency and also allows manufacturers to address ethical and labour issues. This consequently allows manufacturers to gain control over suppliers and other supply chain partners and helps identify poor working conditions, child labour and so on. Consequently, this supports initiatives such as the Ethical Trading Initiative (ETI). Moreover, the software also allows manufacturers to address environmental challenges by documenting for example carbon footprints of their products throughout the entire supply chain.

At the moment, there are no existing commercial solutions for creating MRBs, let alone digital MRBs. One of the key innovations and central functions of the eMRB solution is the process for uploading and parsing (i.e. a process of analysing for example a string of symbols) of documents, which enables automatic extraction of user specified information from different types of digital documents for storage in an indexed database. This feature reduces the probability of human errors since it more or less eliminates the need for human interaction. Furthermore it significantly reduces the time and effort to create a MRB and enables users to gain better control of the MRB-creation process. The system may also be implemented throughout a company's complete supply chain, which in turn allows for complete tracking and traceability. Another innovation and feature of the eMRB solution is that the system is able perform automatic

translations to and from different languages in order to produce a coherent MRB in a single language. This is especially helpful for the large manufacturers with international supply chains in which individual companies often produce documents in different languages. Moreover the eMRB system is scalable, which means that it can be customised to meet any foreseeable end user-requirements and allow 'seamless' uninterrupted expansion of capacity due to for example new production lines or additional facilities. The eMRB system can be installed on a company's personal servers or accessed as a SaaS Solution via CodeIT's secure private cloud.

Although the eMRB solution can be used for most manufacturing and processing operations in which a product's complete lifecycle must be managed and documented, it is best suited for high value low volume products where reliability and safety of the product is critical. This includes for example aircrafts and their subsystems, oil and gas production equipment and automobiles.

#### *8.3.3.1 Key Features and Benefits of eMRB Implementation*

The key features of the eMRB system are:

- Automation
- Increased MRB quality and simplified validation processes
- Flexibility
- Delegation and streamlining of workflow
- Creation of complete lifecycle MRBs
- Easy access, use and configuration
- Standardised and custom MRB structures
- Integration with other systems
- Security and reliability

##### Automation

The eMRB system allows for automatic collection, parsing, processing and compiling of documents to enable creation of a complete electronic MRB that confirms to a specified structure and file format, which contains all of the relevant data (manufacturing, testing, logistics and supply chain data) regarding a manufactured product. When the manufacturing process and testing of a product is complete, a final MRB can be delivered to the eMRB user's customer as either a hard copy (for example printed physical documents) or in digital format of their choice by simply pressing a button on the computer. Hence, automation benefits end users in terms of time saved and reduced personnel costs for creation of MRB documentation, as the system requires significantly less practical involvement of personnel.

##### Increased MRB Quality and Simplified Validation Processes

Today, most MRBs are produced manually (usually by company personnel). The process of creating a MRB starts with manual creation of a specific MRB document template. Thereafter, all documentation that is deemed relevant for the creation of the MRB has to be read individually in order for personnel to identify what data to include in the MRB. Lastly, in order to finalize the MRB, the relevant data has to be entered manually (i.e. typed) into the MRB document template. Due to the time consuming, repetitive and tedious nature of this task, it is prone to both errors and discrepancies. Furthermore, in order to assure that the MRB is correct, the manually produced MRBs have to be checked by 'proof reading' and comparing its content with that of the individual

documents used to create it in the first place. However, the eMRB enables automatic MRB creation and thus minimises the amount of manual labour needed for the creation, checking and validation processes. In other words, through automating the extraction and import of as much data as possible from the individual documents into a single database, the risk for data entry errors is reduced. It also enables automated consistency checks as well as validation, which consequently increase the overall quality of the generated MRBs.

### Flexibility

Aside from the fact that the eMRB can be used for automatic MRB creation, the software can also be used to create other user specified documents (for example test summaries, process summaries and MRBs for sub-systems of larger products). The eMRB user interface also allows the software users to query the database at any given time to extract specific information and monitor the overall progress of the manufacturing process. This is a feature that is not available with alternative methods for producing MRBs.

### Delegation and Streamlining of Workflow

The eMRB software architecture enables for creation of user accounts, which in turn allows companies that are using the software to specify which of its personnel and authorised supply chain partners that can upload documents. The company may also specify which personnel that can approve and authorise the creation of MRBs. Furthermore, the process of collecting, uploading and registering information can be delegated to the people at the location where the information is creating (for example uploading of welding logs can be delegated to the actual welder). As all authorised users have access to the eMRB system (with the exception of any access limitations the company using the software wishes to impose), the documentation workflow is streamlined. Consequently this further decreases the amount of time and effort needed to create a MRB document.

### Creation of Complete Lifecycle MRBs

Current processes and solutions for MRB creation (especially paper based processes) mainly address the manufacture of products up to the stage where they are ready for delivery to the customer. Consequently, these solutions do not allow the MRB to be updated (for example if subsequent alterations are made to the product) after the product has been delivered to the customer. Furthermore, they do not either take into account that there might be a need for recertifying a product if its service lifetime is expanded later on. The eMRB however allows revised MRBs to be generated instantly when new documentation regarding the product (for example revised blueprints or test reports) has been uploaded to the system, even after delivery.

### Easy Access, Use and Configuration

The eMRB software system is accessed via a web browser, which implies that the software is accessible from wherever there is Internet connectivity. The eMRB system can also easily be configured to suit specific user needs (concerning for example document formats and user accessibility), either by the users themselves or by CodeIT. Furthermore, the eMRB software interface has been developed through collaboration with and feedback from three different piloting companies in order to create a user-friendly interface and common terminology.

### Standardised and Custom MRB Structures

MRBs that are created today usually contain multiple reports provided by different suppliers or sub-suppliers involved in the manufacture of a given product. These reports often have different layouts and structures that consequently differ from those used by the organisation creating the MRB (the end user). The eMRB software however is able to transform these documents into a common generic template, which is configured to a layout or structure that the end user prefers. This allows the users of the eMRB software to specify the layout and structure of the MRB on their own. Furthermore, for different reasons some customers may require a specific layout or structure of the MRB that they receive when purchasing a product. When using the eMRB software, users are able to customise the layout and structure of the MRBs to better suit the need of each individual customer.

### Integration With Other Systems

The eMRB software can be configured to operate with the users existing IT systems or 'back-end-systems" (for example ERP systems and MESs), which enables automated import of documents from them. Moreover, the eMRB system can also be configured to connect and interact with the IT systems of the eMRB user's supply chain partners.

### Security and Reliability

The eMRB system is provided as a SaaS solution, meaning that it may be hosted on the end users own IT system or on CodeIT's private cloud system. The private cloud system runs on high-end servers, provides data security and complies with national privacy and data protection laws (for example the EC Data Protection Regulation). The cloud consists of two duplicate systems at two different geographical locations, which provides security in the case that one of the systems should develop problems. Furthermore, the cloud-based solution provides the software users with the benefit of avoiding additional IT investment and operational costs. Using the cloud-based system also means that the software user outsources the service of the system to the software provider (i.e. CodeIT), which consequently offers a 'piece of mind' to the software user.

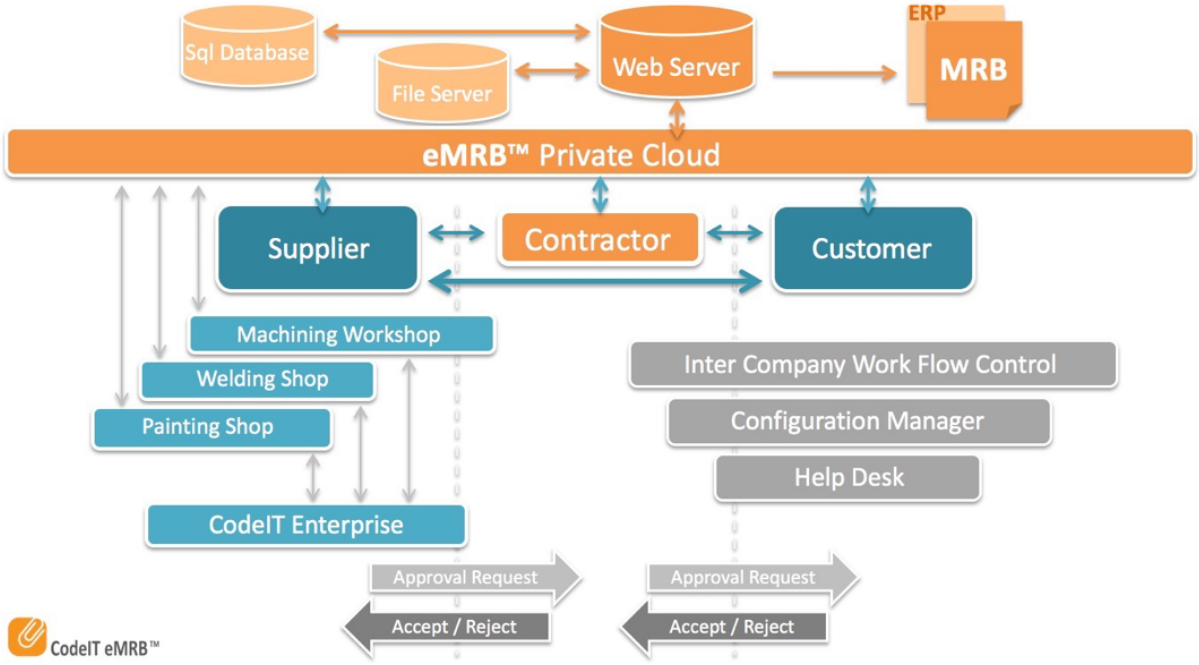


*Figure 14: Illustration of the eMRB System (CodeIT)*

#### 8.3.3.2 Economic Benefits Related to eMRB Implementation

As previously mentioned, the eMRB system reduces the amount of resources (both in terms of personnel and material) needed for both creating and managing MRBs. It also significantly reduces the need for paper-based archive storage and thus prevents delays in delivery and billing. As an indicator of the economic benefits one potential software user (Bestra AS) estimates that implementing the eMRB will result in a reduction of the personnel resources required to create and manage MRB documentation by at least 50%. Consequently, this frees up valuable personnel who in turn are able to work on more demanding activities. The system also considerably reduces 'industrial tourism', i.e. the need for staff to be onsite to control, document and evaluate production. This implies that the eMRB system enables savings in terms of reduced travelling and personnel time costs, but also in terms of decreased material costs (due to a reduction in paper consumption, printers, printer ink and so on).

Complete forward and backward tracing of manufactured equipment, components and products also reduces the time needed for identifying problems in the production process. It also enables these problems to be identified in an early stage, sometimes even before the problems have had any actual affects. This allows companies to address the problems before they become acute issues, which subsequently reduces the amount of production errors as well as product recalls and thus saves the company monetary resources.

#### 8.3.3.3 Eco-Benefits Related to eMRB Implementation

In addition to the operational and economic benefits related to eMRB implementation, the system also enables companies to reduce their environmental impact due to:

- Reduced need for travelling related to 'industrial tourism'
- Substantially reduced paper consumption
- Decreased amount of waste from manufacturing processes (due to fewer production errors and product recalls)

#### 8.3.3.4 eMRB Implementation Requirements

In order for the end users to get the most out of their eMRB system, the following activities should be performed during the implementation process:

- Identify the user facilities that will need access to the eMRB.
- Identify the existing IT systems that are to be integrated with eMRB.
- Implement on-site training in the use of the eMRB.

##### Identify the user facilities that will need access to the eMRB

Companies that manufacture complex products often have a number of facilities that are involved in the manufacturing process. Therefore, before implementing the eMRB software, all of the facilities (including facilities of sub-contractors, suppliers and other supply chain partners) that will need access to the software should be identified. Furthermore, a survey of personnel at the different facilities should also be performed in order to establish their role in the manufacturing process, and thus the degree of access that they will require (for example ability to upload specific documents into the eMRB database or ability to approve MRBs).

##### Identify existing IT systems that are to be integrated with the eMRB

As previously mentioned, the eMRB system is designed to allow data exchange with existing software and IT systems (for example ERPs and MESs). In order to properly

integrate the eMRB with a company's existing systems, all of the systems that will need to be configured to operate with the eMRB software have to be identified prior to the implementation.

#### Implement on-site training in the use of the eMRB

For some of the eMRB users, CodeIT implements on-site training of personnel in the use of the eMRB software. During the on-site training, so called 'dummy MRBs' are created based on existing documentation in order to highlight the work flow in the eMRB as well as the responsibilities of the individuals involved in the MRB creation process.

### 8.3.4 End User Needs Addressed by the eMRB

The key user need that is addressed by the eMRB software is the efficient and low cost production of electronic or digital MRBs for industrial manufacturers. In addition to this, a summary of additional end user needs addressed by the eMRB solution is presented below:

1. Automatic real-time collection and processing of all the documents required for the creation of a complete MRB.
2. Automated consistency checks and validation of the MRB according to the rules specified by the end user.
3. The ability to delegate different parts of information registration directly into the MRB to the people at the location where the information is created.
4. Tracking and tracing capabilities throughout the production process as well as the ability to obtain a continuous overview of the progress and status of documentation.
5. Integration with existing back office and IT systems (including the back office and IT systems of supply chain partners).
6. Digital signatures for individual documents and final MRBs.
7. The ability to print and/or deliver the MRB to the customer by the press of a button.

### 8.3.5 Standard and Regulatory Compliance

Standards and regulatory issues affect the eMRB software system at two levels. The first level concerns standards and regulations regarding the eMRB system's general functionality (for example functions related to document creation, management, storage, security and privacy). It involves standards and regulations such as the EC Data Protection Regulation and ISO standards. To assure that the eMRB system complies with these standards and regulations, CodeIT co-operates and exchanges information with relevant standard bodies such as the European Committee for Standardization and ISO.

The second level concerns the standards and regulatory requirements that the eMRB users have to meet. These standards and requirements are usually dependent on the industrial sectors that the users are part of as well of what type of products that the eMRB users produce. However as the eMRB software allows for customisation of documents as well as the MRB structure and layout, this aspect is addressed during the installation and configuration of the eMRB system for each user.

Furthermore CodeIT ensures that the eMRB system complies with all relevant standards, legislation and regulatory requirements for document creation, management and protection.

### 8.3.6 Improvement Potential

ICT (Information and Communications Technology) products, such as the eMRB, generally have to be developed continuously through incorporation of new technologies in order to adapt to changing user requirements. Hence, in order for the eMRB system to function as a long-term solution it has to be kept up to date in terms of its component technologies (such as communication protocols, encryption algorithms and database technologies).

As technological development progresses, measures have to be taken to ensure that the eMRB system can be configured to operate with new technologies. For example, DOM (Digital Objective Memory) is an emerging technology for tracking products during manufacturing. DOMs are, similarly to RFID tags, small devices that allow collection and storage of data records during all phases of a products life cycle. The information captured by the DOMs can be transmitted to a central server and could potentially be used to help create a MRB by providing specific information related to the production process. Therefore, once suitable standards for the DOM technology have been established, CodeIT plans to incorporate suitable connectivity into the eMRB technology in order to enable interoperability between DOMs and the eMRB system.

In a more long-term perspective, CodeIT also plans to incorporate functions such as data mining (technology for identifying patterns in large data sets) and data analysis in order to increase value creation in the supply chain.

# 9 Framework 1.1

In this chapter the updated version of the framework described in Chapter 7, *Framework 1.0*, is presented. Findings from the empirical case study have been compared to *Framework 1.0*, and accordingly new features have been added to the framework design in order to create a more comprehensive model. The chapter begins with an analysis of the findings from the empirical study, and is concluded with a presentation of the final model of the framework for implementation of a digital DMS, i.e. *Framework 1.1.*

## 9.1 Case Study Analysis

As presented in chapter 8, the eMRB system is a digital software solution for creation and management of documentation. Even though the eMRB is mainly focused on digital creation and handling of specifically one type of documentation (MRB documents), the system may be used create and manage other types of documentation as well. Furthermore, the eMRB system also fulfils the requirements of the generic digital DMS described in chapter 6 (see *Table 17).*

*Table 17: Digital DMS Requirements Resolved by the eMRB System*

| Requirement to be fulfilled by digital DMS | Resolving eMRB feature |
|---|---|
| *The digital DMS should facilitate the process of generating and handling large volumes of documents (Requirement 1).* | *The eMRB allows for automatic collection, creation, processing, validation and storage of digital documents in a cloud-based database. Furthermore, the system aims to simplify the handling of large volumes of documents.* |
| *The digital DMS should simplify processes for checking and validating document content (Requirement 2).* | *Due to the automatic data collection and processing operations, the eMRB system also allows for automatic validation and consistency checks of the collected data.* |
| *The digital DMS should minimise the amount of errors caused by the human factor (Requirement 3).* | *Automatic data collection and processing operations reduces the amount of human interaction in these processes and thus also reduces probability of errors due to the human factor.* |
| *The digital DMS should reduce the amount of time needed to find, access and deliver desired information in company documentation (Requirement 4).* | *Complete documents may be either printed or electronically delivered (for example to customers) simply by 'pressing a button'.* |
| *The digital DMS should simplify tracking and tracing of produced products (Requirement 5).* | *The eMRB system can collect information directly from network-connected equipment and through the registration of all production events in a manufacturing process, the eMRB system enables tracking and tracing of all identifiable units.* |
| *The digital DMS should simplify backward and forward tracing of equipment (Requirement 6).* | *The eMRB system can collect information directly from network-connected equipment and through the registration of all production events in a manufacturing process, the eMRB system enables tracking and tracing of all identifiable units.* |

Consequently, this implies that the eMRB system could be described as a type of digital DMS. Therefore, many of the eMRB features and requirements mentioned in chapter 8 are not only relevant to specifically the eMRB system, but also to the generic digital DMS model discussed throughout this Master Thesis. The insights from the eMRB case study have therefore been used for both validation purposes and inspiration for development of *Framework 1.0.*

### 9.1.1 eMRB Features Relevant to a Generic Digital DMS

The design of a digital DMS affects its implementation process since certain system features have to be accounted for before, during and/or after the implementation processes in order to obtain successful results. In turn, specific features of the eMRB system, that are relevant to the generic digital DMS model and thus affect its implementation process, have been identified during the case study. These features are:

- Scalability
- Status report creation
- Cloud-based database
- Automatic collection, parsing, processing and compiling of documents
- Automatic translation
- User-accounts

The eMRB features and their relevance to the generic digital DMS are presented in the following sections.

#### Scalability

The eMRB system is a scalable software solution, which means that it can be customised to suit specific needs of users of various sizes, turnover and activity. The scalability also enables adaption to potential changes in user needs, if for example the user expands its production capacity by adding new production lines, additional facilities or gains additional supply chain partners.

In order for a digital DMS to be able to meet the requirements from different customers, scalability is more or less a requirement and has to be accounted for during the implementation process. As scalability also enables the system to be integrated with any number of supply chain partners this feature consequently facilitates *collaboration within the supply chain*, one of the critical steps in phase 2 of *Framework 1.0.*

#### Status report creation

The case study uncovered that the eMRB system allows for creation of different types of status reports (based on current project data) as well as 'trace-back reports' (based on historical data). The eMRB system also allows the user to query the database at any time in order to extract specific information and to monitor the overall progress of the manufacturing process.

Status and trace-back report creation is relevant to the generic digital DMS model, and thus the framework, since it facilitates the activities for reviewing, monitoring and analysing operations and processes within the company. This feature could therefore be used to facilitate the process of monitoring, measuring and analysing data from QMS processes and thus *encourages proper utilisation of the QMS* (the first critical step in phase 3 of *Framework 1.0*). It also facilitates the process of controlling and validating quality data and thus helps *assure improved quality control through monitoring of quality*

(the second critical step in phase 2 of *Framework 1.0*). Furthermore, different types of status reports can be used to *evaluate the results of implementation of the digital DMS* (the first critical step in phase 4 of *Framework 1.0)*.

### Cloud-based database

The eMRB system is cloud-based, meaning that it can be accessed via a web-based interface, which enables users to swiftly link data up and down-stream in the supply chain and across geographically dispersed manufacturing facilities.

This feature is relevant to digital DMS solutions other than the eMRB as well as it enables anyone anywhere that needs access to a specific set of data to access it at any time (within certain limitations). As this feature helps 'provide the right people with the right information at the right time', it *enables personnel* to properly utilise the DMS (the first critical step in phase 2 of *Framework 1.0*). The feature also facilitates processes for sharing and disseminating information throughout the organisation and to supply chain partners and can thus improve communication within the supply chain. In other words, the feature improves the user's ability of *enabling collaboration within the supply chain* (the third critical step in phase 3 of *Framework 1.0*).

### Automatic collecting, parsing, processing, translating and compiling of data

One of the central features in the eMRB software is a an automated process for collecting, parsing, processing, translating information and compiling it into complete and comprehensible digital documents that confirm to a user specified structure or file format. This feature reduces the probability of human errors since it significantly decreases the need for human interaction during document management related activities, and thus enables users to gain better control of these processes. Consequently, this facilitates the process of *creating comprehensible and complete documentation* (the fourth critical step in phase 2 of *Framework 1.0*). The automatic collection of information is partially enabled through networked manufacturing and testing equipment that is able to automatically upload information directly to a digital database, a function that consequently *encourages the use of Connected Manufacturing* (the second critical step in phase 3 of *Framework 1.0)*. This eMRB feature also enables automatic extraction of user specified data from different digital documents in the eMRB database and could potentially be used to facilitate processes for reviewing and monitoring quality data, an activity that supports the second critical step in phase 2 of *Framework 1.0*. Furthermore, automatic extraction of user specified information from a digital database also *facilitates procedures for recovering specific documents* (the fifth critical step in phase 2 of *Framework 1.0*).

### Standardised and customised MRB structures

The eMRB software allows users to change the layout and structure of existing documents to make them confirm to a specific form that the users prefer. This in turn facilitates the process of *creating comprehensible and complete documentation* (the fourth critical step in phase 2 of *Framework 1.0*), due to an increased coherency of company documentation.

### User-accounts

The eMRB software architecture enables for creation of user account, which consequently enables users to specify who (personnel and supply chain partners) is allowed access to the system and what level of authority in the digital DMS they possess.

Furthermore, this feature enables the process of collecting, uploading and registering information to be delegated to the people at the location where the information is created (i.e. the data owners). This enables the data owners to directly upload relevant documents and records to the digital database, which facilitates the process of *creating comprehensible and complete documentation* (the fourth critical step in phase 2 of *Framework 1.0*). Furthermore, as the user accounts help establish clear roles for document management related activities, they also help delegate and streamline workflow for document management related activities both within the company as well as within the supply chain. In turn this feature facilitates and *enables collaboration within the supply chain* (the third critical step in phase 3 of *Framework 1.0*) and *enables personnel* to utilise the digital DMS properly (the first critical step in phase 2 of *Framework 1.0*.)

#### 9.1.1.1 Framework Validation Based on eMRB Features

Through analysis of the eMRB features the relevance of a number of the critical steps in *Framework 1.0* has been validated. A summary is presented in *Table 18*:

*Table 18: Validation of Critical Steps in Framework 1.0 Based on eMRB Features*

| Critical Step | Validated by eMRB feature |
|---|---|
| *Enable collaboration within the supply chain (phase 2)* | - *Scalability*<br>- *Cloud-based database*<br>- *User-accounts* |
| *Encourage proper utilisation of the QMS (phase 3)* | - *Status report creation* |
| *Assure improved quality control (phase 2)* | - *Status report creation*<br>- *Automatic collecting, parsing, processing, translating and compiling of documents* |
| *Evaluate the results of use of the digital DMS (phase 4)* | - *Status report creation*<br>- |
| *Enable personnel (phase 2)* | - *Cloud-based database*<br>- *User accounts* |
| *Create comprehensible and complete documentation (phase 2)* | - *Cloud-based database*<br>- *Standardised and customised MRB structures*<br>- *User accounts* |
| *Create and facilitate procedures for recovering specific documents (phase 2)* | - *Automatic collecting, parsing, processing, translating and compiling of documents* |
| *Encourage the use of Connected Manufacturing (phase 3)* | - *Automatic collecting, parsing, processing, translating and compiling of documents* |

#### 9.1.1.2 Framework 'Add-Ons' Based on the eMRB Features

One of the eMRB features have been used as basis for the creation of an 'add-on' (i.e. additional critical step) to *Framework 1.0*. The critical step that has been added to the framework for implementation of a digital DMS is:

- Enable system scalability

#### ‘Add-on’ 1: Enable system scalability

The first framework ‘add-on’ is based on the eMRB feature *Scalability*. This eMRB feature allows the system to be customised to suit not only the existing needs of the software users, but also to adapt to potential changes due to for example an increase in production capacity. During the process of implementing a digital DMS, companies should therefore assure that the implemented system allows for this kind of flexibility. If this is overlooked complications might arise if changes that affect the DMS occur in the future. This should be accounted for during the *Installation* phase, i.e. phase 2.

### 9.1.2 eMRB Implementation Requirements Relevant to a Generic Digital DMS

In addition to the eMRB system features described in the previous sub chapter, a set of implementation requirements for the eMRB system where also identified, some of which are applicable for a more generic digital DMS as well. The implementation requirements that have been deemed relevant to the generic implementation model of a digital DMS are presented below:

- Identify the user facilities that will need access to the eMRB
- Identify existing IT systems that should be integrated with the eMRB
- On-site training
- Regulatory compliance
- Continuous system improvement

The eMRB implementation requirements and their relevance to the generic implementation model of a digital DMS are presented in the following sections.

#### Identify the user facilities that will need access to the eMRB

In order to obtain the full potential benefits of the eMRB system, all of the user facilities (including facilities of sub-contractors, suppliers and other supply chain partners) that will need access to the system should be identified before the implementation process commences. Moreover, to be able to properly implement the system, the roles of the different facilities in the manufacturing process should be also be established. This is done in order to determine the degree of access that the different facilities will require (for example ability to upload specific documents into the eMRB database or ability to approve MRBs), i.e. to establish access limitations. Even though this requirement specifically concerns the eMRB system, it could be applied to more generic digital DMSs as well in order to avoid complications due to inattentive implementation.

#### Identify existing IT systems that should be integrated with the eMRB

As described in the eMRB case study, the eMRB system is designed to allow data exchange with the existing IT systems of both the primary user and its supply chain partners. However, in order to obtain successful results from the implementation, all of the existing IT systems that will need to be configured to operate with the eMRB software have to be identified. Although this requirement concerns the eMRB system, it could and should be applied to more generic digital DMSs as well.

#### On-site training

In order to *enable personnel to utilise the system properly* (the first critical step in phase 2 of *Framework 1.0*.), on-site training in the use of the eMRB system may be performed. Other than providing instructions on how to utilise the system properly, the on-site training can for example also help to highlight the responsibilities of personnel that will be in contact with the system, which consequently helps streamline workflow.

### Regulatory compliance

CodeIT assures that the eMRB system complies with both existing requirements on software functionality (for example functions related to document creation, management, storage, security and privacy) as well as industry specific regulations regarding document creation and document management. To assure regulatory compliance, CodeIT co-operates and exchanges information with relevant standard bodies (such as ISO and CEN).

As similar regulations and requirements concern other digital DMS models as well, this implementation requirement also affects the implementation of a generic digital DMS. Consequently, similar measures for assuring regulatory and standard compliance are also relevant for the generic digital DMS models.

### Continuous system improvement

Due to the short life span of ICT products (such as the eMRB and other digital DMS technology), they continuously have to be developed and upgraded in order to stay up-to-date. Consequently CodeIT actively works with improving their eMRB technology. Continuous improvement of the digital DMS technology should however also be accounted for by the companies utilising it. This requirement is addressed in the fourth critical step of phase 3 of *Framework 1.0.*

#### *9.1.2.1 Framework Validation Based on eMRB Implementation Requirements*

Through analysis of the implementation requirements related to the eMRB system, the relevance of two of the critical steps in *Framework 1.0* has been validated. This is presented in *Table 19* below:

*Table 19: Validation of Critical Steps in Framework 1.0 Based on eMRB Requirements*

| Critical Step | Validated by eMRB requirement |
|---|---|
| *Enable personnel (phase 2)* | *On-site training* |
| *Strive for continuous development of the digital DMS (phase 3)* | *Continuous system improvement* |

#### *9.1.2.2 Framework 'Add-Ons' Based on eMRB Implementation Requirements*

The implementation requirements for the eMRB system have been used as basis for the creation of four 'add-ons' to *Framework 1.0*, namely:

- Identify the user facilities that will need access to the digital DMS and determine accessibility
- Identify existing IT systems that need to be integrated with the digital DMS
- On-site training in the use of the digital DMS
- Assure regulatory compliance

**'Add on' 2: Identify the user facilities that will need access to the digital DMS**

The case study concluded that, in order to achieve the desired results of from the implementation of a digital DMS such as the eMRB system, companies should identify what facilities (including personnel) that will need access to the digital DMS. As for the eMRB system, the roles of the different facilities should also be established in this activity in order to determine what degree of access each facility should be granted. In turn, this facilitates the process of establishing appropriate access limitations so that

sensitive company data does not come into the wrong hands. Furthermore, carefully determining the degree of access is helpful if the company potentially wishes to implement user accounts later on.

This critical step should be performed before the actual implementation process begins in order to avoid re-implementation, and is therefore added to phase 1, *Pre-Installation*.

#### 'Add on' 3: Identify the existing IT systems that need to be integrated with the digital DMS

Similarly to the eMRB system, other digital DMSs may also be required to co-operate with the existing IT systems of both the digital DMS user and its supply chain partners. Therefore, in order to successfully be able to integrate the digital DMS with existing IT infrastructure, all of the IT systems that will need to be configured to operate with the digital DMS have to be identified. Furthermore, the company implementing the digital DMS must, prior to the implementation process, also ensure that the digital DMS is compatible with the existing IT infrastructure. This should be done before investments in digital DMS technology are made in order to avoid unexpected implementation costs. For this reason, this critical step should also be performed in phase 1*, Pre-Installation.*

#### 'Add on' 4: Assure regulatory compliance

In order to avoid issues with regulatory and standard bodies, companies should make sure that the digital DMS complies with the existing regulations and requirements. This should be done prior to the installation as corrective action is more costly and resource consuming than preventive action. Furthermore, assuring regulatory compliance also increases the chances of obtaining specific forms of certification. Accordingly, this critical step should be performed in phase *1, Pre-Installation*.

#### 'Add on' 5: Perform on-site training in the use of the digital DMS

In order to assure that the digital DMS is utilised properly, on-site training in the use of the system should be performed when necessary. As for the on-site training activities described in the eMRB case, these training sessions should for example instruct personnel how to properly use the system and highlight the roles and responsibilities of the people who will be in contact with the system. The goal is to reduce the amount of delays caused by confusion and misinterpretations regarding system functionality, and thus to enable streamlining of workflow for document management related activities. This critical step should be performed in phase 3, *Post-Installation*.

### 9.2 Final Result - Framework 1.1

In conclusion, the eMRB case study has contributed with a total of five new critical steps to the framework for implementation of a digital DMS. Furthermore, nine of the critical steps from *Framework 1.0* have also been validated through analysis of the insights obtained from the case study.

The final framework, i.e. *Framework 1.1,* is presented in *Figure 15* below. The phases described in the framework should be performed in the following order:

1. Phase 1 – *Pre-Installation*
2. Phase 2 - *Installation*
3. Phase 3 – *Post-Installation*
4. Phase 4 – *Evaluation and Corrective Action*

Each phase has to be completed before moving on to the following phase. However, the critical steps in within a certain each phase must not be performed in any specific order.


*Figure 15: Framework 1.1*

# 10 Conclusions and Discussion

The tenth and final chapter of this Master Thesis report begins with presenting answers to the research questions listed in *chapter 1.5 – Research Questions*. This is followed by a concluding discussion regarding the validity and reliability of the project results and further on, the academic as well as de general contribution of the Master Thesis project is presented. Lastly, the chapter is concluded with a presentation of recommendations for further studies.

## 10.1 Conclusion of Research Questions

The following sections present answers to the research questions listed in *chapter 1.5 – Research Questions*, with references to the report.

***RQ1: What are the main issues related to manual DMSs?***

The main issues related to manual DMSs are presented in *Table 15*.

*Table 15: Issues Related to Non-Digital Document Management Systems*

| Issues related to non-digital DMSs |
|---|
| *Difficulties with generating and processing large volumes of documents* |
| *Difficulties regarding processes for checking and validating document content* |
| *Manual systems are prone to error* |
| *Inability to create, find, access and deliver relevant information on time* |
| *Complicated tracking and tracing of produced products* |
| *Complicated backward tracing of manufacturing equipment* |

More details may be found in *chapter 6.2 – Issues related to Non-Digital Document Management Systems.*

***RQ2: How does document management influence quality assurance and quality control activities?***

Activities for quality assurance and control are affected by the quality or level of document management system in many ways. As mentioned in *chapter 3.1 - Good Manufacturing Practice*, there are two requirements related to documentation, and thus document management, that companies must fulfil in order to comply with GMP. These activities are:

- Write good procedures and follow them.
- Keep good records.

GMP compliance is an essential part a company's QMS and since a company's ability to comply with GMP is correlated to the level of its activities for document management, so is the company's QMS. Hence, a poor system for managing documentation will undoubtedly result in poor quality assurance while effective and efficient document management will enable QMS improvements.

Proper creation and management of documentation enhance visibility of processes and operations. Increased visibility consequently facilitates activities for reviewing the quality of processes, operations and products and in turn reduces the time needed for performing quality assurance and control activities. Maintaining accurate and proper documentation also enables tracking and tracing of products and equipment throughout the supply chain, which is crucial in order to properly be able to perform quality control

and assurance. Properly created and managed documentation can also provide evidence that companies are following certain procedures and that their processes are under control, which in turn saves time during audits.

Further details may be found in *chapter 3.1 – Good Manufacturing Practice* and *chapter 7.2.2.4 - Create Comprehensible and Complete Documentation.*

***RQ3: What are the incentives for companies to develop effective and efficient DMSs?***
The manufacturing of complex products, i.e. complex manufacturing, is characterised by the need for many different manufacturing and assembly operations that all require significant work. In order to assure consistent quality of the produced products as well as to comply with GMP (or other standards for quality management) these operations, including the processes related to them (such as example test and calibration results for manufacturing equipment), should be documented, controlled and reviewed. In turn, many complex manufacturing and assembly operations result in a higher need for documentation and proper document management. However, due to scandals such as the BP oil spill, the Fukushima meltdown and countless food scandals, documentation requirements are increasing even for companies performing 'regular' manufacturing. In turn, this implies that over time more or less every manufacturing and service providing company will be required to create and keep specific documentation to provide evidence that certain requirements are being met. In other words, all companies will sooner or later be required to establish some sort of system for document management.

Effective and efficient systems for document management, whether they are required or not, both facilitate and improve activities for quality control and assurance. This is explained in the section above (*RQ2).* Furthermore, this implies that a well-functioning DMS enables improvements in a company's QMS, which in turn increases a company's chances of obtaining specific certifications (for example ISO certification) and thus also increases the chances of obtaining the benefits related to these standards. This is illustrated in *Figure 16*.

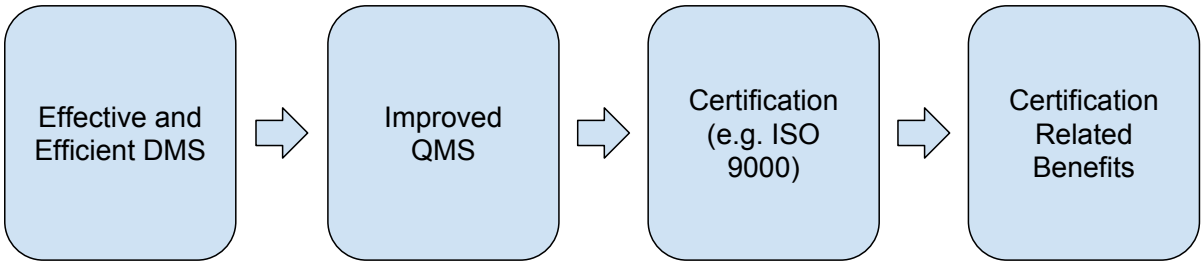


*Figure 16: Benefits Related to an Effective and Efficient DMS*

Moreover, as effective and efficient DMSs enable complete tracking and tracing of equipment, components and products, they also facilitate and speed up processes for identifying problems within the supply chain. This makes it possible for companies to detect potential problems at early stages, which in turn enables many of these problems to be fixed before they cause severe or irreparable damage to. Consequently, this leads to a reduction of the amount of product recalls due to for example production errors, but also a reduced amount of waste from manufacturing activities. As a result, companies are also able to lower their production costs and reduce their environmental impact.

In addition to the above-mentioned incentives for companies to develop an effective and efficient DMS, complete documentation of every step in the supply chain also enables supply chain transparency. This allows companies to address for example ethical and labour issues. Moreover, by documenting for example the carbon footprints of produced product, companies are also better able to address environmental challenges.

More details regarding specific benefits and thus incentives for the developing effective and efficient systems for document management may be found in *chapter 4.3.2. - Benefits of ISO 9001 Implementation.*

***RQ4: What are the potential benefits of implementing a digital DMS?***
The main reason for implementing a digital DMS is to eliminate the need for paper-based processes. By digitising paper-activities, companies can completely eliminate the costs directly associated to the paper-based system (for example costs for printers, printer-ink and paper). In addition to the costs directly associated to paper-based documentation systems several hidden costs exist as well (such as handling, storage and retrieval of paper), all of which have a significant impact on a company's financial results. In order to comply with GMP, documents should be stored in a location that ensures adequate protection from loss, destruction, falsification and damage. Safety measures may also require significant documents to be duplicated. In turn, the duplicated versions of these documents require a separate but equally secure storage location. Thus, one single document can in some cases render the need for two separate storage locations, which both consequently generate costs for rent and security systems (locks, alarms, guards etc.). Hence, digitising paper-based processes can help eliminate these costs.

Through digitisation of paper-based processes companies are also able to automate processes on a larger scale. This consequently enables companies to better monitor activities and processes within the company and thus enables increased analysis of factors such as product quality, yield issues and drivers behind waste and inefficiencies. Elimination of paper-based or manual systems also reduces the amount errors caused by the human factor.

Furthermore, within paper-based systems, traceability is both limited and time-consuming. In turn, this generates increased personnel costs. However, through digitisation of paper-based processes traceability can be improved (due to for example increased visibility), which consequently reduces the time for activities such as document retrieval and thus also labour costs. As previously stated, short time for document retrieval is also favourable when handling for example warranty issues.

Moreover, digital DMS solutions can also help to companies reduce their environmental impact through for example:

- Reduced need for 'industrial tourism' (i.e. the need for staff to be onsite to control, document and evaluate production)
- Eliminated need for paper, printer-ink and other material directly related to paper-based processes.
- A decreased amount of waste from manufacturing processes due to fewer production errors and product recalls.

The fact that the digitisation of paper-based processes reduces a company's environmental impact could for example also be used as a marketing tool to improve company image.

Except for the substantial long-term cost savings and the above-mentioned benefits related to the elimination of paper-based processes, digitisation has today more or less become a necessity for companies that want to achieve effective operations. Many of the benefits related to digitisation of paper-based processes such as the possibility of analysing RTD, instant sharing of documents and information with people all around the world (which consequently facilitates communication and collaboration with supply chain partners) as well as the elimination non-value adding production time, can today be used by companies to leap-frog competition. However as competition increases, so does the need for digitalisation. This consequently implies that digitised processes will become more common over time. In turn, increased competition and digitisation will over time more or less force laggards to digitise in order to stay alive. Consequently digitised processes that today are considered benefits might tomorrow be considered mandatory requirements for companies that want to have a chance of competing against the best. Hence, it should not be a question of 'whether' to digitise paper-based processes, but rather a question of 'how soon' to do it. By implementing the change sooner than later, companies have a chance of reaping the benefits of what is still considered to be new technologies, which in turn will help them get a head start in the race. Finally, digitisation will also provide companies with the ability to leverage more advanced technological capabilities as their needs increase over time.

***RQ5: What aspects should be considered when implementing a digital DMS?***
Framework 1.1 (illustrated in *Figure 15*) provides guidelines that enable companies to effectively and efficiently implement a digital DMS. The aspects that should be considered during the implementation process are presented in the framework.


*Figure 15: Framework 1.1*

Further details may be found in *chapter 9 – Framework 1.1.*

## 10.2 Validity and Reliability Analysis

In this sub-chapter, an analysis regarding the validity and reliability of the study is presented. Lastly, the sub-chapter is concluded with a discussion regarding the limitations of the applied methodology.

### 10.2.1 Validity

The validity of a study denotes whether the research method has actually measured what it was intended to measure. In order to assure validity of the Master Thesis project, two different triangulation methods have been used, namely *data source triangulation* and *methodological triangulation*. *Data source triangulation* implies that data has been collected from more than one data source at different occasions, and throughout the entire project data has been collected continuously (at countless occasions) and from various data sources (both primary and secondary). Furthermore, as different methods

for data collection has been used (the literature study, the interviews and the archival data study), *methodological triangulation* has been also been applied.

As discussed in *chapter 2.7 – Validity, Reliability and Representativeness*, an analysis often benefits from having more than one researcher as it reduces the risk of biased results. However, since there was only one researcher conducting this Master Thesis study, other measures had to be taken in order to reduce this risk. Consequently, the project supervisor, Senior Lecturer Nilsson, closely monitored the project from start to finish. Moreover, in order to further reduce the risk of biased results, an objective third party supervisor, Mr Charles Lawrence from Nordic Innovators, also helped to monitor the project. Regular meetings were held at the university with the project supervisor and a routinely contact was established with case company, CodeIT. The report was also regularly sent to the university supervisor, the case company and the objective third party supervisor for regular reviewing in order to further increase the validity of the study.

### 10.2.2 Reliability

As mentioned in *chapter 2.7 – Validity, Reliability and Representativeness*, the reliability of a study is considered high if another researcher conducts the same study later on and obtains the same results. Since the interviews have not been transcribed and the design of the interview guides have not been presented, the reliability of the study is somewhat compromised. However, due to the large amount of interviews that were conducted with the case company, it was not deemed to complicated and thereby not appropriate to present complete transcriptions of them. Furthermore, due to the fact that a majority of the interviews were open or semi-structured in nature the interviews seldom followed a specific design. This subsequently complicated the transcription of the interview results further. However, as the purpose of the interviews was to obtain in-depth knowledge regarding the subject, it was necessary to utilise the flexible data collection approach provided by the open and semi-structured interview format. Moreover, the interviews were in some cases complemented with archival data studies to fill information gaps from the open and semi-structured interviews. Consequently, one could argue that these archival data studies served the purpose of a more structured data collection technique such as the structured interview.

Furthermore, the majority of the data that has been collected during this Master Thesis project was based on peer-reviewed literature, and is thus considered reliable. However, a smaller portion of the of the information that has been gathered during the project has not been reviewed (for example information from certain websites), and could therefore be considered less reliable. Although, since academic studies on the area of document management is still quite new to the world, the amount of data in academic literature regarding the subject is limited. Therefore, in order to fill the information gaps in academic literature, it was deemed necessary to gather certain information from un-reviewed data sources as well.

Lastly, the data collection methods used during the Master Thesis project have been carefully described and the data sources have been cited meticulously. Moreover, the results from the case study have also been presented in such a manor that it is deemed possible for other researchers to conduct similar case studies in the future. Hence, the reliability of the study is considered relatively high.

### 10.2.3 Limitations of Methodology

As different methodologies serve different purposes, they consequently lead to different possibilities. However, depending of the choice of methodology there are also certain limitations to consider. For example, the results obtained from a case study should normally not be generalised, due to their low degree of representativeness. However, as mentioned in *chapter 2.7 – Validity, Reliability and Representativeness*, the representativeness of a case study may be increased if the context that the researcher wishes to draw general conclusions about is similar to the context in which the research is conducted. As *Table 17* (presented in *chapter 9.1- Case Study Analysis*) concludes there are several similarities between the eMRB and generic digital DMS. Additionally, a detailed description of the context or subject that is studied (provided in *chapter 8 – Case Study: CodeIT and the eMRB*) also results in a higher degree of representativeness. Hence, the representativeness of the case study performed in this Master Thesis project is deemed relatively high considering the circumstances. However, the representativeness could have been increased further if additional case studies had been performed.

Throughout the Master Thesis project a large amount of interviews have been held with the case company, all of which were conducted with Mr Torsnes. Even though Mr Torsnes is considered a highly qualified and reliable source of information (due to both his position at CodeIT and his previous merits in general), there is a significant risk of achieving biased results when interviews are conducted with one single person. Consequently, performing interviews with more people at the case company could have reduced this risk.

The data analysis technique applied in this Master Thesis project was Grounded Theory. As discussed in *chapter 2.5 – Data Analysis*, theories created by the use of the grounded theory principals can in some cases become context specific. On the other hand, since the theory is grounded in data that has been gathered from reality, it can be used as a solid base for investigation and research and the generated theory still has significant meaning as a result of research. The goal of the project was to create a generic framework supporting the implementation of a digital DMS, which potentially could be developed further in order to better suit the needs of a specific company, organisation or industry. Therefore, Grounded Theory was deemed a suitable data analysis technique.

## 10.3 Academic and General Contribution

Today there exists little to no academic literature on the subject of digitalisation of document management. Therefore an academic case study on the area is interesting. Furthermore, the Master Thesis contributes to academia since it demonstrates how academic theory and research methodology may be applied on a real life business problem.

From a more general perspective, many companies are still turning a blind eye to the potential gains that effective and efficient document management (not to mention digital document management) may generate. Moreover there seems to be a common misconception regarding the significance of digitalisation of processes related to document management. However, this Master thesis report highlights the above-mentioned issues by discussing the importance of effective and efficient document management, as well as which effects digitalisation of document management-related

activities might have on a company's financial and operational results. Hence, the general contribution of this report is that it increases the understanding of proper document management and the significance of adapting to our increasingly digitalised environment. Furthermore, the aim of framework presented in *chapter 9* is to provide guidelines for companies that are in the process of implementing a digital DMS. Due to the generic nature of the framework, it could however potentially be developed to better suit certain needs within for example a specific company, organisation or industry. Hence, the framework provides a foundation for future studies within the area of digital document management.

## 10.4 Recommendations for Further Studies

The framework created during this Master Thesis project is generic in nature and therefore aims to be generally applicable for more or less any manufacturing or service providing company that wishes to implement a digital DMS. For this reason, the framework does not take any company specific factors such as size, industry or operational goals into account. A recommendation for further studies is therefore to investigate the specific document management-related needs for individual companies or industries in order to create specialised guidelines. A suggestion would be to target companies within industries that are highly affected by requirements, legislations and directives regarding document management and traceability (for example the airline and aircraft industry or the oil and gas industry). Moreover, as the results of this Master Thesis project are based on a single-case study, additional case studies (similar to the one in this project) are recommended in order to assure the representativeness of the study.

It would also be interesting to perform quantitative studies on the effects of digital DMS implementation, in order to more precisely be able to calculate the potential savings that such a system may generate. Another aspect to consider during future studies is how to handle *openness with data*, which is a great idea in theory but might be problematic to apply in reality (due to for example confidentiality and companies' unwillingness to cooperate).

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# Appendices

The appendices consist of two parts, *Appendix A* and *Appendix B*. *Appendix A* contains a description of the Inspection and Test Plan (ITP) and the Hazard Analysis Critical Control Point (HACCP) system. *Appendix* B contains a summary of the product realisation process according to the ISO 9001:2008 standard.

## Appendix A - The Inspection and Test Plan

Appendix A begins with a presenting a description of the ITP and is concluded with a presentation of the HACCP.

### The Inspection and Test Plan

The ITP, also called the Quality Inspection Plan (QIP), is a set of documents with the purpose to:

- Define the process and the crucial activities within the process.
- Monitor the process.
- Monitor reference procedures (SOP, main project procedures, qualifying procedures etc.).
- Define acceptance criteria.
- Record activities by the use of verifying as well as validating documents.
- Confirm activities through the signing of different parties.

The ITP could be described as a detailed, step-by-step list of operations and requirements where a supplier identifies the process of how, why, when and who will perform tests or inspections of produced products throughout the supply chain. The ITP is also used to schedule hold points at different stages within a process, which are often established during pre-production meetings or pre-inspection meetings. At each hold point, an inspection or verification activity is conducted in order to make sure that the process activities are progressing as planned[237]. A common hold point for manufacturers inspection is when goods are delivered from a supplier to the manufacturer. Having an inspection hold point at this stage is a way to make sure that the received goods meet the pre-stated requirements, by for example examining the supplied material certificates[238].

The ITP only carries information regarding at what times inspection or verification activities are to be held. The details of the inspection and how it is to be conducted are instead recorded in a so-called checklist, and the ITP might refer to these checklists at the different holding points[239]. A sample form of an ITP is presented in *Table 21.*

[237] Quality Systems Toolbox, 'Support', *Quality Systems Toolbox* [Website], Inspection and Test Plans, <http://www.qualitysystems.com/support/pages/inspection-and-test-plans>, accessed 23 Sept. 2016.
[238] Ibid.
[239] Ibid.

*Table 21: Inspection and Test Plan Sample Form*

| **Item** | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| No. (1) | Quality Verification Activity (2) | Reference Procedure (3) | Acceptance Criteria (4) | Verifying Documents (5) | Party (6) | | | | Record (7) | | Remarks (9) |
| | | | | | Vendor | Contractor | CA | ARH | OR /IR (7) | MDR (8) | |
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## Hazard Analysis Critical Control Point

A management system similar to the ITP that (applied in the food industry) is called Hazard Analysis Critical Control Point (HACCP). It is an internationally recognized system that aims to reduce the risks of safety hazards.

In the HACCP, safety is addressed through analysis and control of biological, chemical and physical hazards within production of raw material, procurement and handling, manufacturing, distribution and consumption of finished products[240]. The HACCP system demands that potential hazards are identified and controlled at specific points in the process and can be used by any company involved in the manufacturing, processing or handling of food products[241].

The HACCP system is based on seven principles:

1. Conduct hazard analysis.
2. Identify critical control points in order to prevent or eliminate hazards that have been identified.
3. Establish maximum and/or minimum limit for processing characteristics (for example temperature, time, pH-value).
4. Establish critical limits, i.e. criteria for each critical control point.
5. Establish monitoring procedures in order to determine what to measure and how to measure it.
6. Establish corrective actions.
7. Establish record keeping procedures[242][243].

[240] U.S. Food and Drug Administration, 'Hazard Analysis Critical Control Point (HACCP)', *U.S. Food and Drug Administration* [Website], 9 March 2015, <http://www.fda.gov/Food/GuidanceRegulation/HACCP/>, accessed 26 Sept. 2016.
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[242] U.S. Food and Drug Administration, 'HACCP Principles & Application Guidelines', *U.S. Food and Drug Administration* [Website], 19 Sept. 2014, <http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006801.htm#princ >, accessed 26 Sept. 2016.
[243] Vinca LLC, 2015.

## Appendix B – Product Realisation According to ISO 9001:2008

Appendix B contains a summary of the product realisation process according to the ISO 9001:2008 standard. The ISO 9001:2008 standard allows companies and organisations flexibility in their ways they choose to document their QMS and verifying documents. In other words, the standard helps companies develop the minimum amount of documentation necessary in order to demonstrate the effective planning, operation and control of their processes and the implementation and continuous improvement of the effectiveness of the QMS[244].

### Requirements for the Product Realisation Process According to ISO 9001:2008

The term product realisation is used to describe what work an organisation has to go through in order to develop, manufacture, and deliver finished products to their customers. The following sections provide a stepwise presentation of the PRP according to the ISO 9001:2008.

#### *Planning Product Realisation*

An organisation is responsible for planning and developing the processes necessary for product realisation and the planning of these processes should be consistent with requirements of other processes of the QMS[245]. In order to comply with ISO 9001:2008, an organisation should determine the following when planning the PRP:

- Product requirements and quality objectives.
- Processes, documents, and resources specific to the product needed for product realisation.
- Required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance.
- Records needed to provide evidence that the realisation processes and resulting products meet the requirements put on them[246].

#### *Customer Related Processes*

According to ISO 9001:2008, an organisation is required to determine and establish comprehensible product requirements. These requirements may be based on customer specifications, law and regulations or generally accepted standards within the industry or market[247]. Furthermore, before supplying customers with products, an organisation must review the requirements related to the product in order to ensure that product requirements are defined and that the organisations is capable of fulfilling the requirements. Records of the review results and actions that arise from this should be documented and maintained[248]. Customer communication channels that allow dialogue regarding product information, questions about contracts, order handling and changes as feedback and complaints should also be defined, documented and maintained[249].

#### *Design and Development*

The design and development process in the PRP consists of the following activities:

- Design and development planning

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[244] International Organisation of Standardisation, 2008, p. 1.
[245] ISO 9001:2008, p. 7.
[246] Ibid.
[247] Ibid.
[248] Ibid.
[249] Ibid, p. 8.

- Design and development input
- Design and development outputs
- Design and development review
- Design and development verification
- Design and development validation
- Design and development changes

### Design and Development Planning

In order to successfully plan and control the design and development process of a product, an organisation must determine:

- The stages involved in the design and development process.
- The review, verification and validation processes that are appropriate to each design and development stage.
- The responsibilities and authorities for design and development[250].

### Design and Development Inputs

Inputs related to product requirements have to be determined and records maintained. These inputs include:

- Functional and performance requirements.
- Applicable statutory and regulatory requirements.
- Information derived from previous similar designs.
- Other requirements essential for design and development[251].

### Design and Development Outputs

The output of design and development should contain sufficient information in order to verify that the output meets the input requirements. The design and development outputs must also:

- Provide appropriate information needed to for purchasing, production and service provision. This might include details regarding the preservation of the product.
- Contain or reference product acceptance criteria, i.e. specify how to determine if the product performance is acceptable.
- Specify characteristics essential for proper and safe use of the product[252].

### Design and Development Review

Systematic reviews of design and development work should be conducted in order to:

- Determine if design and development results will meet the requirements.
- Identify problems and propose corrective actions[253].

The reviews should include representatives from each function that are concerned by the review, and records of the review results as well as potential corrective actions should be kept[254].

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[250] ISO 9001:2008, p. 8.
[251] Ibid.
[252] Ibid, pp. 8-9.
[253] Ibid.
[254] Ibid, p. 9.

### Design and Development Verification

Verification should be performed in order to guarantee that the outputs from design and development meet the input requirements. Records of the verification results and potential corrective actions should also be maintained. Moreover, descriptions of the processes used for verification and testing should be included[255].

### Design and Development Validation

In order to assure that the final product is able to meet the requirements for intended use, validation of design and development must be conducted. It is not specifically stated how the validation process should be performed. However the validation should be completed before delivery or implementation of the product. Records of validation and potential corrective actions should also be kept[256].

### Control of Design and Development Changes

Potential changes should be identified, documented, reviewed, verified and validated before they are carried out. Furthermore, the potential impacts on the present product design should also be evaluated and records of this maintained[257].

## *Purchasing*

Criteria for how to evaluate and choose suppliers have to be established and the established criteria should be based on the suppliers' ability to provide products in accordance with the organisations pre-set requirements. Furthermore, the type and extent of control of suppliers or purchased components/products should depend on the significance of the purchased item and records of evaluation results should be maintained[258].

Purchasing information should describe the product that an organisation wishes to purchase. Organisations are also required to guarantee that specified purchase requirements are adequate before the requirements are communicated to the supplier. Furthermore, the purchasing information should include the following:

- Requirements for approval of product, procedures, processes and equipment.
- Qualification requirements of personnel.
- QMS requirements[259].

Inspection or other activities necessary for ensuring that the purchased items meet the specified requirements are to be established and implemented[260].

## *Production and Service Provision*

The following sections present how production and service provision is to be conducted in order to comply with the ISO 9001:2008 standard.

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[255] ISO 9001:2008, p. 9.
[256] Ibid.
[257] Ibid.
[258] Ibid, pp. 9-10.
[259] Ibid.
[260] Ibid.

### Control of Production and Service Provision

Production, installation and service processes should be planned and carried out under controlled conditions. Availability of the following factors facilitates this process:

- Information regarding product characteristics/specifications.
- Written work instructions.
- Suitable equipment.
- Suitable tools for monitoring and measuring.
- Criteria for product release[261].

### Validation of Processes for Production and Service Provision

Validation of processes demonstrates their ability to achieve the planned results. This is required when it is not possible to verify the finished product through monitoring or measurement. Furthermore, validation is especially important where flaws or deficiencies are not identified until the product is in use/has been delivered[262].
Finally, evaluation criteria should contain:

- Review and approval of the process.
- Approval of equipment.
- Qualification and competence of personnel.
- Specific methods and procedures used.
- Requirements for records to be kept.
- On-going assessment of process validation (revalidation)[263].

### Identification and Traceability

Where it is appropriate, processes for identifying and assuring traceability of products throughout the supply chain should be established. Where traceability is required, unique identification of products should be recorded and maintained[264].

### Customer Property

Special care must be taken to customer property (including intellectual property and personal data) while it is under the organisations control or being used by the organisation. Hence, customer property provided for use must be identified, verified as well as protected. If any customer property is lost, damaged or found to be unsuitable for use, this must be reported to the customer. Furthermore, records of this should also be maintained[265].

### Preservation of Product

In order to maintain conformity to requirements, the product must be preserved during internal processing and delivery to the intended destination. Preservation related activities should include identification, handling, packaging, storage as well as protection. Furthermore, this also applies to the component parts of a product[266].

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[261] ISO 9001:2008, p. 10.
[262] Ibid, p. 10-11.
[263] Ibid.
[264] Ibid, p. 11.
[265] Ibid.
[266] Ibid.

### *Control of Monitoring and Measuring Equipment*

Organisations must determine how monitoring and measurement is to be conducted. Furthermore, the equipment necessary in order to provide evidence that the product conforms to the pre-set requirements must also be identified. Processes to ensure that monitoring and measurement can be carried out in a manner that is in line with the monitoring and measurement requirements should also be established. Moreover, when and where it is necessary to ensure that the results are valid, the measuring equipment shall:

- Be calibrated and verified at pre-determined intervals (or before use) to international or national measurement standards. If no such standards exist, the basis used for the calibration and verification should be recorded.
- Have identification that enables determination of calibration status.
- Be secured from alterations that could invalidate the measurement results.
- Be protected from damage and deterioration during handling, maintenance and storage[267].

When the equipment does not meet the monitoring and measurement requirements, validity of the measurement results should be both evaluated and recorded. Corrective action on the equipment, including the affected products, should also be taken. Finally, calibration and verification results shall be maintained[268].

[267] ISO 9001:2008, p. 11.
[268] Ibid.