The introduction of risk management within Company X

University of Twente master thesis report

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Abstract

In this report process and risk management are investigated within Company X. Company X operates in the medical branch as a subcontractor. Due to this a lot of regulations and standards are applicable. Human lives are dependent on the gas distribution systems. All requirements stated by law and wishes of clients need to be structured in such a way that it is easily usable in practice. The main goal of this thesis is to research how risks can be managed in a clear, secure and workable manner throughout the work process of Company X.

I started with defining the market. I considered which laws and regulations are applicable to Company X and the activities they perform. Good Manufacturing Practices is obligatory by the European Union and will increase in importance over time in the Netherlands. The importance of structured working with regards to validation is echoing around but has not fully landed. I took the process that Good Manufacturing Practices describes as a scenario and structured a process map accordingly. I compared the Good Manufacturing Practices process map with the current work flow to define differences. The process map constructed for Company X is visible in Appendix B. Documents necessary for Company X in the several stages of a project can be found in Appendix C. Risk identification tools used are SWIFT analysis and Cause-and-Effect Analysis incorporated with 5 Whys. “What if” questions can be answered and consequences of neglecting something are made visible. However the results of digging deeper with the help of Cause-and-Effect Analysis / 5 why is debatable. 5 why is a technique focusing on a problem occurring and tries to get the root of the problem by asking, Why? The level of 5 times why is almost never reached.

The Validation Master Plan is an important critical point which is often neglected in the current workflow. Further steps that still need to be taken according to the Managerial Problem-Solving Method:

- Choosing a solution
- Implementing solutions
- Evaluating solutions

In Appendix D the headers are shown under which I organized all project requirements. The number of statements mentioned in NEN-EN-ISO 7396-1 are as follow:

- For Design: Divided in 13 groups, 394 potential risks.
- Realization: 14 potential risks
- Service and Maintenance: Divided in 10 groups, 82 potential risks.
- Information to be provided by manufacturer should be in accordance with EN1041 or equivalent national standards.

Important note is that the division of risks between Company X and the supplier of components, still needs to be made. After that the risks should be filtered logically according the several types of systems as vacuum and medical air. If the basic set up is good and workable, the risks should be added with project risks from other standards besides NEN-EN-ISO 7396-1.

I recommend to update all procedures and forms in a format aligning with NEN-EN-ISO 7396-1. Discussions when things go wrong are limited that way. Also the distribution of the documents could be made into a computer program based on the expanded matrix shown in Appendix E. This so that with few clicks a complete set of procedures and forms for that specific activity can be compiled.

The thesis starts with the problem statement in Chapter 1. Next, we conduct an investigation about the market Company X operates in. Chapter 3 deals with defining risk management. Chapter 4 structures the main processes comparing Good Manufacturing Practices with other project models used within Company X. Chapter 5 continues and concentrates on making a process map with accompanying documents. Chapter 6 and 7 focus on process and project risks. Next, in Chapter 8 the research will be concluded, followed in Chapter 9 by a discussion.

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1 Introduction

"Begin at the beginning, the king said gravely, "and go on till you come to the end: then stop."
- Lewis Carroll -

In this chapter, I explain the problem situation and the problem statement. After that I set up research questions using the problem statement. This chapter ends with the project boundaries, limitations and report structure.

1.1 Problem statement

Company X was a company which grew at a fast pace. As a consequence, a structured organization within the company was not maintained. At the moment of writing, Company X made a restart after bankruptcy and has been a few months up and running. The core business of Company X is to design, build and maintain medical gas distribution systems in health care institutions and laboratories. The core of my thesis concentrates on the operational field with emphasis on risk management. Figure 1 visualizes that operational control and risk management are influenced by a lot of facets.

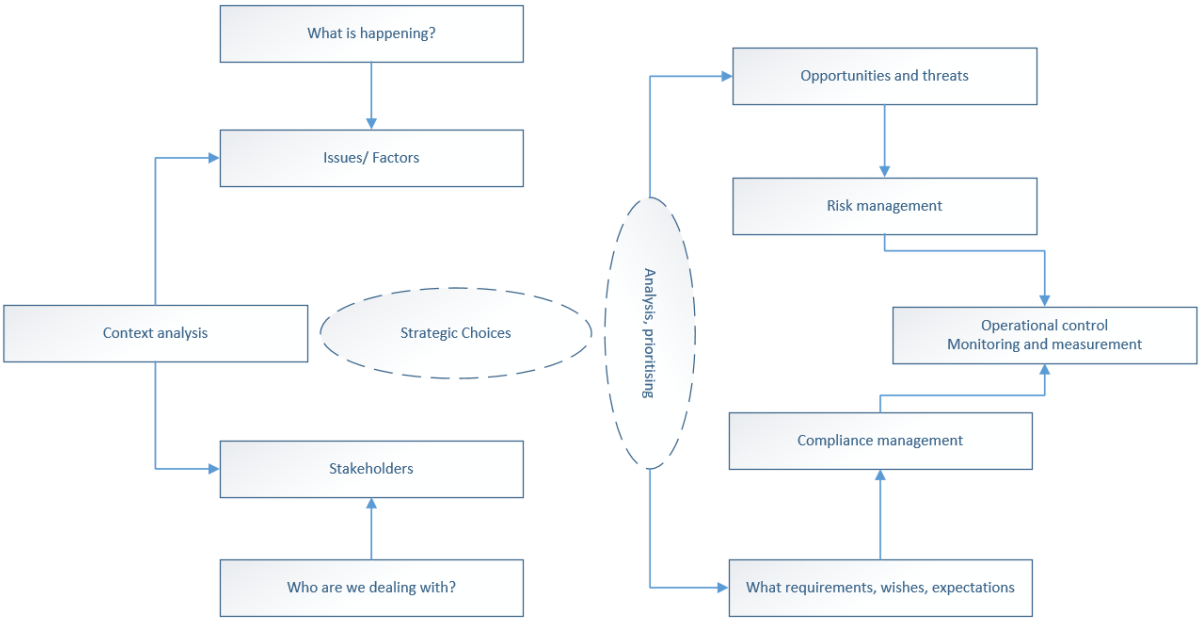

Figure 1: Problem Cluster.
Source: Received by Rivera, M. (October 2018).

1.2 Research questions

In this thesis I concentrate on the research question: ***How can risks be managed in a clear, secure and workable manner throughout the work process of Company X ?***
To be able to answer this question the work process of Company X should be known. I divided the main research question in 3 sub questions. The first sub question concentrates on the market Company X operates in. The second on defining risk management. The third sub question on the operational procedures. The research questions and their sub-questions are mentioned below.

1. How is the current market Company X operates in structured?
    a. What are the European and National regulations Company X needs to act conform?
    b. Which contract types are applicable to Company X?

2. What is the work process of Company X?
    a. What is process management?
    b. What is the goal of Company X?
    c. How does Company X operate currently?

3. Which risks are important for Company X to take into account?
    a. What is risk management?
    b. What are steps necessary to be taken in risk management?
    c. What are project risks for Company X?
    d. What are process risks for Company X?

I start my research with looking at the market and the position Company X holds. After that, process and risk management will be defined. Within the complexity of risk management a solution is searched to manage risks with regard to operational control and monitoring.

Looking at the scope of the research and the eagerness of Company X to implement a risk management system that can handle the complexity, the thesis becomes an action problem. For solving this problem the Managerial Problem-Solving Method (MPSM) can be used. The phases of this method according to Heerkens (2010) are as follow:

1: Identifying the problem.
2: Planning the problem-solving process.
3: Analysing the problem.
4: Generating alternative solutions.
5: Choosing a solution.
6: Implementing the solution.
7: Evaluating the solution.

1.3 Boundaries limitations and report structure

The time span is limited. Therefore not all 7 steps of the MPSM will be completed. The thesis concentrates on the first four steps of the research. This leaves choosing and implementing the solution open for the company to decide on. I will concentrate on the project management of Company X. Which processes are followed at this moment? What is done with risk management? And how can it be improved? By concentrating on the operational side of Company X other facets of running a company and the risks coming with it, are excluded.

The further outline of this report is as follow: In Chapter 2 an investigation is conducted about the market Company X operates in. Chapter 3 deals with defining risk management. Chapter 4 structures the main processes comparing Good Manufacturing Practices with other project models used within Company X. Chapter 5 continues and concentrates on making a process map with accompanying documents. Chapter 6 and 7 focus on process and project risks. Next, in Chapter 8 the research will be concluded, followed in Chapter 9 by a discussion.

2 How is the current market Company X operates in structured?

"It is not wisdom but authority that makes a law"
- Thomas Hobbes–

Company X designs, builds and maintains medical gas distribution systems. They operate most of the time as main or subcontractor. Rules and regulations are extremely important in healthcare. Therefore, I will elaborate on these in a brief way. I will start at European directives followed by the national regulations. I conclude with standards applicable to Company X. After the laws and regulations I will pay attention to contract management. If contract management is not done correctly it can have influence on the project activities.

2.1 European and National regulations

The first important manual is the European Pharmacopoeia (Ph. Eur.). This manual describes quality control for medicines. Or as stated by the European Directorate for the Quality of Medicines (EDQM): "*The official standards published within provide a legal and scientific basis for quality control during the development, production and marketing processes*." The Ph. Eur. was created after World War II based on existing national Pharmacopoeia. According to RIVM (2011), this was done due to the shortage of medicines during the war. The shortage could have been filled with medicines from other countries, but nobody knew whether they could be replaced with one another. Directive 91/356/EEC which has been replaced in 2003 by directive 2003/94/EC, incorporates the pharmacopoeia rules and measures.

The gasses transported are classified by the council directive 2001/83/EC as a medicine. "*Any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product.*" The Council Directive 93/42/EEC, on the other hand, defines a medical device. "*medical device: means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:*

- *Diagnosis, prevention, monitoring, treatment or alleviation of disease.*
- *Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap.*
- *Investigation, replacement or modification of the anatomy or of a physiological process.*
- *Control of conception."*

In this sense, the gas distribution systems transporting the medical gasses can be classified as medical devices. Therefore, Company X needs to act on the law 93/42/EEC.

Regarding medical devices, two other laws are popping up: EU-directive 90-385-EEC, active implantable medical devices and EU-directive 98-79-EC, in vitro diagnostic medical devices.
EU-directive 90-385-EEC applies to medical devices to be implemented in the human body. This is not in accordance with a gas distribution system. Therefore this regulation does not apply to Company X. The 98-79-EC however is applicable in some cases to Company X. It is not the main part of business. However, in some cases, the gasses are for an in vitro Laboratory. In that case, this law comes into force. Another directive linked to Company X in a more subtle way is the EU-directive 89/391/EEC on the introduction of measures to encourage improvement in the safety and health of workers at work. An individual directive under this is the EU-directive 2013/35/EU, *The minimum health and safety requirements regarding the exposure of workers to the risks of arising from physical agents (electromagnetic fields)*. This is important for Company X to keep an eye on. Confrontations with this law can be encountered when working in MRI and X-ray rooms.

2003/94/EC, *GMP (*Good Manufacturing Practices*),* is also applicable to Company X. A work application especially mentioned the GMP Annexes 6, 13, 15, 16 and 20. Those deal with:

- Annex 6: Manufacture of medicinal gases.
- Annex 13: Manufacture of investigational medicinal products.
- Annex 15: Qualification and validation.
- Annex 16: Certification by a Qualified Person and batch release.
- Annex 20: Quality Risk Management.

Other Annexes are not necessarily relevant for Company X. They contain, but are not limited to, information on radiopharmaceuticals, packaging or herbal medicinal products. (NVZA, n.d.).

Taking into account that directives need to be transposed by the EU countries into the national law, I looked up the Dutch regulations applicable to Company X at the government website.

- The European Directive 2001/83 and 2001/82 is implemented in the Geneesmiddelenwet (Hoogervorst, 2007).
- The directive 93/42 is implemented in besluit medische hulpmiddelen.
- The Law on the Dutch Pharmacopoeia is not in force anymore (RIVM, 2011).
  It was in force from 1871-1993. Dutch regulations refer to the European Pharmacopoeia.
- Warenwet.
- Arbeidsomstandighedenwet.
  To reduce accidents and illness due to work.
- Until december 2015 Kwaliteitswet zorginstellingen was active. After this law was withdrawn the Law 'kwaliteit, klachten en geschillen zorg' became in force. This law is not directly linked to Company X . However, the customers of Company X need to meet this law.
- GMP-z.
  The extension "z" stands for Ziekenhuisfarmacie. GMP-z is an interpretation of the GMP, especially for hospitals. It is an addition as the GMP is not completely applicable in several circumstances (NVZA).

It is important to realize that the national law stands above the European law. As long as the European law is not transposed into the national law, the former is not mandatory. A report from TNO states that in the Netherlands, the Inspectie voor de gezondheidszorg (IGZ) guards the quality of health institutions. The inspection takes medical devices into account as well. However, in contradiction to the Medical Device Directive (MDD), which harmonized the norms regarding medical gas distributions, the Netherlands stated during implementing the MDD that medical gas distribution systems were not considered a medical device (Hensbroek, 2015). This has as result, that the CE certification for a medical device cannot be retrieved in the Netherlands. The certifications happen in neighbouring countries.

2.2 Standards

As mentioned before, a European directive should be transposed into national law. Standards, on the other hand, are not mandatory. They provide practical data regarding the current law. Due to this, it is sensible to follow them. However, another method achieving the same goal deviating from the standard is allowed (NEN, n.d.).

The first standard I got acquainted with, is NEN-EN-ISO 7396-1, *medical gas pipeline systems – Part 1: Pipeline systems for compressed medical gases and vacuum*. This standard can be seen as the core business of Company X with a lot of documents referring to it. Within NEN-EN-ISO 7396-1, 20 normative references are mentioned. This means that when Company X claims to work according to NEN-EN-ISO 7396-1, they claim to work conform those 20 standards. The 20 normative references are excluding additional references mentioned in the Bibliography. In totality 48 Standards are mentioned. Take into account that those 20 to 48 standards mentioned are only one layer. Each of those standards refers to other standards. To show this, an example:
When talking about medical gas distribution systems, electrical parts are present. The first standard most people think of when talking about electricity is the NEN1010. However, this norm is inplemented in the Dutch Bouwbesluit. Medical gas distribution systems do not need to be conform Bouwbesluit. This means that a medical gas distribution should have nothing to do with NEN1010. But be aware, NEN-EN-ISO 7396-1 refers to the standard 11197. The standard 11197 refers to IEC 60364. The NEN1010 is derived from the IEC 60364. This means that working according to NEN-EN-ISO 7396-1 means also working according to the NEN1010 despite the fact that it is not directly linked.

While going through the list I found an ISO standard which could provide an interesting starting point regarding risk management.

- NEN-EN-ISO 14971:2007, *medical devices – Application of risk management to medical devices*

A striking point observed is that from the 20 normative standards mentioned in NEN-EN-ISO 7396-1 only 10 are in possession of Company X. Other standards applicable to Company X contain among others: 9170-1, 9170-2, 7396-2 and GPS15. Hensbroek (2015) states that in totality 51 harmonized standards are in force regarding

Medical gas distributions and devices linked to those. However, those 51 standards do not cover all standards. NEN-EN-ISO 7396-1 makes additional standards mandatory. Regulations and standards mentioned before, are only selections. However, going through all standards and regulations checking the applicability to medical devices, would be an investigation on its own. I will concentrate only on NEN-EN-ISO 7396-1. This because it is seen as the core business of Company X. If this norm can be handled in a correct way it can be expanded with other standards necessary later on.

2.3 Contract management

The healthcare market in itself is a high-risk market with a high number of legislations where companies and institutions need to act conform. When healthcare institutions are renovating or adjusting their medical pipelines the work is tendered. The healthcare institution is in this sense the customer initiating a project. Based on a program of requirements a price is calculated for the customer by Company X. To be able to make an offer that makes sense and covers the risks, an understanding of all requirements and wishes is important. If the customer agrees to the offer a contract is set up. Areas of risks linked to contract management mentioned by PwC include:

> *"Poor or perverse incentives, Bad planning, Demand management, Ill-informed buying, Deliberate contract manipulation, Miscommunication,*
> ***Revenue leakage and cost overruns** - including failure to monetize high-value services appropriately.*
> ***Scope creep and quality failures** - including failure of the contract to meet the business needs.*
> ***Damage to business** - from loss of competitive edge to personal reputation.*
> ***Loss of intellectual property** - poorly managed knowledge transfer.*
> ***Loss of bargaining power** - inability to act as an informed buyer."*

When boundaries are not specified clearly regarding exclusions or conditions in an offer, it can lead to tensions. Depending on the stage in which Company X gets involved in the project another form of contract management is applicable. This is nicely worked out by the UAVgc (2005) regarding Ground, Road and Hydraulic Engineering as can be seen in Figure 2. A contract changes with requirements regarding quality, duration and the distribution of roles. A gas distribution system does not fall under Ground, Road and Hydraulic Engineering but it gives an overview of division of tasks. For Company X, in most cases, the design is finished before tendering. Company X has responsibilities regarding preparation, realization and maintenance. However, the design has to be validated on feasibility and conformity with the required standards before calculating a price.

	Traditional cooperation concept			**(Multi-year) Maintenance concept**	**Integrated cooperation concept**	
Construction phase	Public corporation	Functional Contract specification / RAW	Construction team	Framework agreement	Design & Construct	Turnkey
Initiative						
Research	Responsibility client					
Definition						
Program requirements						
Preliminary design						
Final Design						
Implementation Design						
Preparation						
Implementation				**Responsibility Contractor**		
Maintenance						
Tender	**Tender procedure in accordance with prevailing procurement regulations/ directive**					
Implementation	Uniform administrative conditions	Uniform administrative conditions	RVOI/Uniform administrative conditions	Uniform administrative conditions for Integrated Contract forms	Uniform administrative conditions for Integrated Contract forms	Uniform administrative conditions for Integrated Contract forms

Figure 2: Contract types.
Source: https://www.iampro-portaal.nl/Thema-s/Contractmanagement.

Company X has a NEN-EN-ISO 7396-1 certification. A customer can ask for a conformity statement. However, looking at NEN-EN-ISO 7396-1 contradictions can be found. For example, a vacuum system may be made from synthetic material. However, it is also stated that till 600 degrees Celsius the distribution systems should stay intact. This cannot be achieved by any synthetic material. The preferred material is copper. In the healthcare everything needs to be achieved as cheaply as possible. If Company X offers a copper vacuum system which can handle the 600 degrees Celsius while another party tenders a synthetic one it is likely that the synthetic one will be chosen. To tackle such problems decisions between materials could be mentioned in the offer.

However, the question “when is the system conform?” should be answered, and a consideration still needs to be made whether Company X wants to cooperate in building a system that may not be as safe as it should be.

2.4 Goals of Company X

Company X has two main goals they focus on.

Goal 1: Design, build and maintain medical gas distribution systems in a responsible and validated way in cooperation with the client.
To be able to achieve this Company X wants to structure the internal processes in such a way that the process of design, build and maintain can be controlled and validated. Due to the growing number of laws, responsibilities are difficult to be managed independently by the customer.

Goal 2: To be able to take care of some of the responsibilities related to the medical gas distribution system based on certificated systems, resources and methods.
The internal processes and risks Company X has at this moment, should be known. Besides that, the position and additional risks Company X will have by taking over responsibilities should be considered. The position is of importance so that responsibilities for all parties involved can be delineated.

3 Risk management

"Organizations make money by taking risk and lose money by failing to manage risks"
– William G. Parrett –

In this chapter I will discuss how risk management is defined and how risk can be identified and controlled. This by using the risk management process described in NEN-EN-ISO 14971, NEN-ISO/IEC 31010 and GMP. NVZA (n.d.) shows that GMP annex 20 (Quality Risk Management) has been cancelled. However, annex 20 has been adopted as "International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use" (ICH) Q9 guideline. This guideline is still in force and therefore still relevant.

3.1 Definition of risk management

According to the dictionary risk means "the possibility of incurring misfortune or loss".
To reduce the chance of injury or loss, risk management is created. In literature Muhlbauer (2004) and Sutton (2015) risk is given by the following formula:

Risk = event likelihood * event consequence

Risks are defined as the probability of an event that causes a loss and the potential magnitude of that loss. Regarding the given formula, this means that risk is increased when either the probability of a loss or the magnitude increases. It is important to realize that hazards are always present in such a way that risk can never be zero. According to Muhlbauer (2004) and the ICH Q9, risk can be defined by answering three questions:

1) What can go wrong?
2) How likely is it?
3) What are the consequences?

Risk management can be seen as a reaction to perceived risks. A comprehensive model regarding risk management is the COSO model. This model shows how several risk management activities and departments in a company are linked. If one aspect is changed it has influence throughout the whole company. The COSO model is shown in Figure 3.

Figure 3 The COSO model.
Source: http://www.house-of-control.nl/coso-erm.html.

For Company X it is of importance to realize that NEN-EN-ISO 7396-1 is influencing the whole work process. From design and realization until Service and Maintenance. In every phase the standard needs to be followed. To maintain the presence of the standard in the process I used NEN-EN-ISO 14971 as a basis to start the risk management process. I used this standard because NEN-EN-ISO 7396-1 is referring to this. It is a standard regarding risk management specific for medical devices. Besides that I will use NEN-ISO/IEC 31010. NEN-ISO/IEC 31010 was issued in the same series as the 31000 and describes the basic characteristics of 31 different techniques regarding risk assessment. Only a selection of those tools is mentioned in ICH Q9 and NEN-EN-ISO 14971.

Besides the standards dealing with risk management, ICH Q9 method deals with quality risk management. It states that the definition of risk = event likelihood * event consequence is commonly understood, but different people can have different opinions about the likelihood and consequence. Quality and risk are interlinked closely to each other. A system to manage quality is a quality management system and is defined by ASQ (n.d.) as follow: "a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives. A QMS helps coordinate and direct an organization's activities to meet customer and regulatory requirements and improve its effectiveness and efficiency on a continuous basis."

Figure 4 Eight quality management principles
Source:https://www.bureauveritas.com.au/home/about-us/our-business/certification/management-systems/quality

Company X has at this moment a NEN-EN-ISO 9001 certificate. Surrounding the operational core with secondary processes such as purchasing and auditing. NEN-EN-ISO 9001 has the quality management structured as the Plan-Do-Check-Act cycle and has eight quality management principles as can be seen in Figure 4.

To underline the small boundary between quality management and risk management the following: A regulatory requirement can be seen as a quality management issue. However, it is very difficult to comply with standards as NEN-EN-ISO 7396-1. Details of this requirement should be known and statements made which are not fulfilled can be classified as risks. Another point is that a quality management system documents processes and procedures. However at this point in time it is unknown according to which process Company X operates. Documentation becomes therefore quite difficult and can be identified as a risk. Due to this small boundary I concentrate on risks occurring in process and project. After those are identified they could be implemented in a quality management system to continuously evaluate.

3.2 Risk management procedure according to 14971, ICH Q9 and 31010

The NEN-EN-ISO 14971, ICH Q9 and the NEN-EN-ISO 31010 each describe a risk management approach in its own way. I took NEN-EN-ISO 14971 as main guideline and added additional information from the other sources. Risk analysis and risk evaluation are the 2 steps of risk assessment. Risk analysis consists of identifying hazards and performing an estimation of the risks. It answers the question: What can go wrong? It includes as well identifying the possible consequences. Risk evaluation follows risk analysis. At that point in time a decision whether or not risk reduction measures are necessary, is taken for each defined risk. This is done based on the likelihood that a risk will occur and the consequence of this risk. After identifying risks, risk reduction is necessary in the case that the risk level is unacceptable. If required risk reduction is not practicable or residual risks are still not acceptable a risk/benefit analysis needs to be performed on the residual risk. This to determine whether activities should be undertaken.

Other things to take into account:

- Are new risks arising from the control measures?
- What is the risk after implementing a control measure?

ICH Q9 and NEN-ISO/IEC 31010 both start risk management with risk assessment. However, instead of two steps they describe three. In NEN-EN-ISO 14971 risk identification is incorporated in the risk analysis. The ICH Q9 and the NEN-ISO/IEC 31010 mention the identification as a separate first step. The ICH Q9 evaluates also risks towards the quality delivered.

NEN-EN-ISO 14971 does not relate specifically to communication. It is incorporated in the process and documentation. Communication is taken for granted. ICH Q9 on the other hand mentions it explicitly, defining the need of communication to share information about risk and risk management between decision makers. On the other hand ICH Q9 has less emphasis on the documentation. It mentions that the output/ result of the quality risk management process should be appropriately documented.

The NEN-ISO/IEC 31010 describes 31 tools. These are visible in Table 1. However, not all tools are useful to the same degree. Looking at the applicability of the tools in the risk identification stage, 15 tools are strongly applicable. From those 15 tools four are strongly applicable throughout the whole risk assessment process
For process and project risks I will evaluate the 15 tools in the corresponding chapters later in this report.

Table 1 31 risk assessment tools and the applicability.
Source: NEN-ISO/IEC 31010.
This table is not visible in this publication version

NEN-EN-ISO 14971 and ICH Q9 both have emphasis on the medical device. NEN-EN-ISO 14971 even going as far as wanting a risk management report written prior to the release of a medical device for commercial distribution. In case of identical reproducible devices this is realizable. However, in case of Company X it is not about a device which can be reproduced identically. Therefore it can be interpreted that every project needs to have its own final delivery document.

There are a lot of common components in a distribution system but the complete system is never identical. Quality risk management as mentioned in ICH Q9 could be performed on the separate components of the gas distribution system. Asking questions regarding which material will be used? Which type of compressor will be installed? However, a lot of choices are already recorded in NEN-EN-ISO 7396-1. Due to the emphasis on the medical device itself, process risks are stressed less in the norms. It can however be applied on the parts where NEN-EN-ISO 7396-1 is contradictory. Quality risk management can also be used on how the processes could be structured best to deliver the best quality possible.

An important note to keep in mind is the content differences between the 14971 and the EU Directive 93/42/EEC. NEN-EN-ISO 7396-1 refers to NEN-EN-ISO 14971 for risk management. However, the EU Directive 93/42/EEC mentions some requirements regarding risks in Annex I. It is not a model that could be implemented. However, the requirements regarding risks need to be taken into account. The contradictions between NEN-EN-ISO 14971 and the EU directive are mentioned in Annex ZA of the 14971. I included the deviation in brief phrasing in Table 2.

Table 2 14971 contradicting with EU directive 93/42/EEC.
Source: NEN-EN-ISO 14971.
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4 Defining the Main Process

"Time is what we want most but what we use worst"
– William Penn -

GMP will become more and more of importance, as it is already incorporated in the European law. However, the market is not ready to follow. To be able to perform a risk analysis, knowledge about the work process is necessary. How is the work structured? Within Company X they mention the V-model. However, it is unknown whether they really work according to that model. So basically, input about the processes which could mitigate some project risks, is unknown. To set up a process map identifying the core of Company X I started my research with project management and compare several models.

4.1 Project management

The execution of tasks can be done in several ways: improvisation, routine or on project basis (Grit, 2008). It is the way work is organized, prepared, planned, executed and completed. In case of improvisation work is done without structure, everything is done in the moment. Routine work is characterized by repetition. When a result is repeated for different clients with unchanged resources and repetition of procedures, rules and methods. A project is characterized by uniqueness. It is a unique, result orientated activity with limited resources. It has new rules and agreements. Dividing the project in several phases can help to achieve control. The phases are (Twynstra Gudde, n.d.):

- Initiative: What will the project result be?
- Definition: Defining the requirements and wishes.
- Design: Designing the idea.
- Preparation: Preparing for a smooth as possible course of events in the realization.
- Realisation: Building the project result as prepared.
- Post Realisation: Service, management and maintain of the project result.

According to Twynstra Gudde (n.d.) each project stage will be closed by a document. I summarized this in Table 3.

Project Stage	Document to close project stage
Initiative	Project assignment
Definition	Project program
Design	Project design
Preparation	Work plan
Realisation	Post-realization documentation
Post-Realisation	Maintain

Table 3 Project stages and closure documents.

The stages above can be set over the product life cycle. Figure 5 shows the product life cycle (Smith. L., n.d.). When a whole new healthcare project is initiated, designed and executed the existence of a pipeline just started. A product life cycle can be used to see a product lifespan. When built and taken into use the growth and maturity stage of a medical pipeline begins. Service and Maintain is done to keep the pipelines working according to the specifications. After some time a healthcare facility could decide on changing, modifying or expanding the layout built during the project. Modifications therefore are placed in the post realization stage. The decline stage of a product life is reached when modification and expansions are not enough anymore to fulfil requirements of the healthcare facility. Often during the decline stage a new project is started.

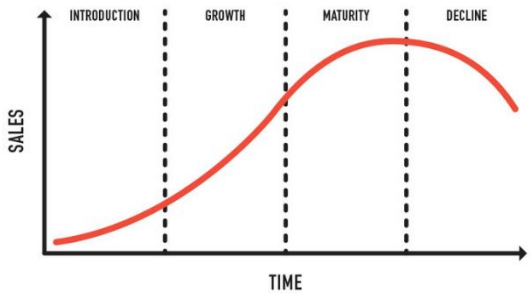

Figure 5 Product life cycle.
Source: L. Smith, The Product Life Cycle: A Guide from Start to Finish.

4.2 V-model

The V-model is used in projects to structure processes. An example is given in Figure 6 (CrackMBA, 2011). The model originates from the Waterfall model as shown in Figure 7. The Waterfall model visualizes that each stage of a project should be finished before proceeding. This so that re-designing during execution is limited as far as possible. Within the Waterfall model validation is incorporated in the realization stage. A project is finished when validated. The V-model emphasises on the validation, dividing the realization stage in the actual realization and validation towards every design step before executing. The V-model originates in the software development. Software is not a physical product everyone can see. To demonstrate that it is sufficient according to the demands of the client, every aspect is tested through (CrackMBA, 2011).

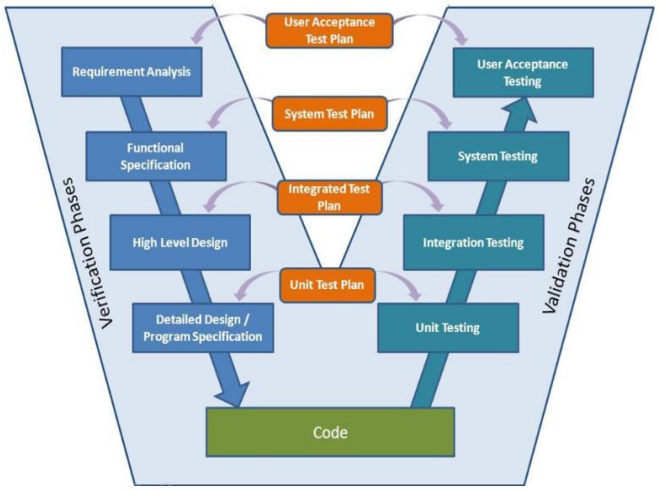

Figure 6 V- Model.
Source: CrackMBA, 2011.

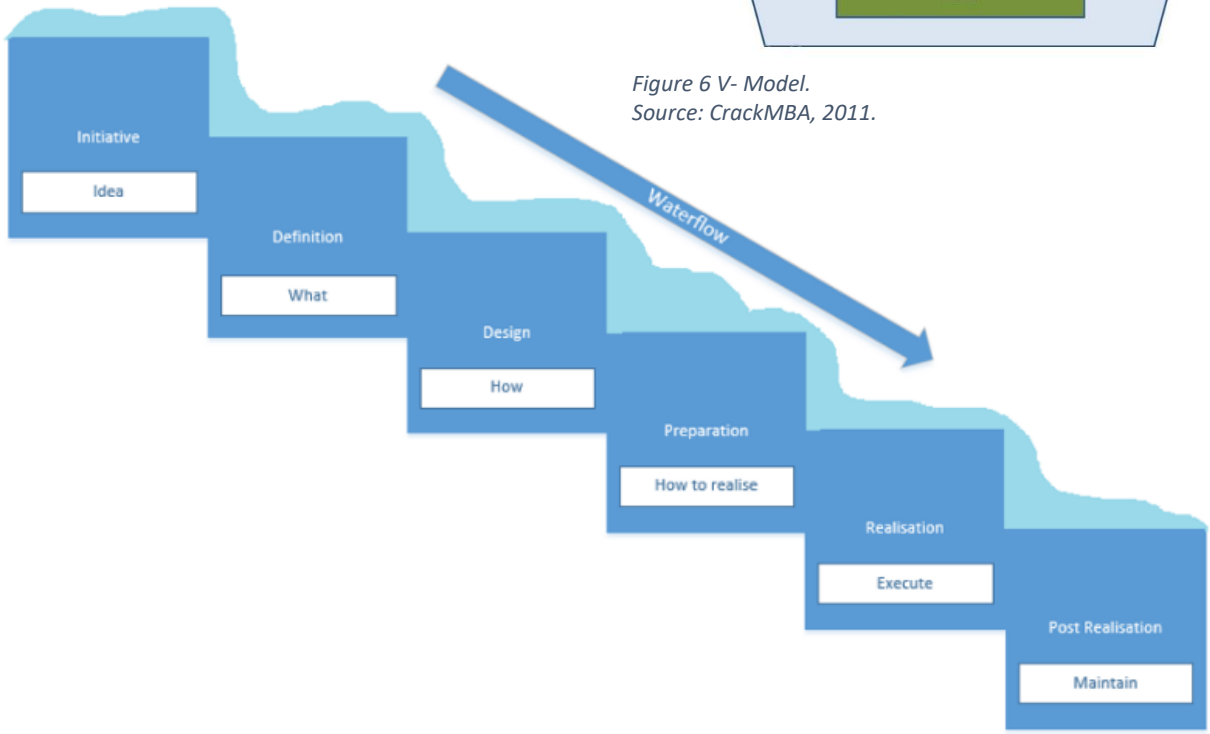

Figure 7 Waterfall model.

4.3 GMP

GMP is part of the GxP, standing for good practices in general. Examples are (European Patients' Academy, 2016):

- Good Laboratory Practices (GLP).
- Good Clinical Practices (GCP).
- Good Manufacturing Practices (GMP).
- Good Engineering Practices (GEP).
- Good Documentation Practices (GdocP).

The last two will be of importance for Company X. GMP relates to the preparation of medicines in hospital pharmacies. Company X designs, builds and maintains a medical device, therefore GMP is not directly related. However, GEP can be used. GEP is defined by Pharma IQ (n.d.) as "*a combination of standards, specifications, codes, regulatory and industrial guidelines as well as accepted engineering and design methods intended to design, construct, operate, and maintain pharmaceutical and/or biotechnology facilities taking into account not only regulatory compliance but also safety, economics, environmental protection and operability.*" This definition relates in more detail to what Company X wants to provide. The medical gasses need to be

transported and must maintain the quality from source until the supply points. Company X guarantees that the gas distribution system is designed in a proper way. With the help of GdocP activities could be tracked, recorded and provided to the customer. GMP on itself is a really strict working process originating from the Food and Drug Administration (FDA). Company X should be able to achieve the stated requirements regarding GMP or GMP-z stated at the beginning of a project with the help of GEP and GDocP. I will continue this thesis with the term GMP. This because it is the general name used. Company X is not responsible for the GMP process itself but wants to work accordingly.

GMP describes a working process which should be maintained to control a project. It defines several documents that need to be finished before moving on to a next stage. These documents include:

- *Validation Master Plan (VMP)*
  This document represents the end of the preparation phase. It contains the details in which sequence the design is built during realization.
- *Design Qualification (DQ)*
  This document contains the final design. It represents the end of the design phase. After this, preparations can start to transform the design into reality.
- *Installation qualification (IQ)*
  This document will be set up in draft during the preparation. During the realization this document will be filled with all the details about the system regarding materials. When the project is finished the document is handed to the client.
- *Operation qualification (OQ)*
  After the IQ is finished the system as a whole will be tested. The tests performed to verify whether it is conform the DQ, are put together into the OQ. When finished it is handed to the client.
- *Performance qualification (PQ)*
  After the OQ is approved the performance will be tested. Load is attached to the system while observing whether it performs as requested.

4.4 Comparison of models

All models so far describe the main process of a project. They have differences in the representation mainly regarding validation. The V-model interlinks all validation steps towards the design stages while the Waterfall model and project management do not emphasize on this separately. GMP-z on the other hand values all stages of validation as the V-model does. Comparing the documents to close a project stage of GMP-z and the project management documents results in Table 4. Visualizing the stages of GMP-z and the V-model over the project management stages results in Figure 8 (shown on the next page).

Project Stage	Document to close project stage	GMP-z
Initiative	Project assignment	Project assignment
Definition	Project program	**VMP**
Design	Project design	DQ
Preparation	Work plan	**VMP detail**
Realisation	Post-realization documentation	IQ, OQ, PQ
Post-Realisation	Maintain	Maintain of DQ, IQ, OQ, PQ

Table 4 Project stages and closure documents.

At this moment Company X does not work conform GMP. Due to the increasing importance and the applicability of the underlying practices I will consider GMP as a scenario Company X wants to work conform in the near future. By taking this as goal, deviations can be later on identified as risks.

Important note on the work process is that Company X realizes projects and provides Service and Maintenance. From the viewpoint of client and advisor the work done can be seen as a project, following the stages as mentioned above. The client initiates a project and works together with an advisor to start designing. Then in the preparation stage subcontractors will be approached to build the design. Company X acts as such a subcontractor. Depending on the specifications of the request, Company X helps with finalizing the design, or when the design is finished will start to be acquainted with a project in the preparation stage. Multiple subcontractors are approached, a possibility of being kicked out of the process after making the calculation is still possible. The request can differ. However, the standard they need to fulfil is every time the same. At the

end of the day a distribution system for medical or technical gasses is built and tested. All specifications the systems need to obey, are stated in the standards. A medical air distribution needs three sources and a vacuum needs to have at least 2. Even the way of building is stated in the standard. For example, rules are applicable to the maximum distance between the supports for the pipeline. The types of tests and even how they need to be executed are stated in the standard. Even forms which can be used to fill in the results are provided.

Until the design stage the process could be seen as a project. Which types of sources will be used? How many sources will be placed etcetera. After the design is finished it becomes more of a routine, ordering the components, writing the detail validation plan based on the given procedures and tests in the standard.

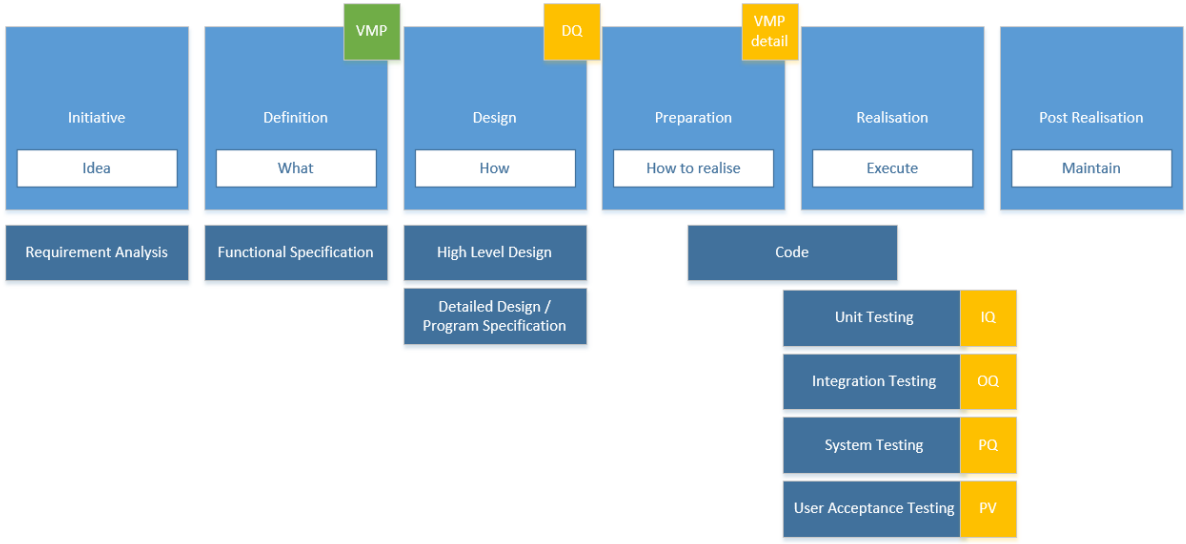

Figure 8 Comparison of models.

5 Detail Process

"Everything should be made as simple as possible but not simpler"
– Albert Einstein -

By defining the main process nothing is said about the actual work activities and the possible risks. This chapter will start by defining in more detail the processes aligning with GMP and the necessary documents for this.

5.1 Process map

The detailed process will be set up as a scenario analysis. How will the work process be structured when GMP is implemented? In the main process it could be seen it has commonalities with other work methods. Differences can be defined by designing a workflow and comparing this with how work is performed at this moment. The literature [Twynstra Gudde, n.d.] defined several activities that should be executed in each project stage I summarized this in Table 5. I added DQ, VMP, IQ, OQ behind the mentioned closure documents. PQ and PV are not added as they are out of scope for Company X. If they are incorporated they should be placed in the Realization stage after OQ.

Stages and closure documents	**Activities**
Initiative	
Project assignment	Investigate current situation.
	Determine problem statement.
	Determine goal / project result.
	Determine feasibility.
	Framing the project scope.
	Description of working method.
	Compose the project assignment.
Definition	
Program of requirements // VMP	Define requirements and wishes:
	Conditions.
	Functional demands.
	Operational requirements.
	Design restrictions.
	Program of requirements.
Design	
Project design // DQ	Design per subproject.
	Designing project tools.
	Coordination of subprojects and project tools.
	Adjust after partial design test.
	Compose the final project design:
	Secure design schedules.
	Describe realization methods and tools.
	Record outcomes of implemented management activities.
Preparation stage	
Detail VMP // IQ	Purchasing.
	Contract third parties.
	Train / instruct executeve staff.
	Compose realization instructions / work plan.
Realization	
Post realization documentation // IQ & OQ	Execute work plan.
	Compose documentation for use, management and maintenance.
	Train users.
Post realization	
Use, maintain	Project result:
	Manage.
	Maintain.
	Modify.
	Optimize.

Table 5 Activities according to literature.

After finding this in literature, I used semi-structured interviews to interview the project manager and the service and maintenance manager. What they wrote can be seen in Appendix A. Combining the two interviews I obtained the results shown in Table 6.

Stages from out client	Activities Company X
Initiative	
Definition	
Design	
Preparation stage	
Contracting third parties --> -->	**Company X receives program of requirements**
	Provided information sufficient?
	Design complies with requirements? (customer specific, requested standards)
	Requirements and expectations in accordance?
	If incomplete, request missing data.
	Calculation:
	Request prices from suppliers.
	Create and send quotation.
	Assignment no, close the quotation.
	Assignment yes, allignment client:
	Everyone the same goal.
	Request for final drawings and circuit diagrams.
	Request definitive work plans issued by client.
	Behaviour on location.
	Schedule:
	Order of work.
	Times of delivery.
	Availability people.
	Placing orders.
	Advance invoicing.
	Creation of workbook.
	Instruct mechanics.
	Materials and tools to location.
Realization	
	Attend construction meetings.
	Arrange building permits.
	Monitoring progress:
	Monitoring hours.
	Problem management.
	Provide material, tools, information.
	Workplace inspection.
	Work inspection.
	Interim invoices.
	Validate.
	Deliver final result:
	Post-realization documentation.
	As Built drawings (draft).
	Document for final delivery.
	Final invoicing.
	Evaluation.

Post-realization	
	Request post realization documentation.
	Service and management Create contract / Execute:
	Schedule.
	Functional:
	Testing of alarms.
	Check functional testing.
	Leak test.
	Overheul.
	Validation:
	Compose Plan of approach.
	Approval client.
	Execute and validate.
	Update post realization documentation.
	Invoice.

Table 6 Result of activities done by Company X in several stages.

I compared Tables 5 and 6 to identify critical points. In Table 5, points identified in literature not done by Company X are highlighted in yellow. The first point of attention is writing a work plan in the preparation stage. According to the work flow of Company X they ask for work plans issued by the client. However they do not write their own. This is strange as Company X is the expert and knows how activities should be done. Furthermore the line between preparation and realization fades. The second point of attention is the documentation that is delivered to the client. According NEN-EN-ISO 7396-1 provided information shall be in accordance with EN 1041. However Company X does not have access to this standard. The post-realization documentation Company X refers to can therefore not be checked on completeness. Delivering documentation is not a routine within Company X. If a client does not ask for documentation, the possibility exists that Company X does not deliver it. The last critical point is 'maintain and modify' of the project in the post-realization stage. Company X requests post-realization documentation and states to update this documentation. However, this is most likely the information internally available for service contracts. For example, a high pressure hose needs to be replaced every 5 year. This is registered in the computer system giving a notification every 5 years. However, the complete information set regarding maintain and modifications of the whole system are in the hands of the health care institutions themselves. Company X only executes a small part of maintenance but does not maintain the whole system. Modifications in the system are on their turn tendered as projects. However, these modifications need to comply with original design specifications. This is most of the time not checked by Company X. Responsibilities for Company X and the client should be made clear in situations like these.

Based on the literature and the interviews, I set up a draft process map how to work logically through the activities mentioned. I took up the GMP key points as well. This can be seen in Figure 9. This draft process was discussed thoroughly within Company X. Decided is that only the main project activities should be shown. Activities as invoicing are seen as supportive tasks and not necessary to take up in the process map. Besides that Service and Maintenance was split up in multiple processes. Because multiple types of contracts are possible each with characteristic of their own. According to GMP when doing maintenance you check the IQ, OQ or both. However to be able to check IQ, OQ or both, information needs to be available. At this moment this is in most hospitals not the case. Meaning that at this moment Service and Maintenance means technical check of components and system measurement. For all possibilities I defined which information is necessary to perform a contract correctly. This is visible in Table 7. Next a decision was made to incorporate the stages before and after the scope of Company X. This to create a broader knowledge base which activities already happened before a project application reaches Company X. The final result of the process map is shown in Appendix B.

	Service and Maintain contracts						
Availability of Information/ Activity	**Component**	**System measurement**	**IQ**	**OQ**	**IQ en OQ**	**PQ**	**PV**
Instrumentation lists	X		X		X		X
Maintenance procedures in accordance manufacturer instructions	X		X		X		X
Drawings of the medical gas installation			X		X		X
P&ID including the flow of mass			X		X		X
List of critical spare parts			X		X		X
Operational management document			X		X		X
Installation is in operation		X		X	X		X
Installation is tuned		X		X	X		X
Installation is stable		X		X	X		X
System requirements present		X		X	X		X
Installation qualification is successfully completed				X		X	X
Operational qualification succesfully completed						X	X
System test under load							X

Table 7 Necessary documentation for Service and maintenance.

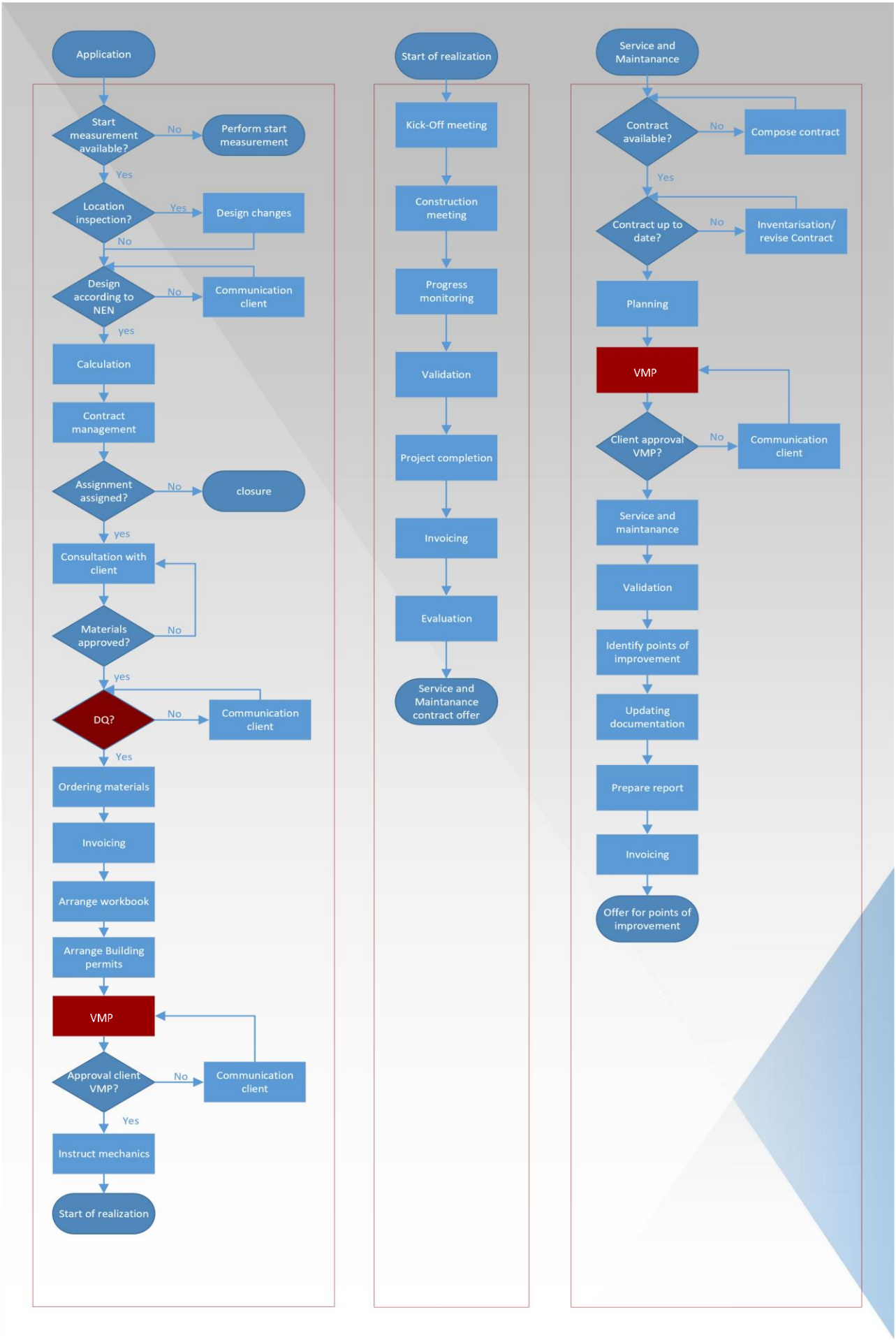

Figure 9 First draft process map.

5.2 Documentation

After setting up this process map, I linked necessary documents to the several main stages. The first stages until design were specified in a presentation from Rouwette (2015). The stages after design are filled based on documents found on the server, literature and how work is done at this moment. For a complete GMP a lot of documents are necessary so that the process and decisions can be reproduced when necessary. It is fairly impossible to work through all the necessary documents necessary as the market is currently structured. Especially while hospitals want to have it as cheap as possible and do not have the necessary documents. Therefore I highlighted the documents which cannot be neglected in Appendix C. I highlighted the necessarily documents and represented this as GMP-light version.

6 Process risks

> *"The first step in the risk management process is to acknowledge the reality of risk. Denial is a common tactic that substitutes deliberate ignorance for thoughtful planning"*
> *– Charles Tremper -*

In this chapter, process risks that could occur when working according to the scenario of the GMP process will be analysed, starting with identifying which tool will be used. Next, the results of applying the tool will be given.

6.1 Risk identification tool

As mentioned earlier, the process map and necessary documents are filled in according to the scenario that GMP will be implemented within the market Company X operates in. Process risks concentrate on the risks occurring when working according to a certain process.

To identify these risks a risk assessment tool can be used. The NEN-ISO/IEC 31010 describes 31 tools as seen earlier in Table 1. 15 of these tools where already selected as strongly applicable for risk identification. 4 of them are strongly applicable throughout the whole risk assessment process, namely: Environmental risk assessment, SWIFT, FMEA and RCM. SWIFT was developed as a simpler alternative to HAZOP. Keeping in mind that the starting point was defining a process map when GMP will be implemented (scenario analysis). It is therefore more logical in my opinion to identify unwanted outcomes and deviations from the process. This is done with HAZOP. FMEA starts with failure modes. However, HAZOP is broad and has a high level of detail. The SWIFT analysis has as well a better applicability towards the whole risk assessment process. Therefore, I decided to start with the SWIFT analysis. Limitations of SWIFT are that if the team does not have a wide enough experience base or if the prompt system is not comprehensive, some risks or hazards may not be identified. Besides this it is a high-level application. The technique may not reveal complex, detailed or correlated causes.

To not limit myself to only one tool I evaluated the other tools in the list of 15. Besides the SWIFT analysis I find the cause and effect analysis useful. Looking at HACCP the critical control points have been defined in the GMP. The points at which the project stage gets checked before proceeding are:

- VMP: To plan how later on the activities should be validated.
- DQ: To qualify the design as definitive before proceeding to the next stage of preparing the realization.
- IQ: Qualification of installation towards earlier defined requirements according to the VMP.
- OQ: Operational qualification of the installation towards earlier defined requirements according to the VMP.

An objection toward this could be that the GMP defines only main control points. Looking at all the documentation necessary, realizing correct closure documents is quite complex. Therefore it can be considered to subdivide those main control points in multiple control points. However, to be able to do this, a thorough knowledge of the process is necessary to be able to define these critical points. As Company X is a subcontractor and has nothing to do with the first stages, I will not dig deeper into this matter and will proceed with the main critical control points essential for Company X. Brainstorming can be an useful tool with a larger group. However there the input is only restricted to 3 people I preferably use the semi-structured interview. It has room for other input but has a basis to start a discussion. I used this technique already while setting up the process map.

6.2 SWIFT analysis

I started with SWIFT to be able to identify risks that could occur when the process map is not followed. At each point in the process map and the addition of the documentation, the question was asked: What if this is not done (correctly)? Risks that can be defined going through the whole process step by step, are as follow:

- Looking at the process it is immediately visible that Company X is dependent on how the process is done before getting acquainted.
    - Are specifications and requirements complete and correctly defined?

    - Are all documents available necessary for Company X to start preparations for building the DQ or is Company X involved in finalizing the DQ?
        - Necessary documents for a DQ:
            - Principe layouts.
            - PFDs.
            - Mass balances.
            - Definitive Space Book.
            - Process control Design.
            - Definitive Equipment list.
            - Design reviews.
            - Process validation plan.
            - Component specification.
            - Pipeline lists.
- Preparation stage.
    - Design not according to the NEN-EN-ISO 7396-1.
    - Mistake in Calculation.
    - No Design Qualification.
    - Not writing a VMP.
    - VMP not approved.
    - Not a correct instruction of mechanics.
- Realization.
    - Safety measures are not taken into account [VGM].
    - Not following of proper procedures.
    - Necessary documentation is not collected.
        - Certification of Cleanness.
        - CE markings.
        - Documentation (work instructions).
- Service and Maintenance.
    - Contract given to a Competitor.
    - Documentation necessary not available.
    - Contract not up to date.
    - Changes not updated in the documentation.
    - Not following proper procedures.

6.3 Cause and effect analysis

For every point identified above causes could be thought of. However to make it more clear and workable so that I will not be bogged down in too much detail, I went back to the defined critical points within GMP. I went through these critical points with the employees of Company X. In a short presentation I explained what I was researching. After that I took the time explaining what a cause and effect analysis means and how it works. Starting with defining a set of possible causes. In most causes this is standardized. Possible choices are 6M, 3M and P, 8M, 4S and 7Ps. Leansixsigmatools (n.d.) explains these categories as:

- "3M and P: Methods, Materials, Machinery and People.
- 4Ps: Policies, Procedures, People and plant.
- 8Ms: Machine, Method, Material, Man Power, Measurement, Management, Maintenance & Milieu/Mother nature.
- 8Ps: Product/Service, Price, Place, Promotion/Entertainment, People, Process, Productivity & Quality
- 4s: Surroundings, Suppliers, Systems, Skills"

Together with the service manager and the project manager I filled in causes why the DQ was not finished. This was quite difficult as the DQ should be finished in most cases before the application is received by Company X. However I wanted to use it to get the employees acquainted with the risk identifying tool and way of thinking. The result of filling this in is visible in Figure 10. After defining causes I expanded the cause and effect with the 5 why strategy. This technique focusses on a problem occurring and tries to get to the root of the problem by asking, Why? It is optimal when answers are given by employees working with the process that is examined. So experience based (mindtools content team, n.d.).

At this moment the work is not done according to GMP, therefore none is experience based. However I found a lot of commonalities between the processes. Therefore I wanted to try this method to see whether a broader way of thinking could be triggered. I used DQ as a basis to get the way of why questioning understandable for the employees.

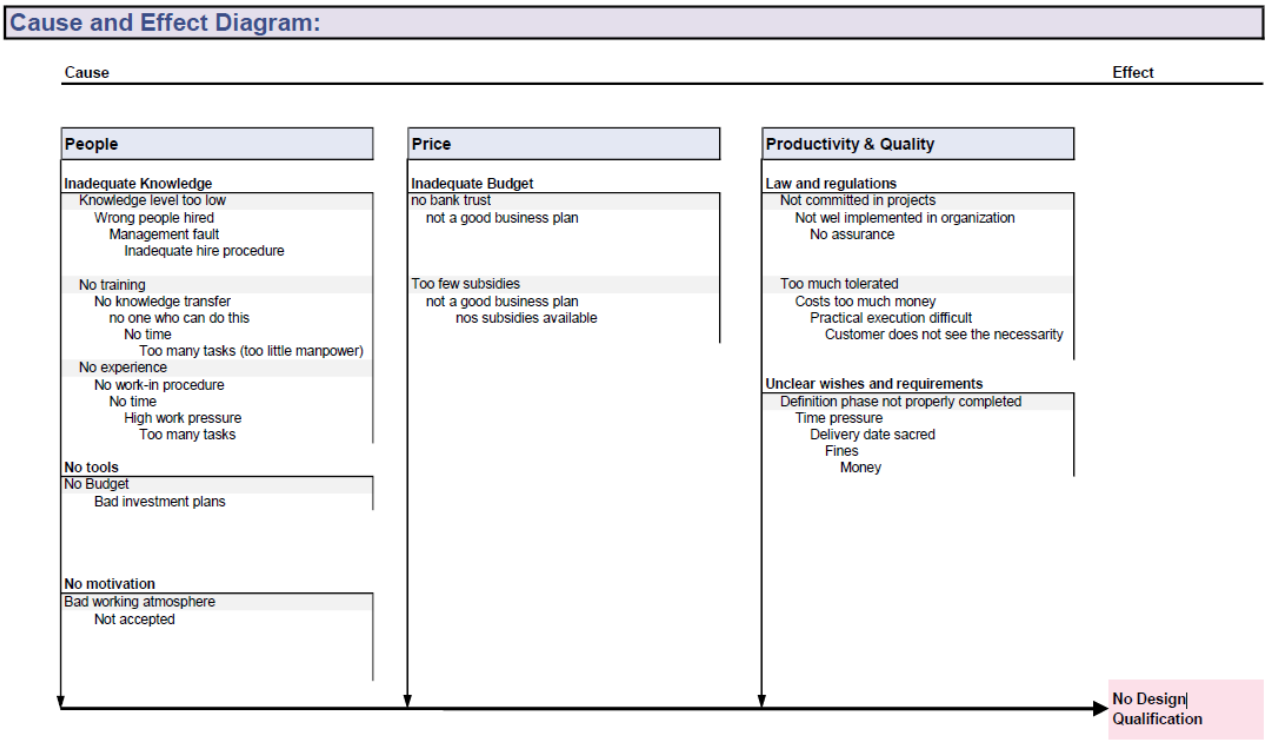

Figure 10 Cause and Effect DQ.

After doing this exercise in a group session I defined the main causes together with the employees so that everyone had the same start point. Next, the critical points where defined by the employees themselves independently. The combined results are shown for the preparation, realization and post realization stage in Figure 11 till Figure 13.

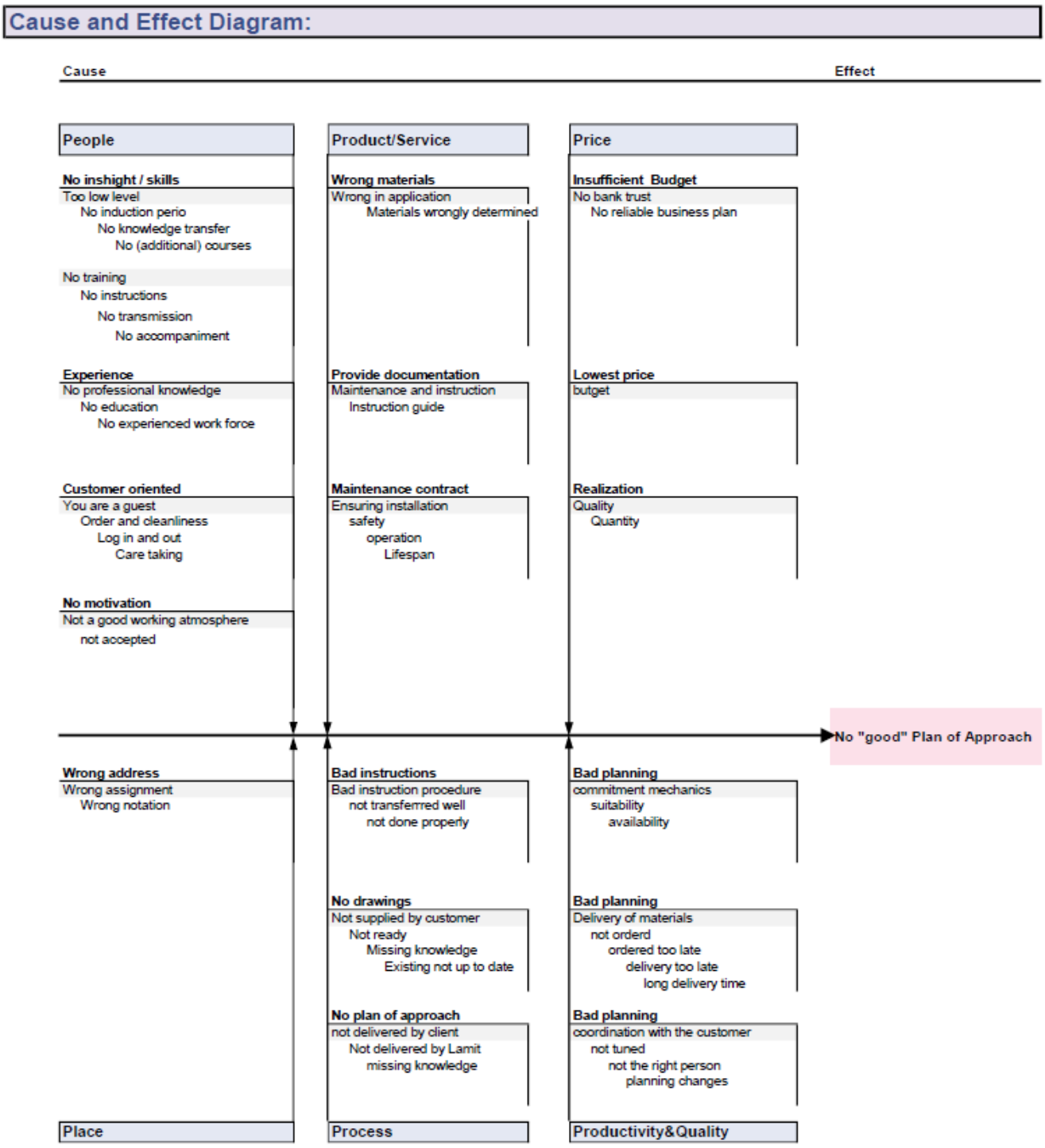

Figure 11 Cause and Effect VMP.

Figure 12 Cause and Effect realization stage.

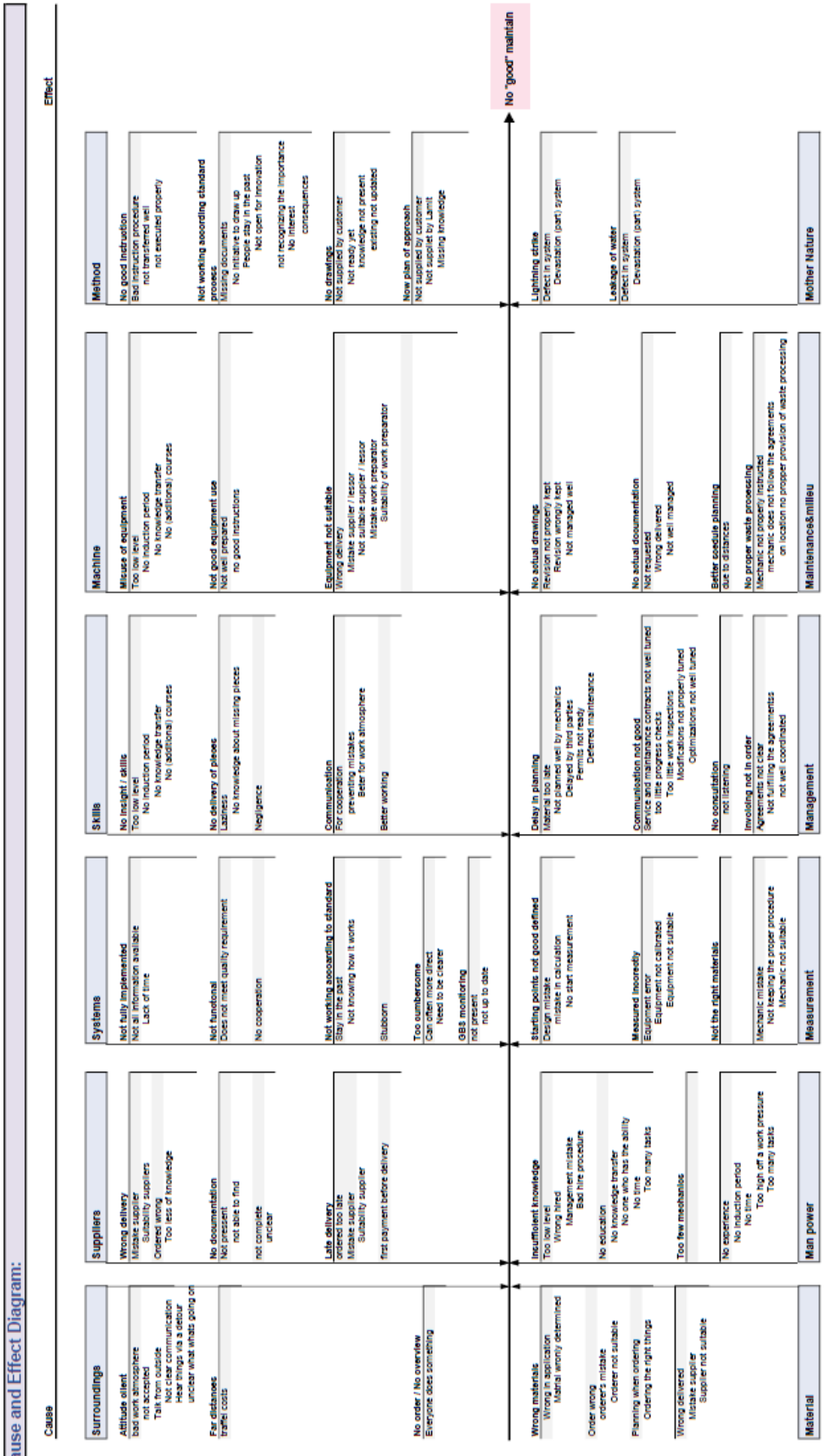

Figure 13 Cause and Effect Post realization.

Input for the critical control points is visible. Noteworthy is that employees working daily with a project and being manager of Service and Maintenance can identify reasons why control points are not reached. However, asking themselves why this occurs is a difficult step. Most of the time we found causes until the 3rd why. The tool assumes that 5 why questions are necessary to get to the root of the problem. This implies that in the case of Company X most of the root problems are not found. However, it is discussable that it could be problem specific how many why questions are really necessary to get too the root of the problem. However taking the created cause and effect diagrams for a closer look it can be seen that the root cause is not defined. For Example: In Figure 11 the cause and effect diagram of the realization stage is given. A main category for a faulty final delivery is measurement under which incorrect measurement is stated. Incorrect measurement can be the result of equipment error or an error due to the mechanic. The last why answered states that the equipment is unsuitable in case of equipment error and that the mechanic is unsuitable in case of a mechanic error. In my opinion these are not root causes and raises multiple questions. Why is unsuitable equipment used? Why is a mechanic unsuitable when a mistake occurs? Every human makes mistakes. Is there not another reason why procedures are neglected by mechanics? Besides that, some information is not linked correctly according to the method. For example stating that an agreement of price (discount) is of influence that the final delivery of a project is not done correctly. Another point of attention is that some critical points are mentioned more than once.

- Workload.
- Attitude client.
- Missing documentation.

Furthermore, causes are mentioned outside the scope of the employees. These causes lie at management or advisors in between of Company X and the client resulting in gaps of information. Therefore in my opinion information regarding risks are far from complete.

On the other hand it is important to identify what happens when critical control points are not finished while the process proceeds. To identify these I asked the employees directly what they thought were consequences. Using again what if questions. This so it can function as a basic fundamental which can be worked out in more detail when deemed necessary.

What are consequences if the procedure is continued?
If DQ is not finished correctly?

- In this case drawings sent with the application are seen as definitive. This is stated in the offer and also asked for confirmation by email. Due to this, if changes are made it can be seen as additional work and will be charged.
- Drawings will be checked based on professional knowledge and applicable NEN norms.
- In the offer a notification will be given that it is assumed the source capacity is enough. This in case mass calculations and schematic diagrams and other information are missing. Be aware that a guarantee for proper functioning of the system cannot be given.

If VMP is not finished correctly?

- Not a clear difference between preparation and realization stage. One of the interviewed implied this does not have any effects.
- Instruction of mechanics happens on basis of VGM instead of what work will be done and how.
- At this moment a VMP is often not written. They assume mechanics have the knowledge to do their job correctly.
- It is not always asked by clients. So therefore not always necessary.
- Validation later on will be done based on system tests if they are within the boundaries of the standard.
- If it goes wrong it is harder to look back what and where it went wrong and who is responsible.

If final delivery is not done correctly?

- An IQ and / or OQ cannot be given.
- Residual points will be listed which need to be improved.
- No or incomplete documentation. No guarantee for the system, and problems for Service and Maintenance.
- Drawings are, where necessary, delivered by Company X in draft. This needs to be maintained in the official drawings. If not, the system is not up to date -> trouble for maintenance.

- If it is a wretched project Service and Maintenance contract could be given to a rival.

If Service and Maintenance is not done correctly?

- Offers not up to date on the actual situation.
- No actual drawings and/or documentation can result that system guarantee cannot be given. Only component test and system measurement.
- The division of responsibilities unclear.

7 Project risks

"Right is right, even if everyone is against it, and wrong is wrong, even if everyone is for it"
– William Penn-

Project risks are the risks that occur during a project. For example a fault in design. In this chapter I will analyse risks that could occur during a project.

7.1 Project risks according to NEN EN ISO 7396-1

Project risks differ for each project. Main given is that it needs to be built according to the given standards. I concentrated on NEN-EN-ISO 7396-1. Annex F of this standard describes a set of risks that could occur. A previous internship student made this table into an FMEA structure as can be seen in Figure 14.

Figure 14 FMEA structure.
Source: Salm van der Koen (2011), Het opzetten van een kwaliteitssysteem voor validatie van medische gasinstallaties.
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My comment to this risk table is that it has been copy-pasted directly from NEN-EN-ISO 7396-1. However, this table is only a selection of risks and far from complete. To identify a complete as possible risk set I read the complete standard. I noted in an Excel file every statement made. I sorted this according to where in the project stage it will become important. In Appendix D the headers are shown under which I organized all requirements. The number of statements mentioned in NEN-EN-ISO 7396-1 are as follow:

- For Design: Divided in 13 groups, 394 potential risks in total.
- Realization: 14 potential risks.
- Service and Maintenance: Divided in 10 groups, 82 potential risks in total.
- Information to be provided by manufacturer should be in accordance with EN1041 or Equivalent national standards.

Important note is that a risk division between Company X and the supplier of components still needs to be made. After that the risks should be logically filtered according the several types of systems as vacuum and medical air. If the basic set up is good and workable, the risks should be added with project risks from other standards besides NEN-EN-ISO 7396-1.

To select a tool which can be used to identify risks applicable for projects, I took again the tools from NEN-ISO/IEC 31010. A FMEA tool is nice and can give insight in the consequences. However, it is important to realize that as soon as rules from the standard are not fulfilled the system does not comply. So all of the possible occurrences that the design of the system does not comply have as main consequence that a conformity statement regarding NEN-EN-ISO 7396-1 cannot be given for the system. The requirements of the standard are qualitative aspects which cannot be changed. It could be stated that risk identification is already done and recorded in the standards. A workable layout for all the risks mentioned is however not provided. I would advise to use checklists for every system separately. So a checklist for vacuum, and a separate checklist for a medical air system, and so on. If this is realized, a design can be checked according to the standard by ticking the box. If a requirement is not implemented in the design, it is then immediately visible. A point of attention is that a lot of requirements are focussed on the conditions of equipment. For example the requirements of a source. As Company X orders these at suppliers it is of importance that documentation and conformity statements are received by the suppliers. It is important to realize that checklist tend to inhibit imagination in the identification of risks. They only address the risks that are already known and encountered but do not identify possible new risks for a specific project. Therefore, checklists themselves should be checked for completeness. At this moment in time there is not a layout to check the alignment with the already noted risks in the standards. Before doing further research about project risks the risks already known should be handled. Therefore I will not try and find other risks outside the NEN-EN-ISO 7396-1.

7.2 Procedures given by the NEN EN ISO 7396-1

Besides design risks the NEN EN ISO 7396-1 provides guidelines for procedures and forms. These need to be followed and filled in during realization. This to measure whether the system stays within given boundaries. The procedures themselves could be checked for process risks. I however did not do this. I concentrated on the underlying project risk of not fulfilling the requirements. Besides procedures, the form shown in Appendix E was found. At this moment this document is not up to date and therefore not used. However, it makes visible

in one glance which tests and forms are necessary for which job. The standard has for every test a separate document. Company X combined these into their own documents. I collected all procedures and forms used currently in one document. The table of contents showing all documents is visible in Appendix F. A general format of the procedures is shown in Appendix G.

All information is retrieved directly from the NEN-EN-ISO 7396-1 and is in most cases copied directly. Only the format of how the information is represented is different. My general comments after reviewing the available documentation are:

- Regarding the dates in the documents, they are set up before the latest norm. Therefore they should be checked upon changes and updated. As it is quite weird that Company X states always to comply with the highest standards, but with dates before the latest standard. This implies they do not comply.

- The procedures are set up by employees not working anymore at Company X.

- Not all procedures are worked out. The following are missing:
    - Check for compliance with design specification.
    - Tests of monitoring and alarm systems.
    - Tests of gas identity.
    - I copy pasted some in procedure format. However they are not finished in detail in compliance with forms.
        - Combined tests for leakage and mechanical integrity of compressed medical gas pipeline systems.
        - Test for cross-connection.
        - System performance.

- Translate mistakes English standard -> Dutch procedures.

- General comments as “precautions should be taken to avoid hazards to personnel arising from possible rupture of the pipelines” are made. However, which precautions, are nowhere to be found.

- Company X combined a lot of forms in only a few to make it in practice more workable, however they do not cover everything as far as I can judge. Missing elements are:
    - F061: Not mentioning specifically mechanical integrity in the fill in fields.
    - C1: Not compliable with test F.
    - A1.2: calibration of instruments cannot be filled in while it is a requirement this is checked before testing.
    - A1.2 and C2 both replace form D.11 out of the norm however system performance cannot be filled in.
    - A1.2: design requirements cannot be filled out while it is required to test if the system complies with design.

- Additional tests not mentioned in NEN-EN-ISO 7396-1 (I did not check these):
    - European pharmacopoeia forms.
    - Work procedure leakage tester LD-229.
    - Microbiological sampling.
    - Quality measurement cleanroom ISO 8573-1/GMP Annex 1.

Procedures are stated in the NEN-EN-ISO 7396-1 so that they are not presented in a Company X format is not the biggest problem. However using fill in forms that do not give the opportunity for filling in every detail necessary is problematic. Validation is therefore not solid. Take for example the calibration. If it really matters Company X does not have it stated somewhere in the forms that it is done before testing. It gives the opportunity for pointing fingers who is to blame. Company X could state it does the procedures according to the standard in which it is stated calibration needs to be done. However proof cannot be submitted.

8 Conclusion

"It's not the heart that compels conclusions in cases, it's the law"
– Sonia Sotomayor-

In this thesis I concentrated on the main research question:
How can risks be managed in a clear, secure and workable manner throughout the working process of Company X?

To answer this research question I broke it down in several sub questions. Starting with a brief market research. I found a lot of European regulations, national regulations and standards to which Company X needs to comply. Good Manufacturing Practices (GMP) came around very fast during this research. GMP is implemented in the European regulation. The importance of GMP is echoing around but has not fully landed. As this is only a matter of time I used the work process of GMP as a basis for my research.
Contract management is very important too. You need to comply with a lot of regulations as cheaply as possible. If you don't set your boundaries it can result in tensions due to a mismatch of delivery and expectation. After the brief market analysis I continued with defining risk and risk management based on the NEN-EN-ISO 14971, ICH Q9 and the NEN-EN-ISO 31010. Important steps in risk management are risk assessment and risk control. I found a list of 31 risk assessment tools which I used as a starting point for further research on process and project risks.

After finding the above mentioned knowledge aspects I started to look at the working process. I firstly structured a main working process based on literature. Models described for project management used in this thesis are the Waterfall model, V-model and GMP. I compared these models and came to the conclusion that they overlap. After constructing a process map based on literature I investigated what the current working process is within Company X, compared this to literature, and constructed a final process map. This process map for the different stages of a project can be found in Appendix B. I continued by defining which documents are necessary in each project stage. This is seen in Appendix C. It is a mission impossible to collect all the documents in the current market structure. I selected the documents which are most important for the work Company X does.

After constructing a process map and defining necessary documentation I started with analysing the possible risks. I divided this into two groups. Process risks and project risks. For process risk I worked with SWIFT, which was originally designed as a simpler alternative to HAZOP and Cause and effect analysis. Besides of those is the HACCP already incorporated clearly in the models such as Waterfall, V-model and GMP. I asked questions what would happen if the step in the process where not executed correctly. Then I applied the cause and effect analysis in combination with 5 why on the critical control points to identify why these points would not be realized. Outcomes of this analysis are debatable as the root causes are not reached in my opinion.

The project risk I could define without a deep knowledge base, was the risk of not complying with the NEN-EN-ISO 7396-1. I compiled all statements made in this standard and sorted these risks according to project stage. In Appendix D the headers are shown under which I organized all requirements. The number of statements mentioned in NEN-EN-ISO 7396-1 are as follow:

- For Design: Divided in 13 groups, 394 potential risks in total.
- Realization: 14 potential risks
- Service and Maintenance: Divided in 10 groups, 82 potential risks in total
- Information to be provided by manufacturer should be in accordance with EN1041 or Equivalent national standards.

However project risks differ between projects. To make sure the design is om accordance with the NEN-EN-ISO 7396-1 I advised the checklist method to identify risks. This because it is easy to use. It is a matter of checking the correct items. If every box is checked the design complies, in other cases it does not. Besides that, I took a look at the procedures and forms present within Company X. I did not use a risk management tool to define risks in these as the procedures and forms in comparison with the NEN EN ISO 7396-1 are not complete and comply with the norm of 2007 instead of the newest version of 2016.

9 Discussion

"The aim of argument, or of discussion, should not be victory, but progress"
– Joseph Joubert -

How can risks be managed in a clear, secure and workable manner throughout the working process of Company X? It is a broad and challenging question. Knowledge about the working process, risks and methods to manage those risks, is necessary. Company X operates in the medical field. Due to this a lot of people have already thought about risks and consequences as human lives are involved. This is noticeable immediately when looking at regulations and standards. Choosing a solution is therefore not always discussable. GMP is for example stated in the European law and becomes unavoidable in time. However, Company X is not working accordingly yet. I set the GMP process up as a scenario Company X wants to achieve. Deviations from that scenario can be marked as risks. A remark to this is that it is purely theoretical. Company X is dependent on information distributed by the client to execute their job. Therefore a full GMP process cannot be reached if clients are not willing to change. Money on the other hand can be classified as a huge impact. Maintenance is necessary and unavoidable however this needs to have the best quality as cheaply as possible. For a complete GMP process a lot of documentation is necessary as can be seen in Appendix C, and it cannot be offered for free. GMP is set up to manage on critical points. With an important note that information is necessary before starting, not after it went wrong in one of the following stages. However, it should be taken into account that GMP highlights only main critical points. If in practice underlying points are found critical, a subdivision of these main points should be considered.

Furthermore, it is important to realize this report is only the beginning and a basic layout far from complete. Risk management is an ongoing process. Even if a Phd study over a time span of 4 years would be conducted, it would still be inevitable that not all the risks have been defined. Results in this report for process risks regarding the cause and effect diagrams trying to identify underlying causes why critical points are not realized, are debatable. Advice is that one should continue this research over a longer period going through every step triggering the people who work with it into broader thinking. Another point is that the working team existed only out of three people, limiting the input. Also the fact that the research has been done only with the employees of Company X makes that gaps in information are unavoidable. Experience in practice would help to identify underlying problems. This by comparing multiple projects and defining common points of disaster.

My advice regarding the steps to manage risk in a clear, secure and workable manner are the following:

- Company X should introduce one working method following GMP and NEN-EN-ISO 7396-1. To achieve that several points of attention need to be taken into account:
    - All procedures and forms should be updated towards the most recent NEN-EN-ISO 7396-1.
    - Staff should be trained with regard to GMP and the critical control points.
    - The Waterfall model can be used to make the steps understandable
- Responsibilities of Company X must be made clear.
- Responsibilities of the client must be made clear.
- A risk assessment standard should be introduced.
    - Project risks of the NEN-EN-ISO 7396-1 have been compiled, filtered and sorted into groups, but are not yet in a usable format.
    - Other standards besides the NEN-EN-ISO 7396-1 should be incorporated.
    - I recommend to group the risks regarding the type of medical system.
- Investigate the possibilities of software.
    - To distribute documents to the users based on an expanded matrix shown in Appendix E.
    - To make working regarding the work method consistent, investigate the possibilities of an application for working on site.

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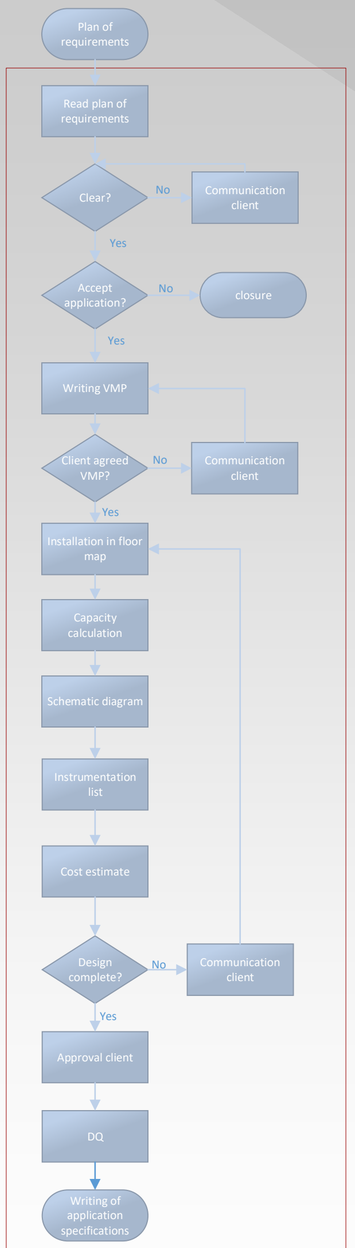
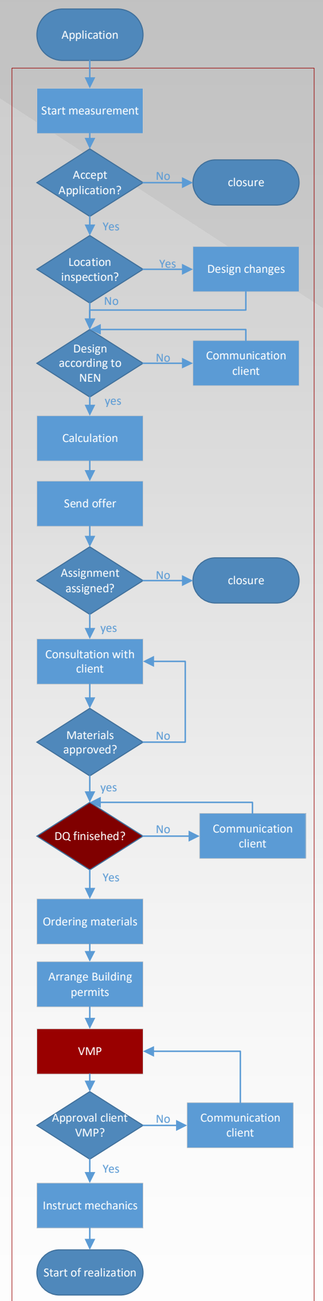
Appendix A Notes of Employees

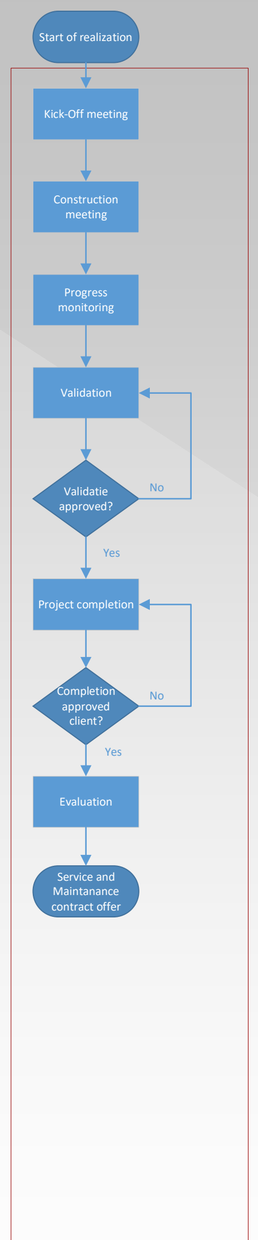
This data is not available in this publication version

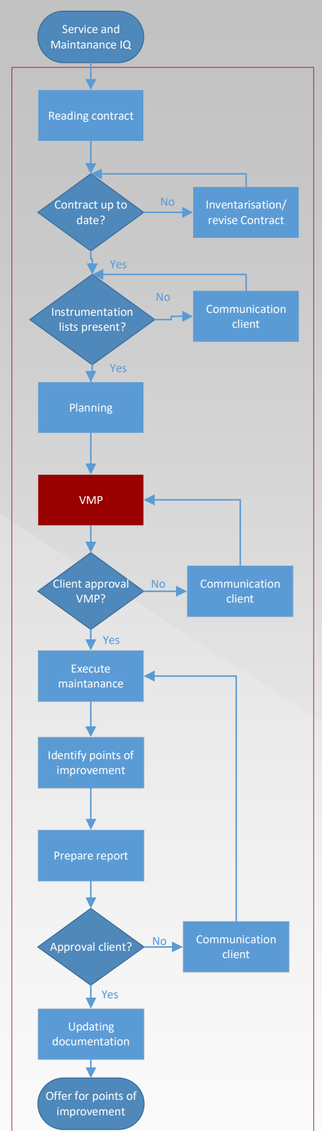
Appendix B Process map

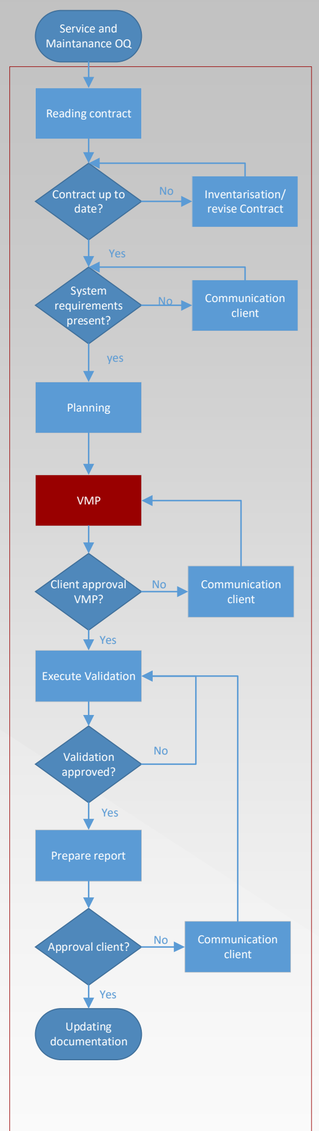
Main process

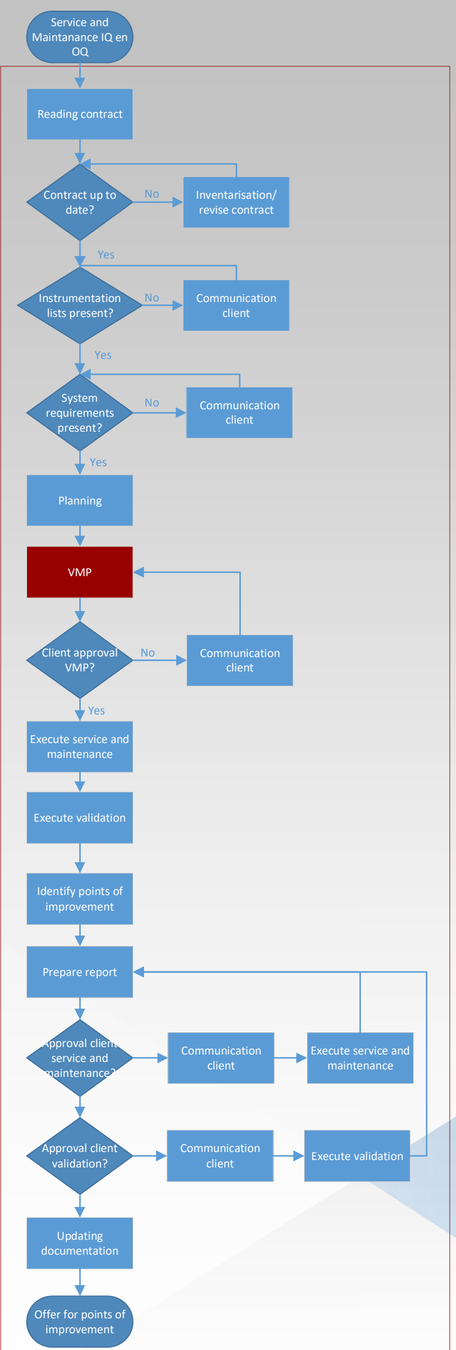


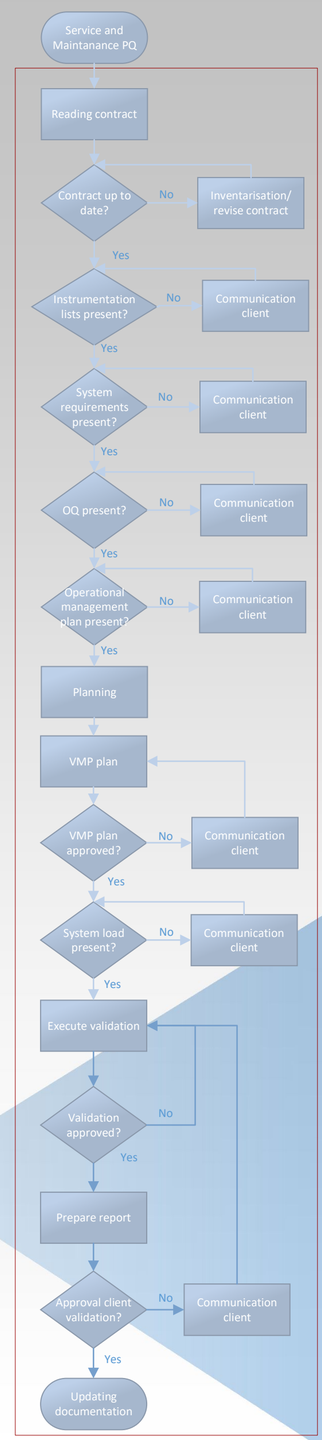












Appendix C Documentation

NEN EN ISO 7396-1 (Process)

Company X

Project stages	Initiative	Definition	Design			Preparation	Realization	Post realization	
		Draft design	Basic Design	Detail design					
Closure documentation	Project assignment	Plan of approach		Project design		Plan of approach	Post realization documentation	Maintain	
GEP Specification-documentation		Temporary PvE	User Requirements Specifications	Functional Specifications	Detail/Purchase Specifications	Work specifications	Realization / Validation	Service and management	
GMP-light GEP Engineering Documents (Typicals)		Principe Layouts	Building Design	Definitive Space book	Component specs	Nulmeting	Monitoring of hours	Nulmeting	
			Difinitive Layout	Floor/ wall/ ceiling systems	Pipeline lists	Recordings	Order list	Post realization documentation	
		Principe Schema's	Process Describtion	Process control Design	Construction drawings	Calculation		Work order	
			Definitive Flow chart	ICT Design	Cable lists	Offer	Inspection of Workplace	Innventarisation list	
		PFDs	P&IDs	Equipment Data Sheets	Setup Drawings	Workbook	Residual list after commissioning	Checklists	
		Draft space book			Isometrics	Planning	OQ	IQ/OQ Validation	
		Mass balances	Instrument Data Sheets	Components list	FDSsen Software	Order list		Report	
		Automation filosofie			MTOs	VGM			
		System Layout	E Design	Definitive Equipment list		IQ			
		Draft Equipmentlist							
GMP-Light QMS / Validatie Documenten (Typicals)		SOPs	SOPs	SOPs	SOPs	Supplier kwalificaties	SOPs	SOPs	
		SWIFT Analyses	FMEA/HAZOP Analysis	FMEA /HAZOP Analyses		SOPs		VMP	
		Design Reviews	Design Reviews	Design Reviews	Peer Reviews	FATs	OQ	PQ	Service and management Contracts
		SIA	Peer Reviews			Risk Management documents		PV	
		Draft VMP	C&Q-plans	DQ Design Qualification		Design Review checklist		Final delivery documentation	
			Process validation plans			VMP			
						IQ			

At the time of project design determine essential characteristics for system construction:
The type of sources of supply
The location of the sources of supply
The flow and storage capacity of the soruces of supply
The number of terminal units per bed-space/work-space
The location of terminal units in each department or area of the healhcare facility
The corresponding flow rate at each terminal unit
The diversity factors
The location and elevation of area shut-off valves
The need ofadditional local sources of supply in designated departments
The need of additional local sources of supply in designated departments
minimize the risk arising from emitted electromagnetic fields which could disturb other equipment and medical devices used within the healthcare facility
All pipes and components should have the appropriate level of electromagnetic immunity to operate safely within the electromagnetic environment of healthcare facilities.
Using materials or having forms of construction different from those detailed in the 7396-1 should have at least an equivalent degree op safety. Evidence for this shall be provided by the manufacturer
The specific hazards of toxic products from abnormal heating, combustion or decomposition of non- metallic materials including lubricants and potential contaminants shall be addressed.
Terminal units shall be gas specific and comply with ISO 9170-1
Terminal units for medical gases and vacuum shall be located only in areas intended for connection of medical devices
Gas-specific connectors shall be either the gas-specific connection point of a terminal unit complying wis ISO 9170-1 or the body of a NIST, DISS or SIS connector
Medical supply units shall comply with ISO 11197
Manifold and line pressure regulators shall comply with ISO 10524-2
Pressure gauge shall comply with the requirements given in ISO 10524-2
Location of cylinder manifolds and cylinder storage ereas
Location of stationary vessels (cryogenic or non-cryogenic liquids)
Location of supply systems
Sources of Supply
Pressure- relief valves shall comply with:
Flexible connections
The materials used for the components shall meet the following requirements
Alarms
Shut-off valves
Pipelines
Mainenance supply assembly

Preparation

Application without design

Check if the design is suficient accoarding to NEN EN ISO 7396

Application with "partial" design

Design risks are applicable

Components ordered should comply with the NEN EN ISO 7396 specifications [suppliers risk] DOCUMENTATION REQUIRED

Realization

Pipelines

Flexible connections

Shut-off valves

Area shut-off valve

Each box shall be vented to the room to prevent accumulation of gas

For compressed gas labeled with: Medical Gas Valves for (description of area controlled) Do not close valve(s) except in emergency

For vacuum labeld with: Vacuum Valves for (description of area controlled) Do not close valve(s) except in emergency

Each box containing: area shut-off valve(s) for one or more gases

Each box containing (except vacuum): means to allow physical isolation of the service(s)

a closed valve shall not be considered an adequate physical isolation when modifications are carried out to existing systems

S&O

Damage to the pipeline is considered a catastrophic event and not a sinle fault conditon, and shall be managed in accordance with the emergency procedure.

Extentions and modifications of existing pipeline systems

The flow, nominal distribution pressure and pressure drop characteristics of the extension or modification to the exitsting pipeline distribution system shall meet the following requirements:

Appendix E Overview of tests linked to activities

Type document
Werkvoorschrift F-100

Doel
Het doel van deze instructie is het schematisch weergeven van de toe te passen rapportageformulieren conform de Nederlandstalige norm NEN-EN-ISO 7396-1 versie april 2007.

Definitie/afkorting
DISS : Diameter Indexed Safety System Connector (veiligheidsaansluiting gebaseerd op verschillende diameters).
NIST : Non-Interchangeable Screw Threaded Connector (niet uitwisselbare schroefdraadverbinding)

Werkwijze
Niet-limitatief overzicht soort werkzaamheden.

Code	Werkzaamheden
A	Plaatsen van 1 of meerdere afnamepunt(en) voor 1 gassoort
B	Plaatsen van 1 of meerdere afnamepunt(en) voor vacuüm
C	Gelijktijdig plaatsen van 1 of meerdere afnamepunt(en) voor meerdere gassoorten
D	Aanleg leidingsysteem voor 1 gassoort
E	Gelijktijdige aanleg van leidingsystemen voor meerdere gassen
F	Gelijktijdige aanleg van leidingsystemen voor meerdere gassen en vacuüm
G	Aanleg van leidingsysteem voor vacuüm
H	Onderhoud aan 1 of meerdere afnamepunten
I	Plaatsen van / onderhoud aan gasleveringssystemen
J	Onderhoud aan afsluiter kasten
K	Plaatsen van / onderhoud aan productie-installatie voor medische perslucht
L	Plaatsen van 1 of meerdere afsluiters
M	Plaatsen van 1 of meerdere NIST of DISS aansluitingen

Overzicht toe te passen rapportageformulier per soort werkzaamheden. De vermelde code heeft betrekking op bovenstaande tabel.

	Code soort werkzaamheden												
Formulier	**A**	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**	**K**	**L**	**M**
Ziekenhuis documenten	X	X	X	X	X	X	X	X	X	X	X	X	X
Algemene werkprocedure Lamit	X	X	X	X	X	X	X	X	X	X	X	X	X
F-D.1.1.	X	X	X	X	X	X	X	X	X	X	X	X	X
D.2 /				X	X	X	X						
D.3 /	X	X	X	X	X		X					X	
D.4.1 /						X	X						
D.4.2 /						X	X						
D.5.1, D.5.2, D.5.3 /				X	X	X							
D.6.1, D6.2 /				X	X	X							
D.7 /												X	
D.8 /			X		X	X							
D.9 /	X	X	X					X					
D.10 /										X			X
D.11 /	X	X	X	X	X	X	X						
D.12 /									X		X		
D.13 /				X	X	X			X		X		
D.14.1 /				X	X	X	X		X		X		
D.14.2 /									X		X		
D.15 /				X	X	X			X		X		
**D.16, D.17 en D.18 /	X		X	X	X	X			X		X		
*D.19 /	X		X	X	X	X			X				
D.20 /	X		X	X	X	X			X		X		
****D21.1, D21.2, D21.3 /	X		X	X	X	X			X		X		

(*) Alleen van toepassing bij afnamepunt voor medische zuurstof.
(**) Alleen van toepassing bij afnamepunt voor medische perslucht.
(***) Alleen van toepassing bij afnamepunt voor medische kooldioxide.
(****) In principe gebruikt meet met op basis van de zuurstofconcentratiemeter.

Inhoudsverantwoordelijke
Hoofd Technisch Beheer.

Documentbeheerder
Kwaliteitsmedewerker ziekenhuisapotheek.

Appendix F Content of available Procedures and Forms

Inhoudsopgave Procedures en formulieren

Appendix G Format of procedures

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Date	7 January 2015

Area shut-off valve leakage, closure, zoning and identification

Table of content:

Written by :
Function :

Reviewed by :
Function :

Approved by :
Function :

Goal

Procedure before starting work

Control / maintain

Write down the results in form **C.1**

Reference
NEN-EN-ISO 7396