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Value Stream Mapping as a Basis for Process Improvement in the Pharmaceutical Industry

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Abstract

Background - The company is a Swedish manufacturer, developer and contract manufacturer of pharmaceuticals. In the last couple of years, the company has entered a growth phase which has led to issues with the internal processes such as material flow, warehouse operations and processes related to the production. The consequence has been occasional issues with delivering the products on time. As a result, the company suspects a need for refining its own processes An issue regarding how to cope with scalability and capacity is also present. The company has therefore expressed an interest in an evaluation of their current state using *Value Stream Mapping*. The company also wants to know how the value streams and processes can be improved through lean manufacturing techniques.

Purpose – This thesis aims to propose improvements to a manufacturing process within the pharmaceutical industry. The purpose is also to evaluate the applicability of Value Stream Mapping as a basis for process optimization in an cGMP (Good Manufacturing Practice) governed environment.

Research questions - What deficiencies are affecting the processes and in what way do they affect the business?

How can the deficiencies be improved through lean thinking with consideration taken to the contextual limitations given by cGMP?

Does Value Stream Mapping constitute a good foundation for process optimization within the pharmaceutical industry?

Design/methodology/approach – A single case study was chosen as the research methodology in this thesis. The study was initiated with the setting of the scope and choosing three product families, followed by the construction of three value stream maps. An analysis where waste and other deficiencies were identified was conducted. Lastly, ten improvement proposals were recommended.

Findings – This study showed that several deficiencies were affecting the company's manufacturing process. The waste was also found to be characteristic to the environment given by cGMP. Further, the deficiencies were found to be actionable and in theory approved through lean thinking. Lastly, the study showed that Value Stream Mapping can be used as foundation for process optimization within the pharmaceutical industry.

Keywords - Lean manufacturing, Value stream mapping, Lean production, Pharmaceutical industry, cGMP, Good Manufacturing Practice

Sammanfattning

Bakgrund - Företaget är en svensk tillverkare, utvecklare och kontraktstillverkare av läkemedel. Under de senaste åren har företaget gått in i en tillväxtfas som har lett till problem med de interna processerna. Materialflödet, lagerverksamheten och produktionsrelaterade processer anses ha god förbättringspotential. Följden har inneburit svårigheter med att leverera produkter i tid. Företaget har uttryckt ett behov av extern hjälp för processutveckling. En ytterligare frågeställning är hur företaget ska hantera den skalbarhet och kapacitetsutveckling som kommer att krävas. Företaget har därför uttryckt intresse för en utvärdering av deras nuvarande tillverkningsprocess med hjälp av Value Stream Mapping. Tillverkningsprocessen är avgränsad från inkommen kundorder till leverans. Företaget vill erhålla rekommendationer gällande hur värdeflöden och processer kan förbättras ur ett lean-perspektiv.

Syfte - Avhandlingen syftar till att föreslå förbättringar till en tillverkningsprocess inom läkemedelsindustrin. Syftet är också att utvärdera tillämpligheten av Value Stream Mapping som underlag för processoptimering i en cGMP-styrd miljö.

Frågeställningar - Vilka brister påverkar processen och på vilket sätt påverkar det företag?

Hur kan bristerna förbättras med hjälp av lean-verktyg, med hänsyn tagen till de kontextuella begränsningar som ges av cGMP?

Kan Value Stream Mapping utgöra en grund för processoptimering inom läkemedelsindustrin?

Design/metod/tillvägagångssätt - En fallstudie valdes som forskningsmetod i denna avhandling. Studien inleddes med en bestämning av studiens omfattning och val av produktfamiljer, följt av skapandet av tre value stream maps. En analys genomfördes där slöseri och andra brister identifierades. Slutligen rekommenderas företaget tio stycken förbättringsförslag.

Fynd - Studien visade flera brister som påverkar företagets tillverkningsprocess. Det identifierade slöseriet konstaterades vara kännetecknande för miljön som ges av cGMP. Bristerna visade sig i teorin kunna motverkas och förbättras genom ett lean-perspektiv. Slutligen visade studien att Value Stream Mapping kan användas som underlag för processoptimering inom läkemedelsindustrin.

Nyckelord - Lean Manufacturing, Value Stream Mapping, Lean Production, Pharmaceutical Industry, cGMP, Good Manufacturing Practice

Preface

This master thesis has been written during spring 2017. It was the final stage of the Mechanical Engineering programme with focus on logistics and production economy.

We would like to send our greatest gratitude towards the company for giving us the opportunity to write our master thesis. Further, we would like to thank our supervisor Eva Berg who has supported us with her guidance throughout this semester. We would also like to thank our friends and families for their moral support.

Lund, 22th May 2017

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1 Introduction

1.1 Note to the reader

The company where this thesis was conducted wished to remain anonymous and will here from be referred to as "the company". Further, the company did not want to publish any details regarding what information system that they use. Consequently, it will be referred to as "the information system".

1.2 Theoretical background

The manufacturing process of pharmaceutical is complicated due to laws, rules and established constitutions. There is a constant need for high-end quality medical products that shall satisfy users' pharmaceutical needs and at the same time be delivered with a reasonable price, resulting in improved public health. These inevitable demands push companies in the pharmaceutical industry to develop and improve the manufacturing process in order to cost effectively produce pharmaceuticals of the highest quality (Burke, 2015). PwC (2015) argues that many challenges for providing a reliable, efficient and cost effective supply chain in the pharmaceutical industry have to be overcome. Among several factors, one of the challenges to unlock value of the supply chain is to streamline the internal operations. Further, small and mid-sized pharmaceutical companies struggle with keeping up and using supply chain management principles. This affects the overall performance in a negative way.

In order to manufacture pharmaceuticals in Sweden, companies must comply to a set of principles known as current Good Manufacturing Practice (cGMP). The European Union (EU) has adopted Directive 2003/94/EC into a harmonized standard applying to all its member countries, thus also applying to Sweden as stated in LVFS 2004:7 which also describes the requirements put on a pharmaceutical manufacturer (Läkemedelsverket, 2015b). The cGMP principles aim to ensure that high quality is achieved and are also in place to hinder the distribution of products with inferior quality. It covers all aspects of the production and involves documentation, testing and validation in connection to various internal processes. Although EU has adopted a harmonized standard, many countries have their own take on cGMP and subsequently the requirements differ from country to country making the definition of cGMP fluid (WHO, 2017).

Lean production, as a concept for systematic waste minimization in manufacturing companies, originated in Japan after the World War II when the Japanese realized that

certain methods and changes had to be taken in order to keep up with the United States without heavy investments (Gershenson et al., 2003). It is derived from Toyota Production System and was popularized in 1990 by Womack, Jones and Roos (Chroneér & Wallström, 2016).

The globalization, growing economies and increasing competitiveness are facts. Customers are demanding highly innovative products to a lower cost (Jasti & Kodali, 2015). Manufacturing companies all over the world face the same issues. This has consequently lead to a race towards reaching efficiency and effectiveness in connection to the production. One way of achieving this state of efficiency is through adopting lean production. The idea behind lean is basically to minimize non value adding activities, i.e. improving the effectiveness and efficiency in connection to the production. This can for example mean removing wasteful activities or amplifying the perceived customer value (Jasti & Kodali 2015; Hines et al., 2004).

Companies in the pharmaceutical industry have experienced difficulties in accomplishing process improvements in the manufacturing function in terms of efficiency and productivity, in comparison to other industries. The underlying reason to the reluctance to change is the high costs associated to strict rules, regulations and principles according to laws. It has been estimated that the total cost savings in the worldwide pharmaceutical industry could reach 90 billion dollars with efficiency improvements (Pavlović & Božanić, 2012). Green & O'Rourke (2006) argues that tools connected to the lean philosophy can be used successfully in order to approve a company that is restricted by cGMP practices, even if it does not appear so at first sight. Further, the authors claim that utilizing lean tools to create an integrated lean-GMP environment should reduce costs and improve lead times. Chowdary & George (2012) has conducted a case study that shows the applicability of using Value Stream Mapping (VSM) to improve the operations in a pharmaceutical company.

VSM was developed by Western companies as a tool for transforming the production according to the lean philosophy (Schmidtke et al., 2014). It is used to document, analyse and improve material flow as well as information flows through elimination of non-value adding activities (Patrocinio, 2015).

According to Bartholdi & Hackman (2010), five major operations within a warehouse can be distinguished; receiving, put-away, picking, packing and shipping. Picking, which is considered to be the most time-consuming operation in a warehouse can be done in many different ways. Pick-by-order is the most common routine. It refers to picking one order at

the time. Batch-picking is another commonly used routine. It aims to let warehouse employees pick several orders in one single round. The orders are later assembled.

1.3 Company situation

The company is a Swedish manufacturer, developer and contract manufacturer of pharmaceuticals situated in the southern part of Sweden. The company offers its customers the entire process from phase 2 development through validation, manufacturing, packaging and labelling. Moreover, the company produces on order, i.e. make-to-order. The last couple of years, the company has entered a growth phase, resulting in an increased production and order volume.

There are three primary strategy orientations connected to the company's business model. Firstly, the company act as a contract manufacturer for their parent company. The focus for the first strategy orientation is manufacturing of aseptic injection preparation. Secondly as a manufacturer of aseptic injectables for other partners. The final orientation of strategy is development and producer of products in the company's own name. The company's business production strategy is based on flexibility so that the customers can place orders with short notice.

The internal processes are complex and often depend highly on both manual labour and frequent controls as a result of the nature of the pharmaceutical industry. This is due to strict requirements on various attributes such as quality, labelling and documentation. The requirements and regulations that define and delimit the context of the pharmaceutical industry will be covered thoroughly further on. A telling example of how the company is affected by the nature of these limitations is the packaging process. It is mostly executed by persons rather than machines. To further complicate the packaging process, the company has to make small adjustments to e.g. the documentation found in the packages. The packages contain the same compound but the list of contents vary between countries and is due to local regulation differences. On the basis of the high cost associated with manual labour, the company has to make their processes more efficient and effective in order to dispatch the orders on time without increasing the labour force and thus increasing the costs. This has become an issue, as the company has had a hard time managing the order deadlines.

The company believes that there is great potential in improving certain business processes regarding their internal material flows, warehouse operations and processes related to the production. The presumed potential is partly based on the fact that there have been no

external efforts before to manage these processes, as well as visibly easy rewards that need external assistance to achieve improvements.

The material flow between the large warehouse (warehouse B) and the smaller warehouse (warehouse A) with direct connection to the production facility have already been pinpointed as an issue with improvement possibilities. The smaller warehouse is suffering a too high utilisation rate and the flow between the warehouses are lacking e.g. re-order points, which means an ad hoc replenishment procedure of some articles. Further specific areas of improvements are up for discovery within the limitations.

As the company finds itself having insufficient documentation of how the processes are being executed, as well lacking how the processes actually perform, the study will initially focus on identifying in what sub processes and where in that specific sub process improvements are likely to be viable. These identifications are later to be analysed in terms of its effect on the entire process. As a consequence of an apparent vague overview, no specific deficiencies have been declared as matters for improvement, but the result is intended to deal with time waste and money saving.

There is no general consensus within the company of exactly how the process from order to dispatch actually is carried out. Subsequently, this leads to communication issues and makes prioritization difficult. The prioritization issue is especially pressing as the company already experiences a bottleneck in terms of capacity. Since the flows never have been thoroughly mapped, the company suspects that other hidden bottlenecks and unwanted low hanging fruit might be present that further affects the effectivity. In order to investigate the current state of the operations - and ultimately improve the same - the company wants to map the processes utilizing the lean tool VSM.

1.4 Purpose

This thesis aims to propose improvements to a manufacturing process within the pharmaceutical industry. The purpose is also to evaluate the applicability of Value Stream Mapping as a basis for process optimization in an cGMP governed environment.

1.5 Research question

Due to the versatility of the task, i.e. the problem requires a multidisciplinary (although within the disciplines represented by the faculty) approach, the problem was broken down into three research questions. This approach also allows focusing on the different stages of the study; mapping the processes, identifying problems and improving the situation. The following issues are to be answered during the study:

RQ1 *What deficiencies are affecting the processes and in what way do they affect the business?*

RQ2 *How can the deficiencies be improved through lean thinking with consideration taken to the contextual limitations given by cGMP?*

RQ3 *Does VSM constitute a good foundation for process optimization within the pharmaceutical industry?*

1.6 Delimitations

The company has requested that the flows are to be mapped by using a VSM. This consequently limits the choice of method for the analysis.

There are three focal points of the study, namely the order process, packaging process and internal material flow. These flows and processes shall be mapped using VSM and the mapping is delimited to assembling and packing, which means from an order is received to delivery. The production of the substances, i.e. the process of mixing the raw materials of the pharmaceuticals will not be considered as it was not requested by the company. Internal communication and quality controls can be seen as separate processes within the company. Since many touch points with the focal processes are current, internal communication and quality controls will be considered, however as elements of the focal processes. This is mainly due to the time limitations given the time frame of the master thesis. The study is delimited to the generalized process depicted in *Figure 1*:

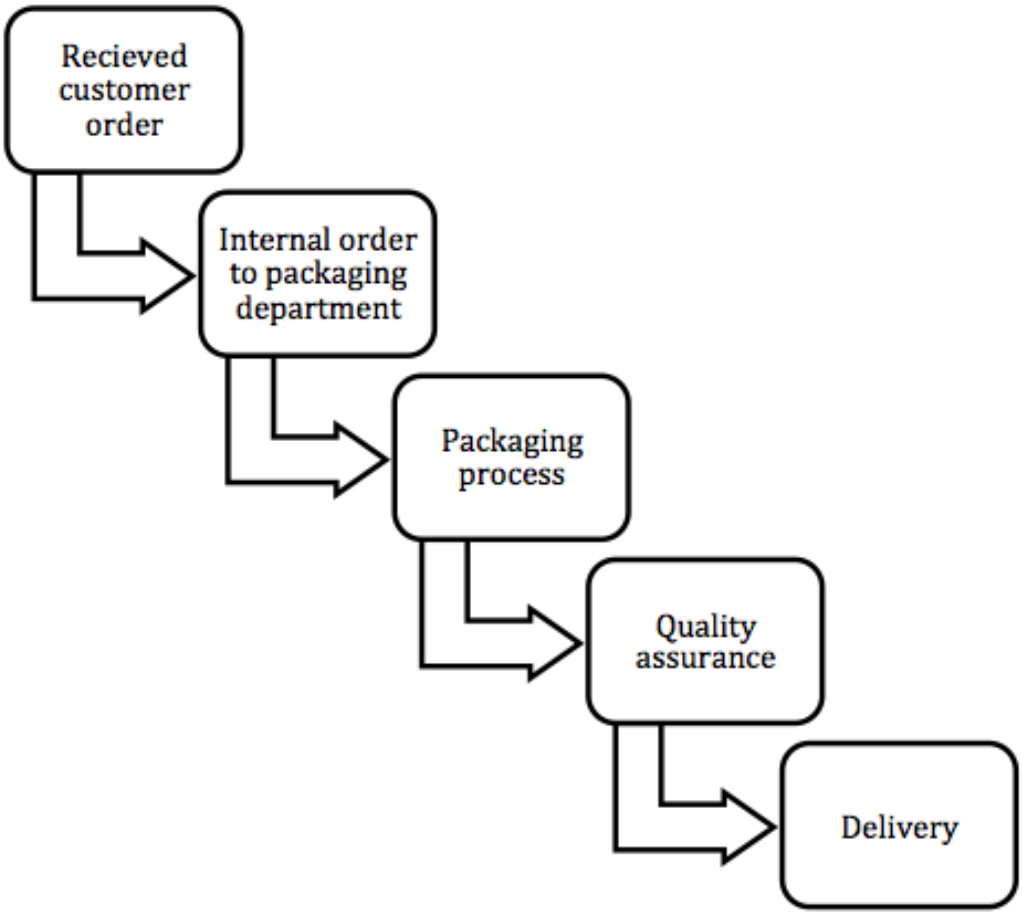


Figure 1: Generalized Process

Consideration has to be taken to the economic situation and the number of employees when proposing changes. Solutions that require large investments and are time-consuming would not be optimal with regard taken to the company's situation and the contextual limitations. Moreover, the pharmaceutical industry is complex. The nature of the operations is limited by various standards, regulations and quality demands, which in turn will limit what is feasible in terms of proposing solutions.

Lastly in the VSM process, an implementation plan should be presented. The plan shall divide the amendments into carefully selected work packages that are portioned out on a realistic timeline. However, an implementation plan is not comprised in the assignment declared by the company. Further, the time limitations connected to the thesis also makes the construction of an implementation plan unlikely. In case of excess of time, an implementation plan could potentially be created.

1.7 Target audience

The audience this study concentrates upon is the company and similar actors in the pharmaceutical industry. The study also aims to target an academic audience to some extent, i.e. other students and researchers active in the same field.

1.8 Report outline

The outline of the report is presented in *Figure 2* below. Following the introduction, the theoretical framework of this thesis is presented. Useful tools, methods and techniques to attain the purpose in a satisfying way are demonstrated. The research methodology used in this thesis is later explained, declaring what philosophy, approach, strategy, time horizon and data collection methods are applied. The current state is thereafter introduced, followed by an analysis of ditto. The analysis is used as a basis for the proposed recommendations. A conclusion finishes the report, answering the three research questions.

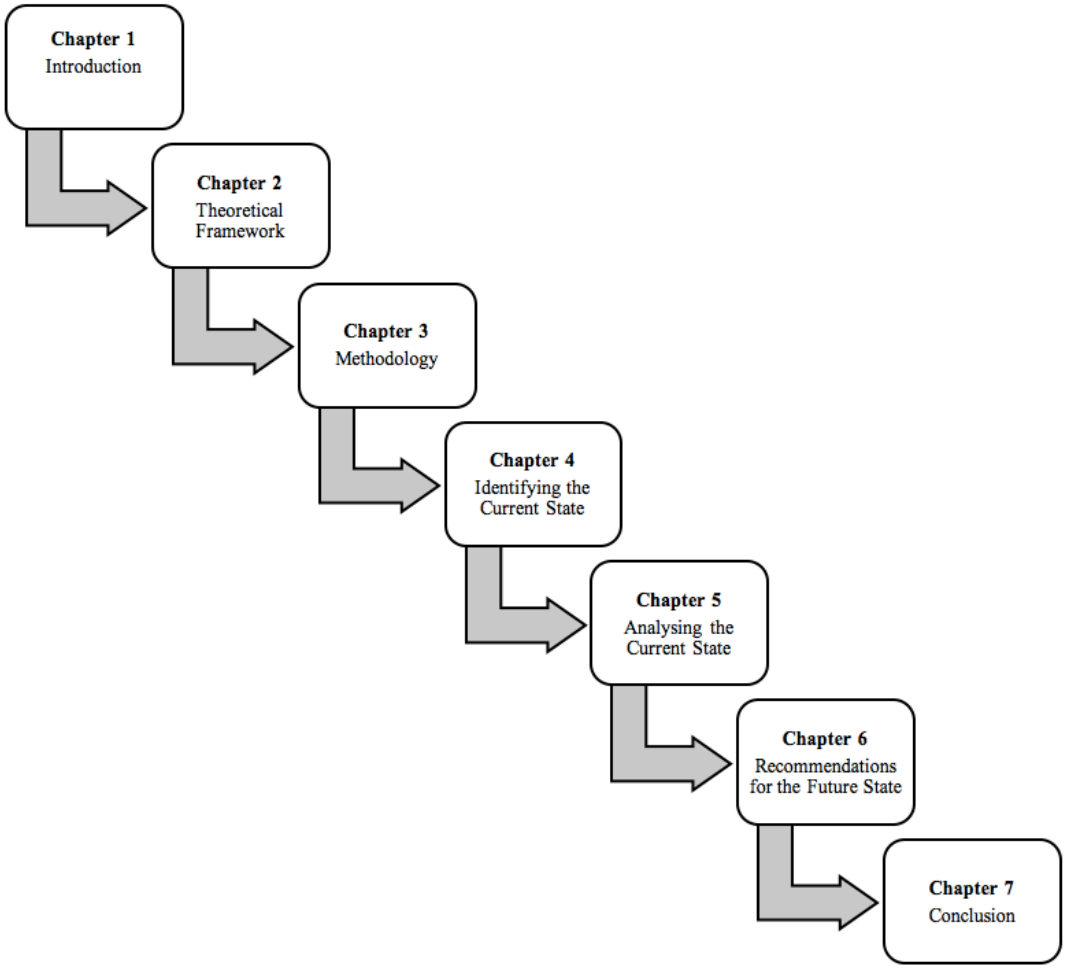


Figure 2: Report outline

2 Theoretical framework

The theoretical framework will act as the knowledge foundation for the data gathering and consequently the analysis. Relevant theories, previous research and other material that is considered pertinent will thus be covered in this section. The purpose is to give the reader a good understanding of the subject and provide her with information that is crucial for comprehending the contextual aspects.

2.1 Conceptual Framework

In order to outline how the theoretical insights will be applied to the case study, a conceptual framework was created. The framework will grant the reader a comprehensive understanding of relevant theories and models needed to follow the logical reasoning towards an analysis based on the research questions. The conceptual framework is depicted in *Figure 3*. The process steps marked with grey, i.e. information flow and quality assurance, packaging operations and warehouse operations are the main activities performed by the company. The surrounding describes the contextual aspects as well as the theory used to analyse and improve the current state.

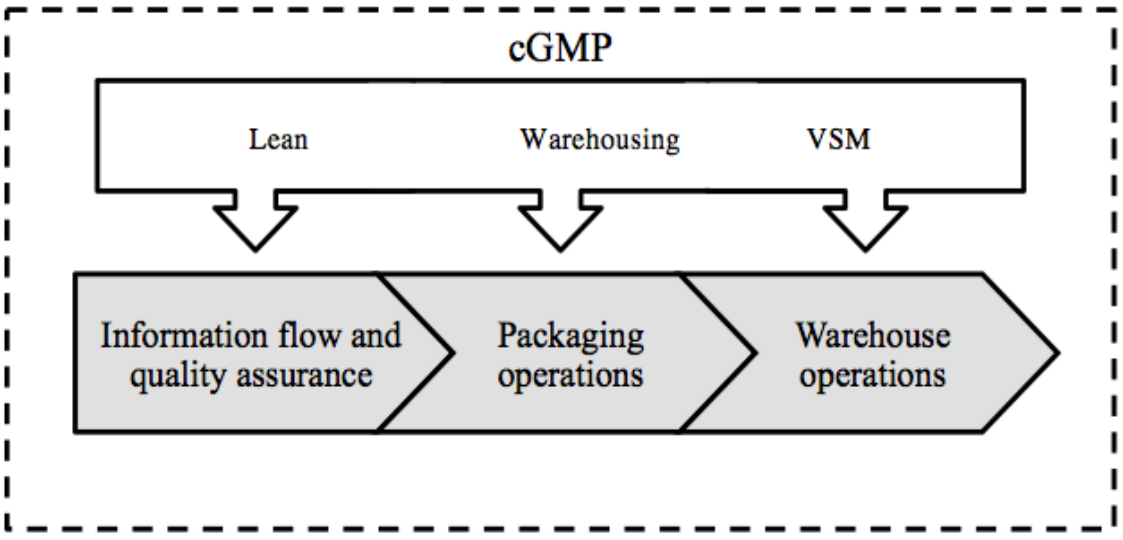


Figure 3: Conceptual framework

Understanding the context which the company operates within is crucial. The legal limitations that the pharmaceutical industry conforms to are thus essential to be aware of when conducting the case study. Without a review of cGMP, the feasibility of improvement proposals that ultimately will be recommended cannot be guaranteed. Since VSM was given as the tool of analysis, a review of VSM and various lean tools will also be needed.

VSM is a lean tool and therefore issues and areas of improvement will be seen from a lean perspective. In order to understand the issues and how to tackle them, an understanding of the lean philosophy is required. Further, the company has expressed concern regarding the warehouse operations. Therefore, it is of importance to understand the theory and concepts behind warehouse operations.

2.2 Good Manufacturing Practice

The foundation for Swedish pharmaceutical legislation can be found in Läkemedelslagen (2015:315). The Swedish Government has issued Läkemedelsförordningen (2015:458) which is a constitution that gives the Swedish Medical Products Agency the right to govern the area (Läkemedelsverket, 2015a).

The right to manufacture pharmaceutical products in Sweden is consequently granted by the Swedish Medical Products Agency. The regulations regarding the rights can be found in LVFS 2004:7 which also describes the requirements applicable to the manufacturer (Läkemedelsverket, 2015b).

Under 4 § in LVFS 2004:7 which deals with the issuance of permits, it is stated that in order to gain the right to manufacture or import pharmaceutical products, one must follow cGMP. The cGMP principles aim to ensure that high quality is achieved and are also in place to hinder the distribution of products with inferior quality. It covers all aspects of the production and involves documentation, testing and validation in connection to various internal processes. Although EU has adopted a harmonized standard, many countries have their own take on cGMP and subsequently the requirements differ from country to country making the definition of GMP fluid (WHO, 2017). The harmonized standard that has been approved by the EU member states is described in Directive 2003/94/EC and applies to medicinal products for human use. The directive serves as a regulator of the lowest requirements. Guidelines for the interpretation of Directive 2003/94/EC is available in volume 4 of "The rules governing medicinal products in the European Union" issued by the European Commission (The European Commission's Directorate for public health and risk assessment, 2017).

The basic requirements found in 2003/94/EC covers a wide scope. Demands on quality management, personnel, process equipment, documentation et cetera can be found. Next, some of the basic requirements that are of interest when investigating the research questions posed in this thesis will be addressed.

2.2.1 Quality management

Quality management is one of the main pillars of the cGMP principles (Key2Compliance, 2014). Quality should permeate the whole organization and all persons involved should take responsibility of maintaining high quality. One of the requirements is concerning the existence of a quality assurance department as well as a quality control department. The quality assurance department is concerned with all documentation while the quality control department is to perform clinical test of material and substances. All conducted work should be recorded to maintain full traceability (Ibid.).

The quality departments should be responsible for ensuring that all material, substances and documentation are reviewed and approved (Key2Compliance, 2014). Further, the departments are responsible for the investigation of deviations and reviewing and approving validation protocols. The obligations also stretch to cover the production activities. Below follows some of the responsibilities connected to the production of pharmaceuticals (Ibid.):

- Reviewing all production batch records as well as ensuring the completion and signing of the same
- Approving validation records
- Assuring the cleanliness of the production facilities
- Investigating production deviations

2.2.2 Documentation

Documentation is a vital part of cGMP since it enables traceability (Key2Compliance, 2014). Some basic principles regarding the documentation are recommended in order to follow cGMP. All the documentation in connection to the production of pharmaceuticals should be prepared, reviewed, approved and distributed according to written procedures, e.g. Standard Operation Procedures (SOP). All records concerning production, control and distribution should be kept for at least 1 year after the batch expiry date. If any documentation has to be revised, revision history must exist (Ibid.).

The extent of the documentation is very general (Key2Compliance, 2014). All major steps of refining, testing and decision making has to be documented. For example, all batches that have been processed in a certain machine needs to be recorded. The time and date should be specified and signed by the persons operating the machine. Cleaning of machines and workstations also needs to be documented in a similar manner. This procedure is applicable in almost all major steps within a pharmaceutical company. Next follows a list of some of the necessary content in a batch production record (Ibid.):

- Dates and, when appropriate, times
- Identification of major equipment
- Specific identification of each batch such as all batch numbers of raw materials or intermediates
- Actual results recorded for critical process parameters;
- Any sampling performed
- Signatures of the persons performing and directly supervising or checking each critical step in the operation
- Results of release testing

There are additional requirements when the batch documentation should be examined before it is released, i.e. ready to be shipped out (Key2Compliance, 2014). The batch documentation should basically follow the product through the entire value stream and gain approval and scrutiny throughout the process steps (Ibid.).

2.2.3 Warehousing

In this section, the most commonly used warehouse operations will be described. Additionally, one mathematical method of minimizing the labour for a fast-pick area is presented. The need for this theoretical pillar can be found in the current premise with two warehouses and an increased need of efficient warehouse operations as a result of cGMP. As previously stated, small adjustments to e.g. the documentation has to be made due to local regulations and the fluid definition of cGMP across country boarders. This leads to a complex warehouse environment with a high number of components in stock. The complexity is aggravated due to the size of warehouse A and the relatively small batch sizes.

Bartholdi & Hackman (2010) refers to five operations within a warehouse; receiving, put-away, picking, packing and shipping:

The receiving operation can begin in advance if there is notification of arrival goods, so that the warehouse operators are able to schedule their activities. After the arrival, the goods are typically scanned for the sake of availability in the information system and for payment agreements. Subsequently, the goods are available for the put-away operation. The receiving process require little labour if the goods are handled in the same units as when they arrived. Consequently, the labour cost could increase if the goods is to be unpacked in smaller units (Ibid.).

Followed by the receiving operation comes the put-away operation (Bartholdi & Hackman, 2010). It is of importance to put-away the goods at the right location, because of the costs

associated both put-away and picking. Before selection of location, one must know the stock levels on the pallet positions, how much weight it can bear and the volume of the location. After the goods have been put-away, they are often scanned for recording where they have been put and for future picklists (Ibid.).

Picking is the operation when an operator is locating and extracting the goods, probably as a result of a customer order or as a make-to-stock production approach. There are several routines for this operation, which is the most labour intensive warehouse operation. An order can be picked by one or more pickers, depending on the situation. Bolten (1997) presents a short description of four commonly used picking routines:

Pick-by-order is the most common routine. It refers to picking one order at the time. Batch-picking is another routine where several orders are picked in one round and assembled with the rest of the items in another location. Wave-picking is the third routine, referring to picking orders in accordance to routing or shipping criteria. Lastly reverse-order picking, meaning that a part of an order is held for combination with another order.

The final warehouse operation, in terms of material flow, is the shipping operation (Bartholdi & Hackman, 2010). It normally includes larger units, which puts shipping as one of the less labour intensive operations. As with the other warehouse operations, the goods are often scanned when shipped, for inventory update and for customer notification (Ibid.).

2.2.4 Fast-pick area

A fast-pick area is basically a warehouse within a warehouse to minimize travel distance and consequently costs associated with the picking operation, see *Figure 4* for a simple demonstration of a fast-pick area (Bartholdi & Hackman, 2010). The idea is to have a pick-area and a reserve area in the same warehouse, where goods from the reserve area are being replenished in the pick-area, to reduce travel distance. The number of replenishment within the warehouse will be higher, but the concept of the decreased distances is intended to return cost savings regardless of the increased replenishments (Ibid.).

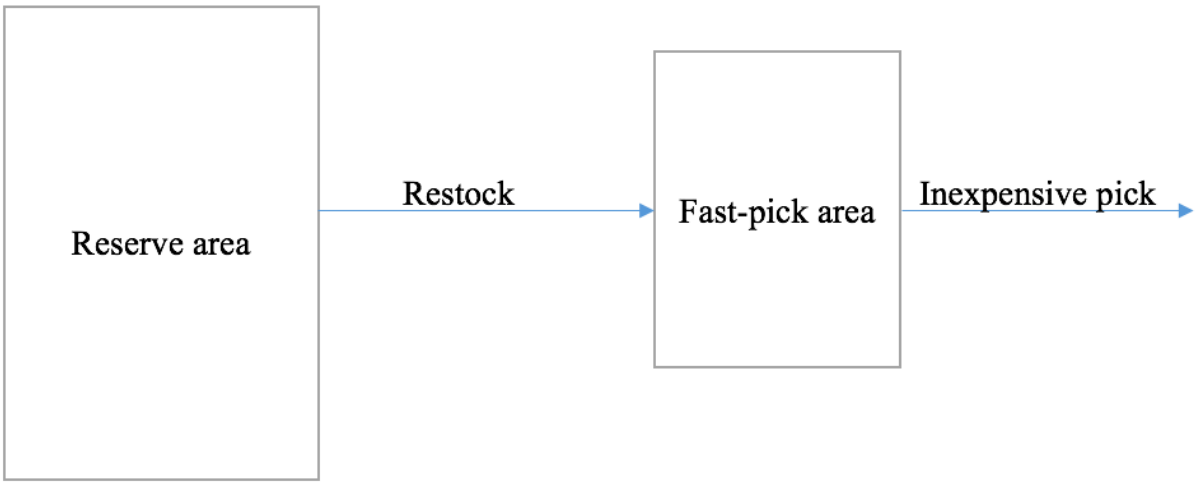


Figure 4: Simple demonstration of a fast-pick area (Bartholdi & Hackman, 2010 p. 93)

2.3 Lean

As described in the section *Theoretical Background*, lean production is derived from the Toyota Production System (TPS) (Chroneér & Wallström, 2016; Čiarnienė & Vienažindienė, 2012). The objective is to use the company's resources in the most effective and efficient way (Hines et al., 2004). The two persons who popularized lean production discuss five essential lean principles; value, value stream, balance, takt and perfection (Womack & Jones 1996, cited in Olhager 2013 p.460):

1. Value - The value is defined by the final customer.
2. Value stream - The value stream is defined by the number of specific activities required for a product to go through the internal value stream.
3. Balance - Balance between value adding production steps is required to create a smooth flow.
4. Takt - A takt based plan shall be used.
5. Perfection - Perfection suppose that the principles above are to be made a permanent habit.

Before continuing, the term value stream needs further notice and clarification due to the central role of that VSM holds in this thesis. Another definition of value stream is *"a chain of activities that a firm operating in a specific industry performs in order to deliver a valuable product or service for the market*" (Porter 1985, p.11).

Becoming lean is synonymous with being long term. This is mainly because the transformation towards becoming lean takes long time, it is an iterative process. The focus on continuous improvement is central in the lean philosophy (Sörqvist, 2013). The so called

lean house, depicted in *Figure 5*, gives an overview of the central concepts and focal areas of the lean concept.

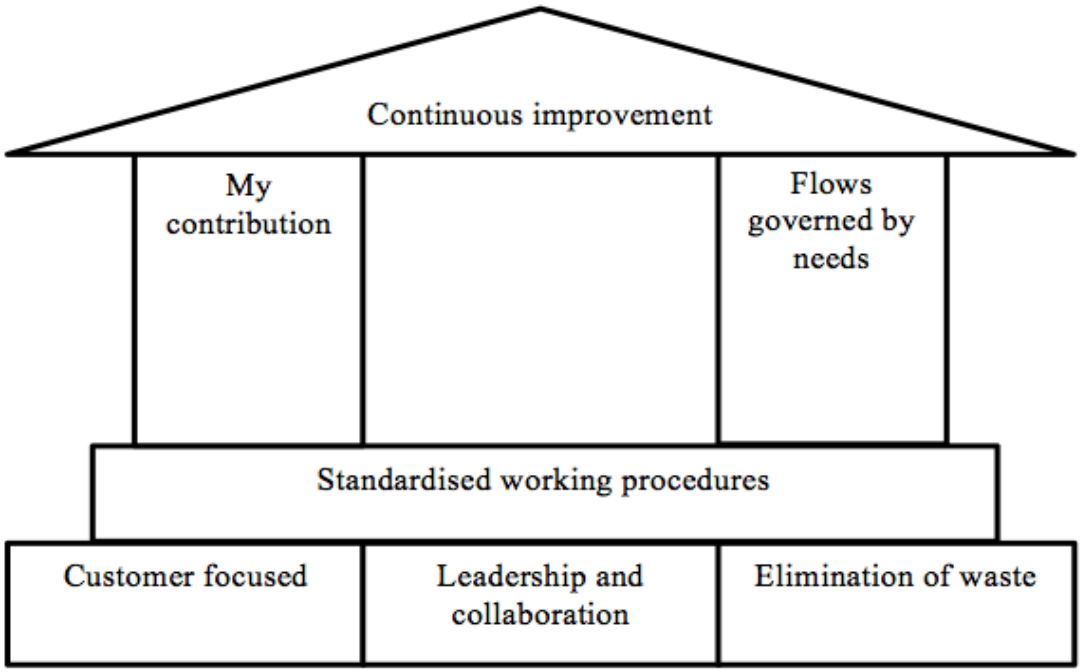


Figure 5: A version of the lean house (Sörqvist, 2013, p.77)

There is no exact blueprint of how an organization can incorporate the lean philosophy. Situational factors make different approaches applicable. There are however some fundamental approaches to becoming lean, like the PDCA-cycle. PDCA is an abbreviation of plan, do, check and act and functions as a general approach to continuous improvement within an organization. The process should be considered a perpetuum mobile that outlines how continuous improvement can be reached (Sörqvist, 2013). The four stages of the PDCA-cycle are described below:

1. Plan: A plan of action is developed in which the change is thoroughly planned. Consideration is also taken to possible hurdles and how risks can be mitigated.
2. Do: The changes proposed in the plan are implemented.
3. Check: The implementation is evaluated through benchmarking or other techniques.
4. Act: Any improvement suggestions that occur during the check-phase is acted upon. It could for example be rectifications of machine settings et cetera.

In order to follow a PDCA-cycle, there are several tools associated with the lean philosophy. These tools are developed to facilitate and realize the implementation of lean concepts like waste reduction or standardized working procedures (King, 2009). Some

useful tools will be covered further down in this chapter. The reader is advised to remember that VSM also is a lean tool, but due to the nature of this thesis, it will be dedicated a separate chapter.

2.3.1 Lean and the pharmaceutical industry

Lean and cGMP have different objectives, focuses et cetera. An overview of the different aspects of lean and cGMP are visualized in *Table 1*. Chowdary & George (2012) concludes that cGMP does not focus so much on cost, but rather efficiency and quality.

One touchpoint between lean and cGMP can be found in the standardization of work. The SOPs that are used to comply with cGMP are seldom changed other if quality or safety issues occur. One reason for the low frequency of change could be the need for validation. This is not aligned with the continuous improvement philosophy found in lean. The operational procedures in companies that comply with cGMP are however often not so structured and lack details and a process to follow. Here, lean improvements can be applied to ensure a more structural approach to operation procedures (Green & O'Rourke, 2006).

Another area where lean and cGMP can be aligned is internal communication. Pharmaceutical companies often have cross-functional communication issues and little information sharing between departments. This can lead to ignorance regarding what complications a delay can result in. Product cycle time is very often quality driven, while in a lean manufacturing plan, it is equally driven by time and quality. The latter approach might actually facilitate the identification of quality issues since for example a time driven setup of a machine can initiate a call for help. The pharmaceutical industry could benefit from implementing lean strategies for assigning responsibilities and sharing information (Green & O'Rourke, 2006).

Green & O'Rourke (2006) argues that there are more touch points between cGMP and lean where the latter can provide valuable learnings for the pharmaceutical companies. Some examples are how flows should be considered and reduction of variation. Further, a case study conducted by Chowdary & George (2012) showed that waste such as high inventory can be reduced through the usage of VSM. The production flow could also be improved through implementation of lean tools. The final result when the changes had been implemented are showing that lean can be successfully implemented in the pharmaceutical industry. Among the improvements were; storage area reduced by 38 per cent and a halving of the production staff.

Table 1: Comparison of cGMP and lean manufacturing principles (Chowdary & George, 2012, p.61)

Area	**cGMP**	**Lean manufacturing**
Objectives	Product effectiveness	Reduce/eliminate waste
	Adequate confidence	Create value
	QA	Improve flow
Focus	Storage, process traceability, starting material approval and precise documentation	Product value stream, Material flow, Information flow
Approach to manufacturing	Quality is built into product throughout production	Quality along with productivity
Typical goals	Independence QC from production Follow validated processes	Reduce cost
		Improve quality
	Stage inspection GLPs	Decrease CT
		Reduce inventory
		On-time delivery
Typical tools	Approved procedures	Value stream mapping
	Complaint reviews	5S
	Quality audits	Kaizen
		Kanban
		CM
		QFD

2.3.2 Kaizen

One of the foundations of lean is to continuously work for improvement (Sörqvist, 2013). A widely applied philosophy within lean is named kaizen. Kaizen is a Japanese word meaning "continuous improvement". A continuous improvement approach within a business can express itself in an infinite set of procedures, so can also kaizen. In order to be successful with continuous improvement, three components serve as the foundation for achieving it, see *Figure 6*; Result oriented leadership is the basis for continuous improvement. To organize the work with continuous improvement, an infrastructure with

defined roles with defined responsibilities, authorizations and competences is needed. Lastly, a problem solving methodology with relevant tools is crucial (Ibid.).

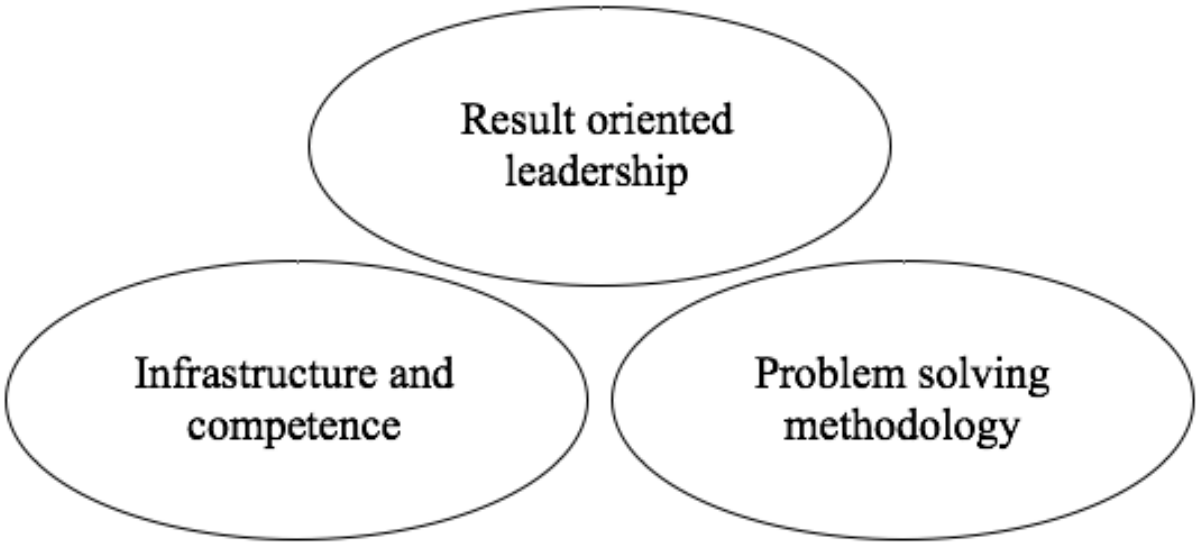


Figure 6: Three main components for continuous improvement (Sörqvist & Höglund 2007, depicted in Sörqvist 2013, p.216)

Kaizen is referring to all employees in the organization contributing to continuous improvement, in all levels within the organization. When practicing kaizen, defined targets and goals for improvements shall be established. Every improvement has to undergo a thorough assessment before implementation (Olhager, 2013). The kaizen philosophy aims to, with assistance from employees who are performing the activities, remove waste and to design and implement more effective processes. One activity in the kaizen philosophy is the kaizen events. Kaizen events are team activities, where the employees shall maintain a high focus in order to make improvements (King, 2009). Kaizen events can be described as "a focused and structured improvement project, using a dedicated cross-functional team to improve a targeted work area, with specific goals, in an accelerated timeframe" (Farris et al., 2008 p. 1, cited in Wiljeana et al., 2013 p. 1167) and they should be identified from strategic objectives. VSM is a lean tool that is often employed in kaizen events (Melnyk et al., 2008 cited in Wiljeana et al., 2013 p. 1167). Several other lean tools could be employed during kaizen events. Kram et al., (2015) performed a case study demonstrating how lean tools could be during kaizen events with cross functional members. Ishikawa diagram, 5 whys and brainstorming were the tools used. The following is a short summary of the event:

- Explanation of the tools
- Introduction to the problem and the objective of the event
- As-is analysis
    - All members of the meeting made their own Ishikawa diagram
    - 5 whys to find the root cause of the problem
- Solution proposals were discussed
    - Brainstorming
- Selection of a solution proposal
- To-be analysis with the selected solution proposal

Wiljeana et al (2013) conducted an empirical study, partly investigating the outcomes of kaizen events in 16 manufacturing, service and government organizations. Ten out of the 16 organizations considered their kaizen events as overall successful, including measured benefits such as decreased inventory, decreased lead time, decreased costs and increased quality.

2.3.3 Kanban

One of lean's fundamental ideas is the usage of a pull production system. A pull production system could be a make-to-order system, at least in the sense that the production initiates after a demand from one or several customers (Sörqvist 2013). The processes within the production does not necessarily have to be pull oriented within a make-to-order system. In a pull production system, activities only initiate after a request (Sörqvist 2013; Rahman et al., 2013). Consumption in one process step decides the production in the preceding. It requires fast setup times and a well working flow orientation. The opposite to pull production is push production. The difference is depicted in *Figure 7*. In a push production system, activities initiate after plans and orders. It requires buffers of raw materials and finished goods (Sörqvist 2013).

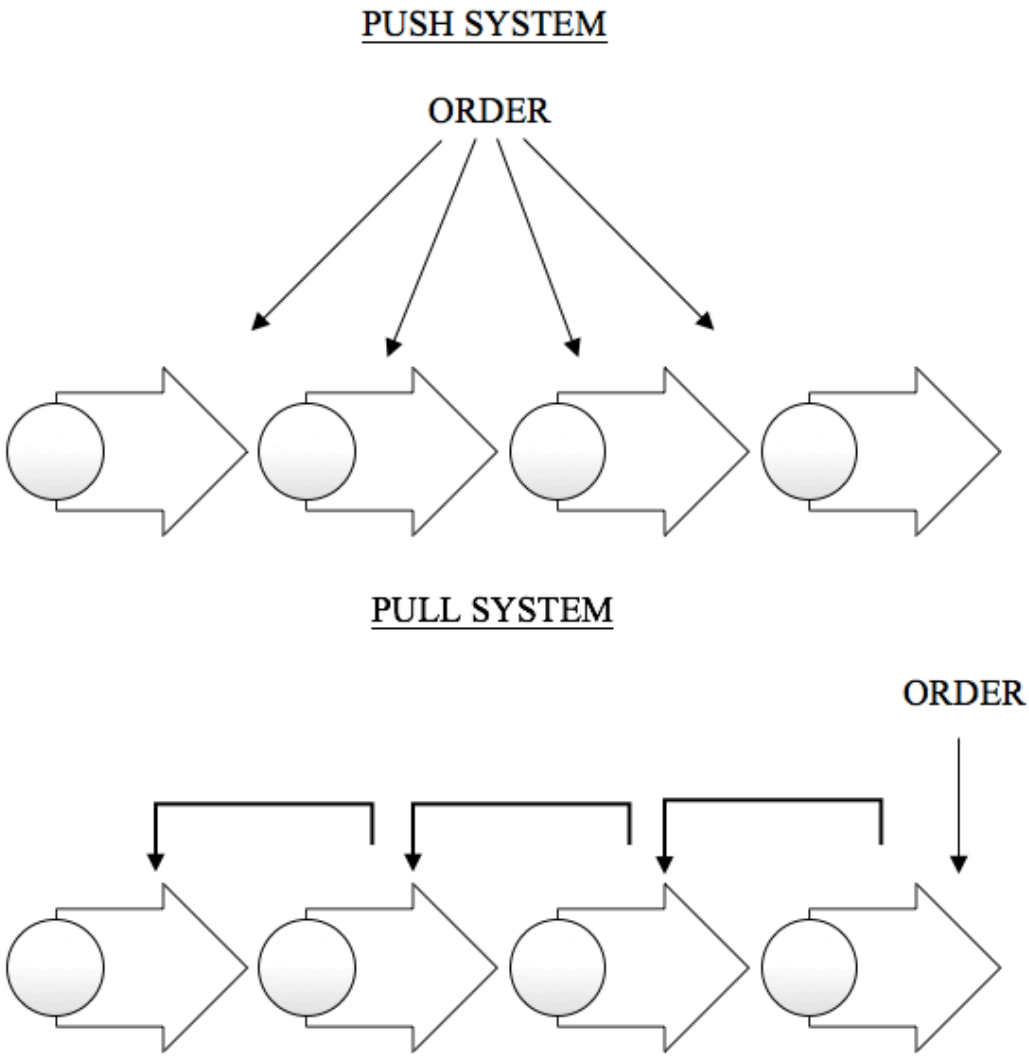


Figure 7: Push and pull system (Sörqvist, 2013 p.168)

Kanban is a Japanese term for "visible sign" and is used to visualize what material that has to be replenished connected to what must be produced (King, 2009). Kanban is therefore a system that can be used to control a pull production system. A kanban system uses an information carrier that is sent backwards to the preceding step when there is a need. A rule of thumb when using kanban is the maximum variation in volume, which shall not exceed +-10%. Sörqvist (2013) presents two formations of kanban:

- Card sent backwards in the flow - when there is a need for delivery to the next step
- Resulting in minimized stock levels (Olhager, 2013)
- Transport box sent backwards in the flow - for replenishment when it is empty or a shelf storage that need replenishment etc.

For a successful implementation of a kanban system, six core practices have been identified (Anderson 2010, cited in Leopold & Kaltenacker 2015 p.18-23):

1. Make work visible
   - Kanban helps visualising the processes.
2. Limit work in progress (WIP)
   - Bottlenecks are made visible in a pull production system.
3. Managing the flow
   - Identify the workflow and be clear about prioritizations.
4. Making policies explicit
   - Kanban can be seen as a working style with a collection of policies that the team must follow.
5. Implementing feedback mechanisms
   - E.g. meetings with the entire value stream about the current situation.
6. Carrying out collaborative improvements
   - Kanban does not contain methods for improvements, but how methods shall be applied.

2.3.4 5S

5S is a five step process that can be used to achieve a standardized workplace organisation. The goal of 5S is to create a visible work area so that the workers can be more effective as well as facilitating identification of problems. The five steps in the process are presented below (King, 2009; Omogbai & Salonitis, 2017):

1. Sort (seiri): The working space should be sorted. All unnecessary items should be removed from the working space on behalf of the necessary tools and materials.
2. Straighten/set (seiton): The items left on the working space should now be arranged in way that supports the flow. Every tool is for example to be placed as close to the point of use as possible. Furthermore, there should be no ambiguities regarding what tool to use. Colouring the tools is one way of avoiding the mistake of picking the wrong tool.
3. Shine (seiso): A clean working place is the next step in the process. A clean working environment will be more attractive for the workers.
4. Standardize (seiketsu): Procedures or standards should be developed in order to keep the working place clean.

5. Sustain (shutsuke): Procedures should also be developed in order to keep the arrangements of tools et cetera constant. Audits or checklists are examples of such procedures.

2.3.5 Ishikawa

An Ishikawa diagram, often referred to as cause-and-effect or fishbone diagram, is used to find the underlying reason for an effect (King, 2009). The idea behind the Ishikawa diagram is to elicitate the problem into smaller elements, thus finding the underlying reason behind the problem (Kram et al., 2015; King, 2009; Luca, 2016). In order to do this in a structured manner, six causes areas are often investigated; machines, materials, methods, environment, manpower and measurements (King, 2009; Luca 2016). An example of an Ishikawa diagram is shown below in *Figure 8*.

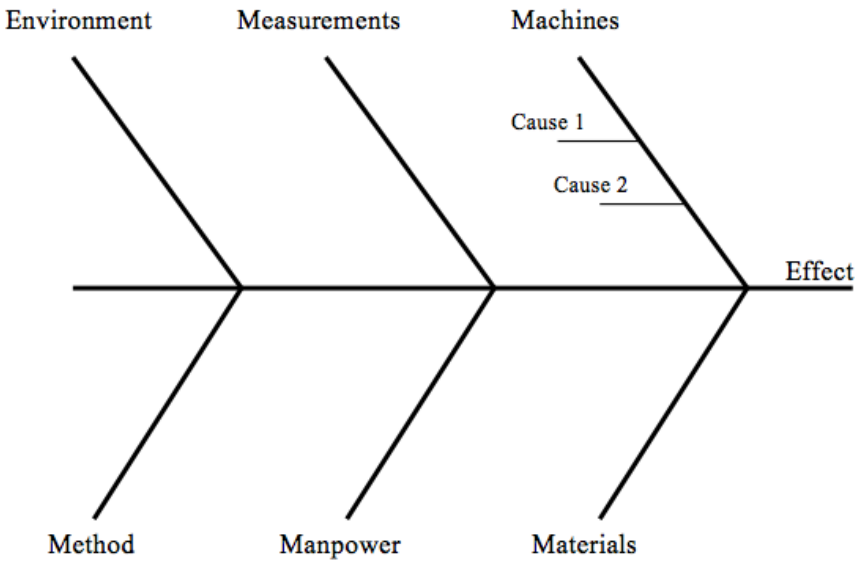


Figure 8: Ishikawa diagram

2.3.6 Pareto and ABC classification

The pareto principle, or the 80/20 principle, was stated by economist Vilfred Pareto who described that 20 percent of the population owns 80 percent of the wealth. It has ever since been used to describe other realities than just the original socioeconomic coherence Pareto found (Grosfelt-Nir et al., 2007). Generally, an attribute is showed on the y-axis and a phenomenon on the x-axis. An example of how an ideal pareto diagram looks like is showcased in *Figure 9*.

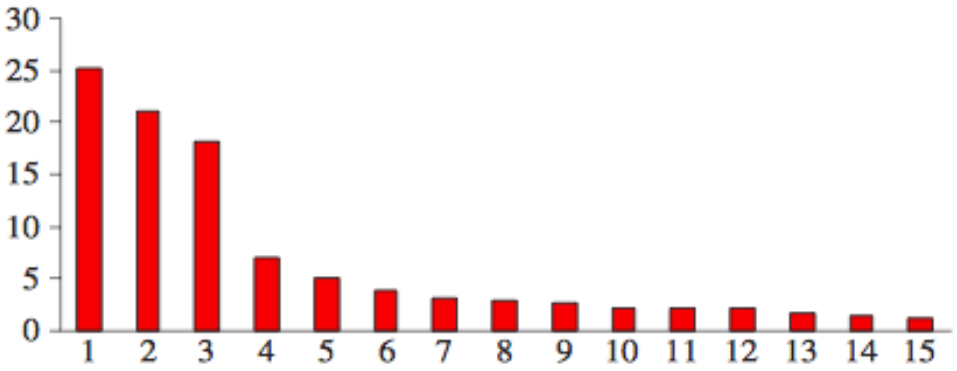


Figure 9: Ideal pareto diagram (Grosfelt-Nir et al., 2007 p.2318)

Drawing up pareto diagrams can be used as an analytical tool for grouping product families and understanding how to improve the quality within a value stream (Langstrand, 2016). Further, King (2009) describes how pareto diagrams can be used to facilitate inventory management, setting safety-stock levels and setting as well as understanding customer service goals.

A derivative of the pareto principle is the ABC classification. The products, or attributes are sorted into groups of A, B and C based on the phenomenon, e.g. revenue. (Grosfelt-Nir et al., 2007; King, 2009). A guideline of how these groups should be arranged are showcased in *Table 2*. This example is based on the attribute product and the phenomenon revenue.

Table 2: Guidelines for ABC classification (King, 2009, p.297)

Product classification	**Percent of products**	**Percent of revenue**
A	10-20%	50-70%
B	20%	20%
C	60-70%	10-30%

2.3.7 Poka-yoke

Poka-yoke is another mechanism with Japanese descent with a lean approach, introduced by industrial engineer Shigeo Shingo in the 1960s at Toyota, derived from Toyota's concept Zero Quality Control. Poka means "errors" and yokeru means "avoid". It had earlier been practiced in manufacturing companies, but not as a mistake-proofing tool (Swamidass, 2000; Michael, 1999). The very idea of the applicability of poka-yoke is the human's' potential of performing mistakes. For this to be prevented, top management in companies

can create mechanisms and tools that are designed in such way that mistakes are unlikely to appear and avoidance of machinery wear. Poka-yoke is one of those mechanisms. It has undergone great success in the 21st century by developing process flows with the highest quality and maintaining the pride of each worker. It has been argued from some academics that the cause of errors is due to operators' mistakes and the inability to address the root cause of why the error occurred. As a consequence, two objectives to achieve with poka-yoke are (Swamidass, 2000):

1. Prevent human error - e.g. to plug in an USB device is impossible if the connector is not turned in the right direction.
2. Highlighting the error for the operator in such a way that the operator immediately recognizes who committed the mistake.

The effects of successfully using poka-yoke is the elimination of spills and accidents, detection of loss before it becomes a problem and detection of a loss before the contingency indicator has warned the operator (Pojasek, 1999).

The poka-yoke mechanism is thus something that is used to prevent or/and correct errors with an apparently straightforward methodology. The practice of poka-yoke is intended to be simplistic in the sense that any operator or supervisor can apply it (Swamidass, 2000; Michael, 1999). Further, it shall be flexible so that every operator can make an adoption at the workstation. The final feature of poka-yoke is the visual highlighting of obvious error, so that the operator always is aware when a mistake has been done (Swamidass, 2000).

In larger industries, such as the process industry, safety systems and automatic process controls is used in order to minimize and highlight errors that occur. These systems have a poka-yoke approach, but they are most often expensive. There are however less expensive alternatives to achieve a poka-yoke approach with low-tech devices. The characteristics of such devices are the constant availability, i.e. it can be used all the time by all workers, simplicity, i.e. it can be used without constant attention and without burdensome from the operator and lastly the low cost of implementation. Additionally, poka-yoke is expected to work well in manual operations, where adjustment is required and where statistical process controls is difficult to apply (Pojasek, 1999).

2.3.8 5 whys

The tool known as 5 whys aims at getting to the root of a problem through asking why a repeated amount of times. When the reason behind a problem becomes apparent, so does the solution to the problem (King, 2009). An example of the 5 whys put into practice is displayed in *Table 3* below.

Table 3: The five whys put into practice (King 2009, p.101)

Why is the inventory at this location so high?
Because we run long campaigns.
Why are the campaigns so long?
Because changeovers are so expensive.
Why are changeovers so expensive?
Because it takes a long time to get properties within spec after a restart.
Why does it take so long to get back within spec?
Because the relationship between basis weight and pump pressure varies over time.
Why does it vary?
Because material builds up in the nozzle and constricts flow.
What causes the build up?
It is the nature of the viscous materials used in this product.

2.3.9 Standard work

Standard work is defining what task an operator shall perform. It intends to describe in what sequence the operations and activities shall be performed and the timing of those. Standard work is often referred to as SOP. The intention of using SOPs is to optimize the performance, clarify how the task shall be executed and leave out variability in the process (King, 2009). Additional benefits with operation guidelines and instructions are improved efficiency, assurance of quality systemic homogenization and minimized miscommunication (Nolen, 2015).

Nolen (2015) describes how a SOP shall be designed:

1. Identify and summarize a task.
2. Describe the task's purpose.
3. Specify when and by whom it is to be performed defining uncommon or specialized terms and addressing concerns.
4. Describe the sequential procedures, using e.g. activity checklists and graphic illustrations.

2.3.10 Just in Time

The Just In Time (JIT) philosophy is concerned with continuous improvement, quality assurance, efficiency and flow (Ríos-Mercado & Ríos-Solís, n.d). A more practical definition is that JIT, or pull as it also is known as, *"enables a company to make what is needed only when it is needed and in the exact quantity needed"* (King 2009, p.15). Some benefits that can be found through utilizing a JIT approach are; reduced inventory levels, no overproduction and a steady, smooth flow. Since the JIT philosophy is built upon timing, the key success factor of JIT are accurate forecasts (Ríos-Mercado & Ríos-Solís, n.d).

2.4 Value Stream Mapping

In order to cope with the increasing competitiveness on the markets, companies will have to redesign their processes in order to make them more effective. VSM is a lean tool that is used to evaluate and ultimately visualize a redesigned production system. As the name is suggesting, the production system or process is to be looked upon as a flow where value is added in each step of the production process. A VSM generally consist of three components (Martin & Osterling, 2014; King, 2009):

1. Material flow: A high level perspective of the flow of material through the entire production. All the process stops are shown, and generally inventory levels are also presented (King, 2009).
2. Information flow: All information flows throughout the entire process are shown in the information flow part of the VSM. It can for example start with customer orders, to be continued with signals to the production et cetera (King, 2009).
3. Time-line: The time-line takes the form of a square wave in the bottom of the VSM. It functions as an indicator of value adding and non-value adding time (King, 2009).

The construction of a VSM is often the first step in a transformation towards a lean way of work. The VSM will enable the identification of bottlenecks as well as create proposals upon how to re-design the process into a lean state. In other words, a VSM can be used to identify where waste occurs and where value is added (Ibon Serrano et al., 2008). Martin & Osterling (2014) points out additional benefits of creating a VSM. It can for example provide a holistic overview of the processes that in turn can be used as a basis for strategic decisions. The quantitative character of a VSM will also function as a foundation for data-driven operational decisions. A VSM can also help a company to understand what value they actually are delivering to its customers. Before initiating a mapping process, the organisation needs consensus regarding the strategic direction and clearly defined business goals (Martin & Osterling, 2014; King, 2009). The process of creating a VSM generally consists of five phases (Langstrand, 2016).

2.5 Waste

As VSM's are used to reduce waste in a value chain, it is important to understand what waste actually is and what different kinds of waste exist. Taiichi Ohno, one of the founding fathers of TPS spent a lot of effort trying to understand exactly what activities that create value and what activities that create waste, or *muda* as the term originally is called in Japanese. Ohno identified seven types of waste, which are shown in *Table 4*. Further, Ohno argued that overproduction was the most serious kind of waste since it often precedes the six other waste types (Liker, 2009). Liker (2009) call attention upon the fact that situational factors must be considered when identifying waste, i.e. the company must understand how a certain activity actually affects the final product. According to Hines & Rich (1997), three types of operations can be distinguished in terms of how they add value:

1. Non-value adding
2. Necessary but non-value adding
3. Value adding

The first type of activity, i.e. non-value adding activities are only adding waste. Necessary but non-value adding activities are as the name indicates not adding any value, but the activities are necessary for carrying out various operations within the supply chain. An example of such an activity could be changing clothes in order to access a certain area of the floor that requires safety equipment. Value adding activities are adding value, an example of such an activity could be processing raw material (Hines & Rich, 1997).

Table 4: The different types of waste (Hines & Rich, 1997; Liker, 2009)

Waste	Examples of waste
Overproduction	The production of components without having an order
Waiting	Supervising of an automatic machine, idle time due to dissimilar process times between the different operations, bottlenecks, material shortages
Transport	Ineffective transports, double handling
Inappropriate processing	Manufacturing products with either too high or too low quality
Unnecessary inventory	Having too much inventory
Unnecessary motion	Moving tools and components back and forth during the operation
Defects	Products that needs to be repaired, adjusted or scrapped

2.5.1 Five phases of establishing a Value Stream Map

This section is devoted to the actual construction of a VSM. The five step model presented by Langstrand (2016) that should be used when conducting a VSM project will be dissected and explained.

2.5.1.1 Value stream scope

The objective of this phase is to set the scope of the VSM, to e.g. ensure that the team that is to perform the activity is appropriately chosen and that the team focus on agreed activities. The team shall be small, but there shall be representation from all concerned functions in the value stream. It is preferred that the team is biased with leadership, i.e. managers and above. Martin & Osterling (2014) mentions three reasons for why it is important. The business goals are often achieved according to the future state. Secondly, the authorization of transformational improvements is stronger. The final reason to involve managers is the managers' ability to look beyond details and are therefore possessing a view of the big picture, which may lead to a more innovative final state.

According to Martin & Osterling (2014), the parameters of the mapping activity are the following:

- Value Stream
  - Value Stream being improved
- Specific Conditions
  - What circumstances are included and excluded? (e.g. type of customer, geographic location etc.)
- Demand Rate
  - How many times this is done per week, quarter, month or year?
- Trigger
  - What initiates the process?
- First step
  - Task on first process block
- Last step
  - Task on last process block
- Boundaries and Limitations
  - What is the team not authorized to change?
- Improvement Time Frame
  - Typically, 3-6 months

Product Families

Another important step in defining the scope is the selection of product families. In order to avoid a large number of VSMs in cases where many products are produced, a categorisation of products into families is appropriate. It is required to distinguish product families before putting effort into the mapping. To avoid the project to be too complex, products that are having similar processing routes should be selected (Schmidtke et al., 2014). O'Connor (2015) suggest the usage of a product family matrix to distinguish the products. The y-axis lists the different products, whereas the x-axis lists all concerned sub processes for each product during the production cycle. Ultimately, it is visualized which products that are related in terms of common sub processes.

Cycle and Takt Time

It is also important to understand the metrics used in a VSM. According to King (2009), cycle and tact time are two of the most critical parameters shown on a VSM. Takt time is a parameter that translates the total customer demand into a time element. It is calculated through dividing the total demand for a certain time period by the total time

available to produce the item (Sundar et al., 2014). Cycle time on the other hand is a measure of the time needed for a process to produce its parts (King, 2009).

2.5.1.2 Current state map

It is fundamental to have a good understanding about the current state of the value stream performance in order to know how to redesign it. The team that is consisted of roles that are representative for all concerned function within the process is gathered to share their roles' involvement in the process and the tiers of the value chain they are interconnected with, i.e. internal and external suppliers as well as customers. The team is intended to understand and have a unified comprehension of the scope and mission of the mapping process. The current state map depicts how the work flows and how the value stream is performing. The first step in accomplishing a current state map is physically walking along the value stream, i.e. gemba walks (Martin & Osterling, 2014).

Gemba is Japanese meaning *real* or *actual place* (Martin & Osterling, 2014). By performing gemba walks, identification of problems which result in non-value added activities or waste can be done. Questions regarding issues of the process asked to operators or other personnel during the gemba walk is to be focused on *why* questions, to challenge them to think about *what* is happening and the causes to the problems (Southworth, 2014). The conversations that occur in the workers own environment contributes to a more comfortable situation for them, instead of experiencing themselves as witness stand in e.g. a conference room. During the walks, it is likely to identify current state conditions that had not been detected if the mapping process was conducted from an office. Observations from external actors is another benefit from making the walks, due to blindness from employees that are used to the conditions (Martin & Osterling, 2014).

The first walk along the value stream is performed to get a basic understanding about the sequence of processes and what function it is who perform the process. The first walk initiates the building of an elementary map (Martin & Osterling, 2014). The first map is constituting the backbone of the process, containing external actors and operations, but only the flow not process data (Langstrand, 2016). In *Figure 10*, process symbols used in VSMs are showed.

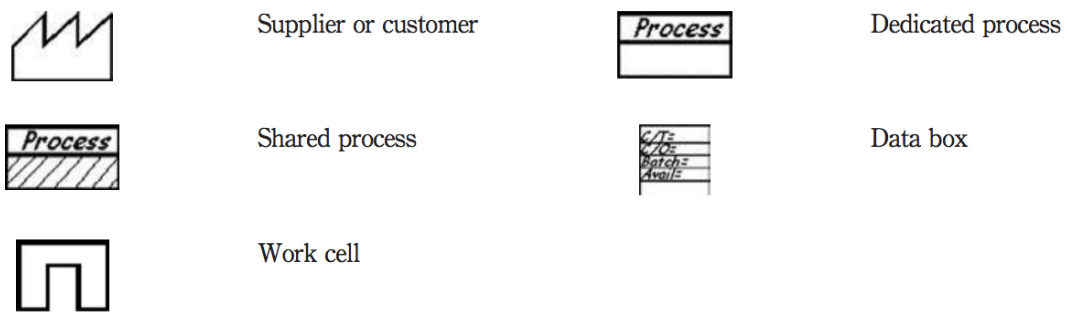


Figure 10: Process symbols in value stream maps (Jasti & Sharma, 2014, p.94)

The next step in fulfilling the VSM is to add information regarding how material and information flows within the value stream. This may require several walks along the value stream. Subsequently, relevant and useful process data is added to the map. However, since the analysis is not performed, abundant process data may be added. Langstrand (2016) presents a list of appropriate data with abbreviations:

- Customer demand
- Cycle time (C/T)
- Process time (P/T)
- Changeover time (C/O)
- Number of operators (OP)
- Capacity (Cap)
- Available time
- Uptime/Downtime
- Quality or defects rate (Q)
- Number of product variations
- Batch size
- Inventory levels

Ultimately, the data is collected and calculations based on that data can be computed. Langstrand (2016) proceeds with some useful calculations:

- Takt time
    - The production rate that need to be achieved in order to meet customer demands.
- Lead time
    - The elapsed time from the one department receives a task to the task is completed.
- Inventory lead time
    - Takt time times inventory level.
- Process efficiency

- Sum of lead time divided by sum of process time

To analyse the current state, process capacity could e.g. be investigated in order to identify if any cycle time is longer than the takt time. In that case, the customer demand is not to be met. Further, bottlenecks within the value stream, waste and variations are supposed to be identified in the analysis. *Figure 11* demonstrates an example of a VSM.

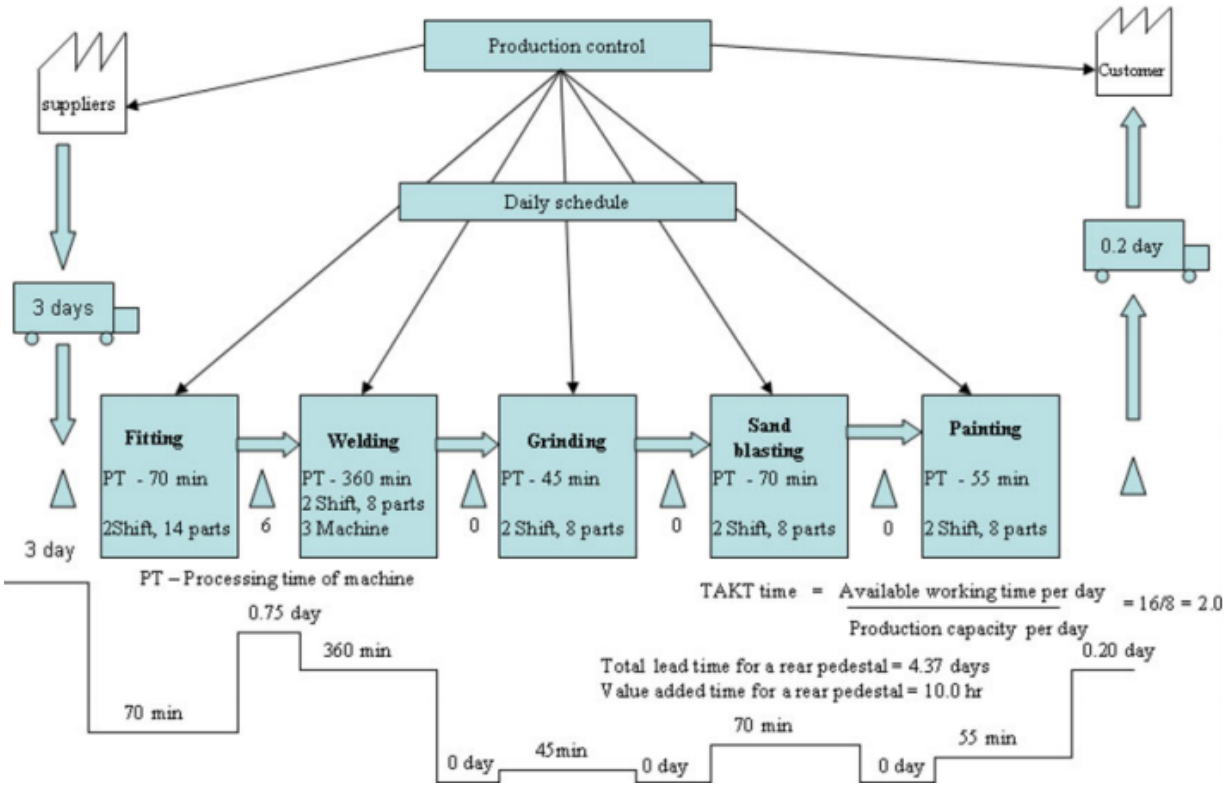


Figure 11: Example of a VSM (Jeyaraj et al., 2013, p.46)

2.5.1.3 Future state map

When an analysis has been conducted on the current state of the value flow, it is time to create a future state map (Langstrand, 2016). During the analysis of the current state, various ideas of how to improve the process will have been developed. These improvement ideas will function as the foundation of the future state map. In other words, the future state map is showing how the value stream would look like after the implementations have been made (Ibid.).

It is important to have a lean perspective when drawing the future state map. For example, the aim should be to redesign the value stream so that it delivers a continuous flow. When this is not achievable, the strategy should be to develop pull mechanisms between the work centres (Rother & Shook 1998, cited in Serrano 2008, p.41). Kanban is a widely used tool for achieving pull production (Langstrand, 2016).

Since most operations have different cycle times, idle time will be present. This will consequently lead to a lack of efficiency since some operations might have to wait for the previous step in the value chain to finish their assigned duties. Langstrand (2016) argues that operations and processes should be balanced so that the idle time is minimized, thus increasing the efficiency. This could for example be done through re-organizing work tasks. Another way of improving the efficiency of- and balancing the operations is altering the batch sizes. Generally, large batches improve the efficiency while small batches improve the consistency of the flow (Langstrand, 2016). Another way of increasing the efficiency and streamlining the flow is to reduce changeover time (Rother & Shook 1998, cited in Serrano 2008, p.41).

Quality should also be considered when constructing the future state map. Decreasing the number of defects will increase the efficiency of the process. Langstrand (2016) list a number of methods for increasing the quality; 5 whys, Ishikawa and pareto diagrams. An important factor to consider when reviewing methods intended to improve quality is the solidity of the facts.

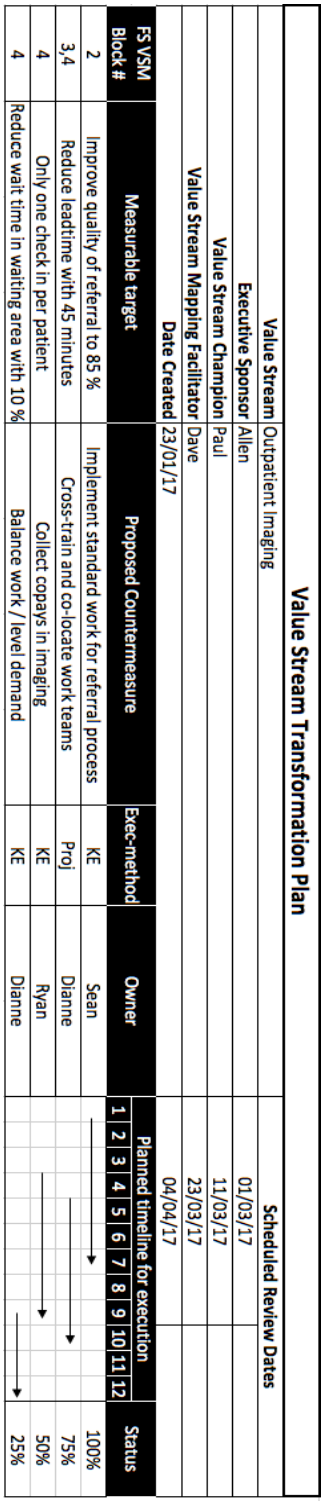
King (2009) distinguishes two approaches to create a future state map. The first approach is the least systematic of the two. The essence of this approach is to study the current state map and try to picture how an ideal future state would look like, i.e. without waste and quality issues. This vision of a future state should then be used as a goal or direction when creating the actual future state map. The second approach that King (2009) describes follows a four step process:

1. Prioritize all improvement opportunities that were identified from an analysis of the current state VSM.
2. Create a future state VSM based on the premise that the highest priority opportunities identified have been successfully implemented.
3. Create a second-generation future state VSM, based on successful implementation of the next set of improvements.
4. Repeat until the future state comes as close to the ideal state as possible.

An ideal state is not always static, which is important to keep in mind when developing the future state map. Another thing that is useful to keep in mind is to define the future state in a broad way. This will facilitate an implementation of the future state. Another key learning is that probably not all waste or problems will be identified in the current state map, the key is the lean maxim of continuous improvement (King, 2009).

2.5.1.4 Implementation plan

Martin & Osterling (2014) recommends that an implementation plan should contain and cover the content shown in *Figure 12*.



Value Stream Transformation Plan

Value Stream	Outpatient Imaging
Executive Sponsor	Allen
Value Stream Champion	Paul
Value Stream Mapping Facilitator	Dave
Date Created	23/01/17

Scheduled Review Dates
01/03/17
11/03/17
23/03/17
04/04/17

FS VSM Block #	**Measurable target**	**Proposed Countermeasure**	**Exec-method**	**Owner**	**Planned timeline for execution** 1 2 3 4 5 6 7 8 9 10 11 12	**Status**
2	Improve quality of referral to 85 %	Implement standard work for referral process	KE	Sean		100%
3,4	Reduce leadtime with 45 minutes	Cross-train and co-locate work teams	Proj	Dianne		75%
4	Only one check in per patient	Collect copays in imaging	KE	Ryan		50%
4	Reduce wait time in waiting area with 10 %	Balance work / level demand	KE	Dianne		25%

Figure 12: Value Stream Transformation Plan (Martin & Osterling, 2014 p.12)

2.5.1.5 Implementation of improvement plan

Generally, leadership commitment and organizational focus can be said to be key factors for implementation of change (Mike & Osterling, 2014). Further, to involve all functions in the change, i.e. cross-functionality, is needed to increase the chance for a successful implementation of the changes. It is also important that companies follow the future state plan as a kind of compass. The directions should be clear, the road of getting there might however change as time progresses. It is therefore equally important to follow some kind of PDCA-cycle when implementing the change (Ibid.).

In order to sustain the improvements that has been achieved when reaching the future state, Mike & Osterling (2014) stresses the need for two critical actions; assigning a person responsible for performance monitoring and choosing relevant key performance indicators.

2.6 Adaptation of the conceptual framework

The theories included in the conceptual framework that was developed for this thesis has been covered extensively in this chapter. An explanation of how the framework was adapted to be able to answer the research questions is however necessary and will thus be presented in this section.

The framework is comprised of four main components, namely cGMP, VSM, lean and warehousing. Due to the nature of the pharmaceutical industry, i.e. hard regulations of documentation and controls, cGMP was included as a delimiting factor. This is clarified in the actual design of the framework, where cGMP comprises both the actual value stream and the remaining three blocks of theory. This means that cGMP will define an area of feasibility for the improvement suggestions presented in this thesis.

VSM was as previously described given by the company as the predestined tool of analysis. The necessity of covering the theoretical aspects of VSM therefore needs no further attention. VSM is a lean tool that is used to evaluate and ultimately visualize a redesigned production system. As previously described, a VSM should depict a process as a flow where value is added in steps of the production process. The construction of a VSM often precedes a transformation towards a lean way of work and the premises for identifying issues given by a VSM is seen from a lean perspective. Thus, it becomes natural to choose tools for analysis and improvement accordingly. Consequently, by choosing lean as a component in the conceptual framework, the analysis will be conducted from the same approach as the foundation of the analysis, i.e. the VSMs.

Warehousing was also seen as an important component to add to the conceptual framework. The company had expressed concerns with the material flow between the two

warehouses and in order to analyse the operations within the warehouses, knowledge of the theory behind warehouse operations was needed.

3 Methodology

In order to actually be able to answer the research question of this study in a satisfying manner, an appropriate method has to be used. A greater understanding of epistemology must however first be developed. The onion model developed by Saunders et al. (2007) gives a clear outline on how to get to the actual core of being able to answer the research question, i.e. the data gathering. Further, it will grant the reader a view upon how the logical reasoning behind the choice of research strategy, data collecting methods et cetera has been conducted. The onion model together with the thesis-specific choices is shown in *Figure 13*.

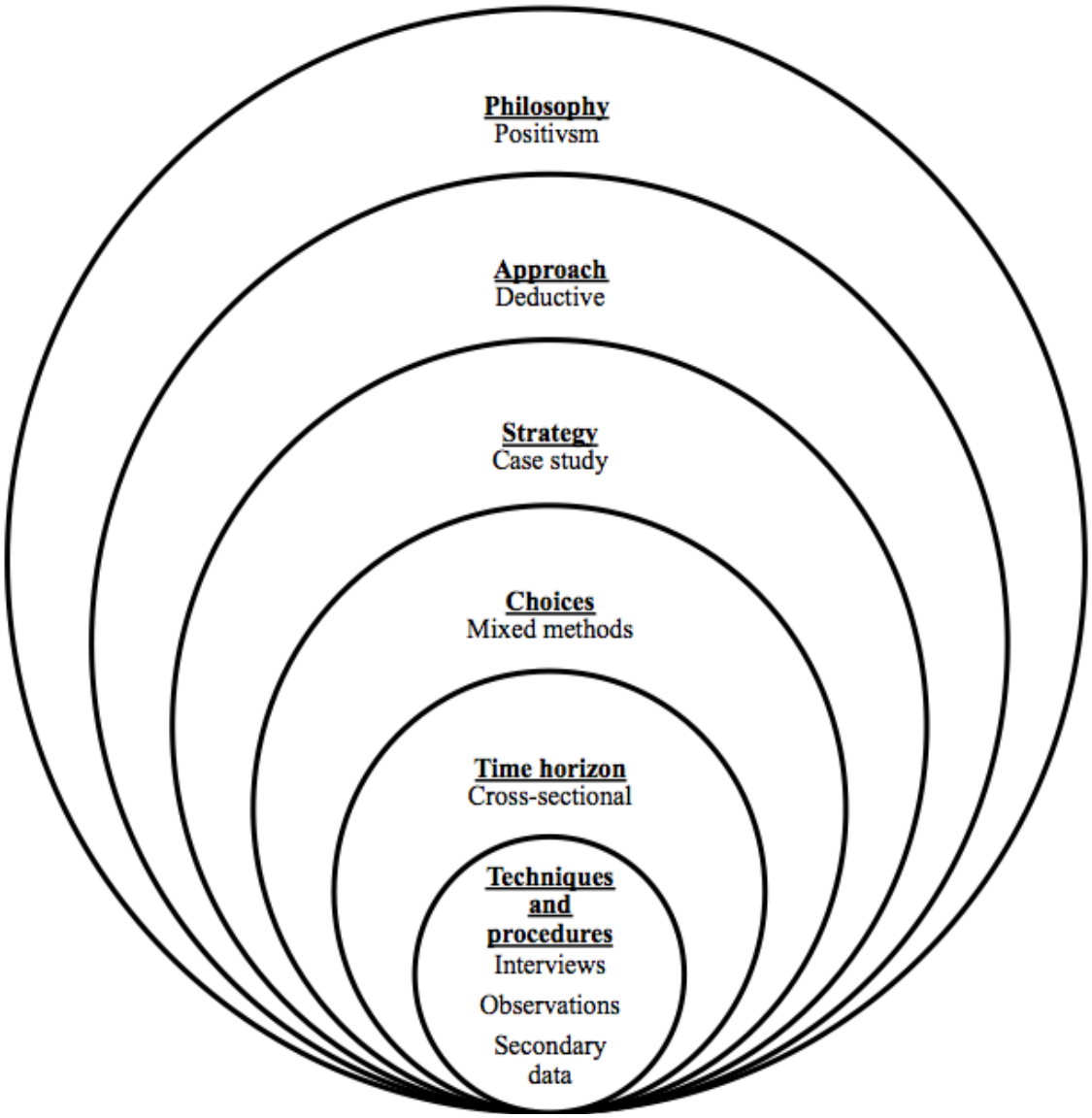


Figure 13: Methodological approach of the thesis visualized in the onion model (Saunders et al., 2007 p.102)

The onion depicts six layers in order to supervise the authors in the work of organizing their research. The chosen *research philosophy, research approach, research strategy,*

research choices, time horizon and *research technique and procedure* is typed in each layer of the onion. However, Saunders et.al (2007) presents several options in each layer. The selected orientation in each layer will be further described and the choices will be motivated in the remaining sections of this chapter.

3.1 Research philosophy

A research philosophy basically reflects the author's view upon the world and what his relationship between knowledge and the process of gathering knowledge looks like. This is according to Saunders et al. (2007) an important factor to establish when choosing an appropriate research method. Since people have different views upon subjects, their perception on what is important also differ. Saunders et al. (2007) describe a number of different research philosophies. However, three of these philosophies were considered most applicable for the thesis, namely *positivism, realism* and *interpretivism.* These three philosophies are sub-philosophies under the epistemological view upon science which was seen as the most applicable flow of thoughts for the thesis due to its nature.

3.1.1 Positivism

A positivistic view upon the world is a reality that can be generalized through observations. Thus can only observable occurrences be investigated in order to gather data. A positivistic research philosophy is characterized by empiric studies and an independent and unbiased approach towards the analysis of the data as well as the result (Saunders et al., 2007).

3.1.2 Realism

The philosophy known as realism is characterised by a scientific approach to knowledge. Realism can be divided into two sub branches, *critical realism* and *direct realism.* The foundation pillar of realism is a firm belief of a reality that is independent of the observer (Saunders et al., 2007).

3.1.3 Interpretivism

An interpretivist would argue that a positivist loses the understanding of a phenomena by generalising too much, thus failing to understand the complexity of the phenomena. Interpretivism enlightens the difference between doing research upon humans and machines. This means that an interpretivist has an empathic standpoint in the research. This approach opens up for an interchangeable reality that is not constant, which for example could be valuable in the changeable world of business (Saunders et al., 2007).

3.1.4 Applicable research philosophy

As the formulated research questions opens up for a generalisation of reality and also suggest that the results could be used as a basis for further investigation. This would point in the direction of adopting to a positivistic research philosophy. Moreover, the thesis is delimited by the choice of analysis method, i.e. VSM. This method or tool has seemingly been researched through a positivistic approach and therefore the choice was made to conduct the study in a positivistic manner.

3.2 Research approach

The design of the research project is determined by the choice of research approach. Saunders et al. (2007) discusses two different approaches; *deductive* and *inductive*. A deductive approach is conducted as the researcher develops a hypothesis and a theory and later design a research strategy to examine the theory/hypothesis. With an inductive approach, the researcher is developing a theory based on the collected data. Golicic et al. (2005) refer to the deductive approach as typically quantitative and the inductive as typically qualitative. The decision whether to use an inductive or deductive approach shall be based on what there is to be know about the phenomenon and the type of research question. Golicic et al. (2015) visualizes the two approaches with its corresponding steps in *Figure 14*, as well as how the both approaches can be integrated in the so called *Balanced Approached Model.*

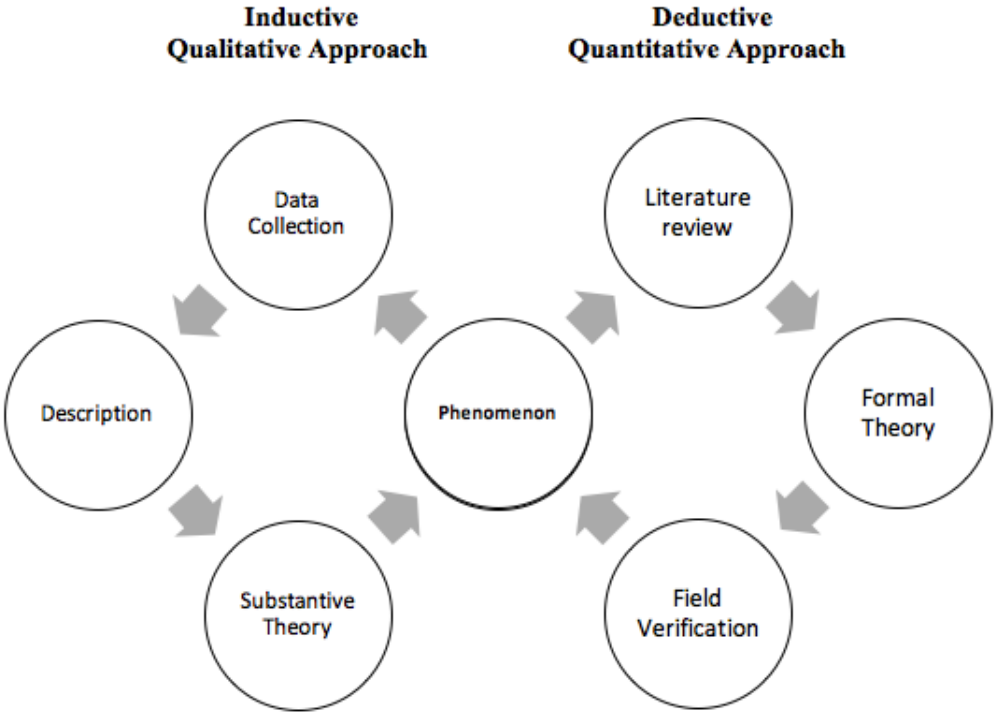


Figure 14: The Balanced Approach Model (Golicic et al., 2007)

The qualitative approach, i.e. the inductive approach, is intended to make its first step with a data collection appropriate to the phenomenon in order to understand it. The literary review is not seen as a separate part of the research, but as embedded as parts in the continuous inductive approach. The selection of literature is emerging from the data subsequently constitutes the substantive theory. (Golicic et al., 2007)

Since the data is collected, the inductive approach is now to describe the phenomenon. In order to describe the phenomenon, qualitative techniques are used with open question formulations in interviews, observations and audio-visual material (Maxwell 2006, cited in Golicic et al. 2007, p21). The final step is to utilise the qualitative data in order to describe the phenomenon in a substantive theory. An inductive approach is often better to utilise for new or complex phenomenon (Golicic et al., 2007).

Further, the quantitative approach dominates the research in logistics. It is somewhat the reverse path in comparison to the qualitative approach. The first step is to build a conceptual framework based on a review of appropriate literature (Bickman & Rog 1998, cited in Golicic et al. 2007, p.21). Subsequently, a formal theory is developed based on research. Lastly, the data is collected in order to verify the formal theory. A deductive approach is often better to utilise for developing and later testing formal theory (Golicic et al., 2007).

Golicic et al. (2007) argues for a balance between the inductive and deductive approach. In order to avoid to limit the understanding because of the complex nature of supply chain phenomena, balance between the approaches shall be achieved. The researcher shall progress through the circle, crossing the circles and even looping the circles.

The study initially started with a phenomenon presented by the company that was to be studied. The inductive approach moves from observation of the phenomenon to a substantive theory. In that sense, an inductive approach is suitable. However, the study relies on subjects that are well-researched, i.e. VSM and additional lean tools, which would imply a deductive approach. Further, a quantitative approach is identified with a positivistic research philosophy, i.e. the same research philosophy for this subject (Golicic et al., 2007). Additionally, operations within the pharmaceutical industry is restricted by Directive 2003/94/EC and Läkemedelslagen (2015:315), inter alia the standard that present the principles and guidelines for cGMP. This variable gets in conflict with an inductive approach, since the phenomenon is so heavy restrained by it. A deductive approach is more suitable, as a result of the approach's build-up, i.e. to begin with building a foundation of theory before investigating solutions to the problem.

3.3 Research strategy

When choosing a research strategy, the most important thing to consider is whether the chosen strategy will answer the research questions. As Saunders et al. (2007) points out, no strategy is significantly better than another, it is rather a question of the characteristics of the instance that will influence the choice of strategy. In *Table 5* some well-known research strategies are explained.

Table 5: Common research methods (Saunders et al., 2007)

Research strategy	**Description**	**Objective**
Experiment	Helps researchers study the possibility of a link between two variables	Answer the "how's" and "why's" of exploratory and explanatory research
Survey	A cheap and accessible method of gaining insight from a population	Accessible tool for answering research questions in exploratory and descriptive research
Case study	The empirical study of a real-life situation where several sources of verification are used	Granting a rich contextual understanding of the research issue
Action research	An iterative strategy where the researcher is involved with the research subject, i.e. research in action	Helping an organisation to develop skills in order to solve actual problems within the organisation
Grounded theory	Gathering data from observations, making assumptions based on the data and then testing the assumption by developing new data	Understanding certain behaviour and develop theory upon the same
Ethnography	A wide grasping strategy for understanding real problems without simplification, often conducted through field studies	Gaining deep understanding of a specific context such as culture
Archival research	Using archival resources as a strategy	Develop understanding of history

The choice of strategy should according to Saunders et al. (2007) be based on how the research questions are formulated, what the objective of the research is and what resources are available. In terms of time, the thesis is delimited to a period of 20 weeks. Further, all 20 weeks can of course not be allocated to the actual research. This consequently narrows the choice of research strategy. The research questions also pave the road towards the choice of an appropriate research strategy. Let's remind ourselves of the research questions:

RQ1 *What deficiencies are affecting the processes and in what way do they affect the business?*

RQ2 *How can the deficiencies be improved through lean thinking with consideration taken to the contextual limitations given by cGMP?*

RQ3 *Does VSM constitute a good foundation for process optimization within the pharmaceutical industry?*

The research questions seek to establish a present situation. According to Yin (2013) this points in the direction of using the case study as research strategy. Yin also points out that case studies are of relevance when an extensive understanding of a complex phenomenon is sought. This is also the case of the purpose of the thesis. However, the subject of research strategy has to be further analysed before an appropriate strategy can be chosen. In order to systematically explore what research strategy is applicable in the context, a checklist, shown in *Table 6* developed by Yin (2013) will be used.

Table 6: Relevant situations for different research methods (Yin, 2013, p.9)

Method	Form of research question	Requires control of behavioural events	Focuses on contemporary events
Experiment	how, why?	yes	yes
Survey	who, what, where, how many, how much?	no	yes
Archival analysis	who, what, where, how many, how much?	no	yes/no
History	how, why?	no	no
Case study	how, why?	no	yes

When comparing the characteristics of the problem formulation and research questions to the information in *Table 6*, the case study seems like the most relevant choice. No control of behavioural events is needed, and as previously stated; the research questions as well as the contemporary focus are aligned with the recommendations of a case study. Consequently, case study was chosen as the research strategy.

3.3.1 Case study strategy

There are two main junctions that has to be noted when choosing the case study strategy. A choice between a single case or multiple case study has to be made as well as choosing whether the case should be holistic or embedded (Saunders et al., 2007). These two junctions were consequently considered when choosing an appropriate strategy, see *Figure 15*.

Defining the unit of analysis basically means defining and bounding the case. Having one unit of analysis means a holistic approach while several units of analysis correspond to an embedded approach. Defining the unit of analysis is however not as easy as it may sound and can be a stumbling block for some researchers. The difficulties that can occur when setting the unit of analysis often relates back to a vague research question. A research question that does not support the circumscription of a unit of analysis can therefore obstruct the successful execution of a case study.

As the research questions revolves around the pharmaceutical industry, the unit of analysis will be the same, i.e. a holistic approach will be taken. This decision also gain approval from literature when considering the contextual nature of the thesis. It is recommended to have a holistic approach to incorporate lean tools with the goal of increasing process quality in the pharmaceutical industry (Miller 2008, cited in Chowdary & George, 2012).

Due to contextual limitations, i.e. the directions given by the company, the choice between a single or multiple-case design was predetermined. The single case study approach will hence be used.

The case design and strategy of this thesis from a case study perspective is clarified and with marked with grey in *Figure 15*, which displays the four approaches to case studies described by Yin (2013).

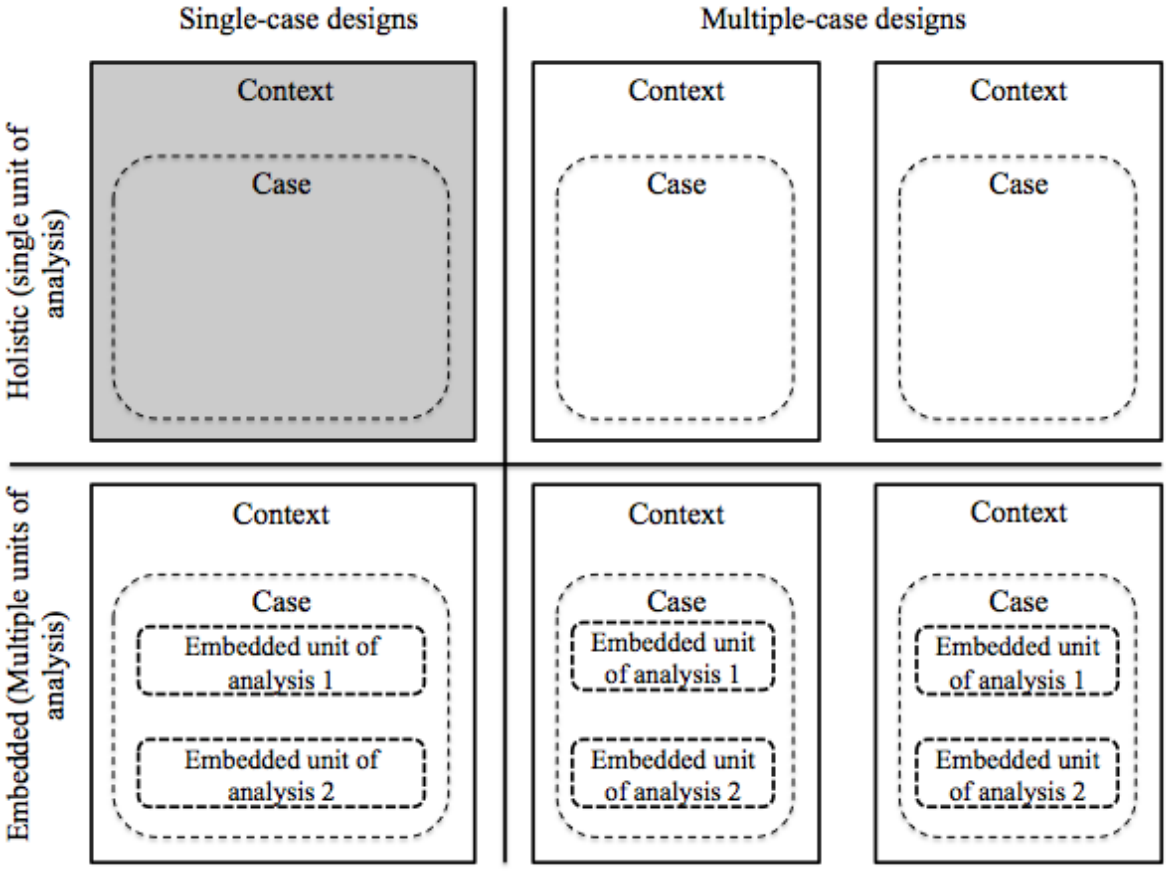


Figure 15: Basic types of designs for case studies including the chosen design for this thesis (Yin, 2013, p.50)

3.4 Research choices

In order to clarify what kind of data procedure and technique the thesis's methodology is constructed of, three different methods will be described; *mono-method, multi-method* and

mixed-method. To make a basic distinction of the two types of data, there is *quantitative* data and *qualitative* data. Quantitative data is numerical data that could be analysed with e.g. graphs and statistics. Qualitative data is non-numerical data e.g. words, pictures and video clips (Saunders et al., 2007).

The mono-method refers to collection of data using only one collection technique and corresponding data analysis procedure. It could be a single quantitative collection method combined with a quantitative data analysis procedure, or the vice versa with qualitative techniques (Saunders et al., 2007).

The multi-method refers to a combination of data collection methods and data analysis procedures, but it is restricted to only use quantitative or qualitative methods (Tashakkori & Teddlie 2003, cited in Saunders et al. 2007, p.145).

Lastly, there is the mixed-method. The method presupposes collection methods that are both qualitative and quantitative with corresponding analysis procedures. Mixed methods research uses qualitative and quantitative techniques that are not combined, but sequels after each other or being performed in parallel. The result is that quantitative collection methods are not mixed with qualitative analysis procedures, or vice versa. Mixed model research on the other hand, combines qualitative and quantitative data collection techniques and analysis procedures (Saunders et al., 2007). *Figure 16* shows the different research models.

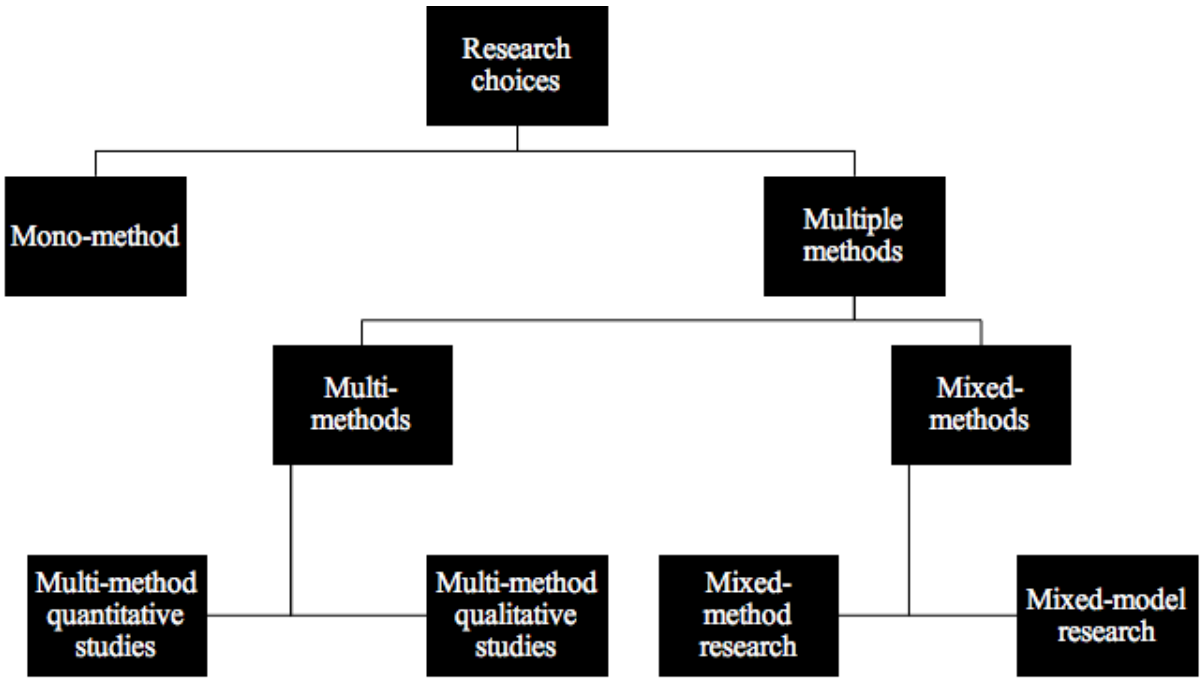


Figure 16: Research choices (Saunders et al. 2007, p.146)

Since the nature of VSM is dependent on numerical data, e.g. customer demand, process times and units per time unit, a mono-method with quantitative collection and analysis methods is used. However, in order to fully establish the VSM, interviews with concerned employees in several functions are performed. The data extracted from these events are qualitative and it is intended to obtain different viewpoints of the value stream. This qualitative data collection method is also applied to answer questions of what quantitative data is available, how the value stream is built-up and evident flaws within the process. As a result of mixed collection methods and analysis procedures that is either qualitative or quantitative, a mixed-method research is used. Saunders et al. (2007) points out two benefits with using a multiple-method. Firstly, to identify key issues before collecting descriptive and explanatory data. Secondly, it enables triangulation of the data, meaning that it could be verified through different sources.

3.5 Time Horizon

Two different types of horizons exist; cross-sectional and longitudinal. Cross-sectional horizons consider research that is reflecting a snapshot at a particular time. Time constrained research projects are often having cross-sectional time horizons. Longitudinal time horizon is reflecting a research that is being represented of events over a given period. The strength of a longitudinal time horizon is the ability to study changes and development over time (Saunder et al., 2007).

This thesis is time constrained and it reflects a snapshot of the current situation of the company, not the development of the process over time. Therefore, the thesis is having a cross-sectional time horizon.

3.6 Data collection methods

A case study demands a lot from the researchers due to the fact that the data collection procedures are not routinized. That is because the researcher needs continuous interaction between the data and the applied theory. In preparing the data collection in case studies, there are some required skills (Yin, 2013):

- Ask good questions
    - Create a rich dialogue with the evidence.
- Be a good listener
    - Comprehend new information without bias.
- Be adaptive and flexible
    - Willingness to change if unprepared events occur.

- Firm grasp of the issues being studied
    - Identify contradictions of data from different sources.
- Avoid bias

The data collection procedure is the core of the research onion (Saunders et al., 2007). This section will describe the three different methods that this study will practice. It is worthwhile adding that consideration was taken to the predetermined VSM tool that functions as the foundation of the analysis when the methods were chosen. Moreover, the relevance of the chosen methods in respect to case studies was taken into account. The construction of a VSM requires both qualitative and quantitative data and the three methods support together both quantitative and qualitative data. Two out of the three methods are presented by Yin (2013) as commonly used in case studies.

3.6.1 Interviews

Generally, an interview can be said to have four characteristic features apart from providing the researcher with qualitative and/or quantitative data (eds Gubrium et al., 2012):

1. An interview is a goal- or task-oriented talk to gather information, in which the interviewer and the interviewee have their respective roles to play.
2. The interviewer acts in the role of questioning and the interviewee in the role of answering.
3. The question-answer sequence is the predominant sequential structure in an interview.
4. The interviewer is empowered to ask questions, and the interviewee is confined to responding.

Interviews are considered as one of the most data important data collection methods in case studies (Yin, 2013). A case study interview shall operate on two levels in order to get answers to *why* questions instead of *how* questions. The interview shall satisfy the researcher's line of inquiry and at the same time keep a friendly and nonthreatening interview atmosphere. The interview sessions could be recorded if it is preferred. There are *three* types of interviews appropriate for case studies. *Prolonged case study interviews* are performed during two hours or more over single or multiple sessions. This type of interview is intended to initially give answers to broader opinions about circumstances and later assist with pursuing the data collection. *Shorter case study interviews* intend to give a deeper understanding and confirm or neglect findings, but it can also be used in the

same sense as a prolonged case study interview. *Survey interviews* collect quantitative data through questionnaires (Ibid.).

As previously mentioned, the construction of the VSM which will function as the basis and main tool of analysis will require both qualitative and quantitative data. Mixing qualitative data with quantitative data can be problematic and choosing an appropriate way of obtaining the data is therefore important (eds Gubrium et al., 2012). In this thesis, the interviews main function is to facilitate the understanding of the flow, i.e. the actual depiction of the processes onto a map. It was therefore decided that the interviews should be used to collect qualitative data.

Three categories of interviews can be identified. The first category is referred to as structured interviews. In a structured interview, quantitative data is collected by asking the subjects the same questions in the same order. The subjects cannot answer the questions freely, but have to select an answer from a number of options. The data set should be formed as a matrix and is analysed statistically (eds Gubrium et al., 2012). Survey interviews, described by Yin (2013) as a tool used in connection to case studies, is an example of a structured interview.

A semi structured interview is intended to collect qualitative data. The questions are developed in advance in such a way that the participant, i.e. the person being interviewed, can answer freely. New questions can arise depending on the responses. The interview approach is that the interviewer knows the questions but not all possible responses. All participants are asked the same open ended questions and data collected from all interviews are analysed after the last interview (eds Gubrium et al., 2012).

Unstructured interviews are qualitative with the purpose of asking short questions with the intention to present the topic to the participant and then letting the participant give her view on that topic. The questions are not prepared in advanced. While the interview is not leading and the interviewer is not interrupting and the participant may answer freely, the validity of unstructured interviews is questionable. An unstructured interview is often referred to as a long, which would correspond to the prolonged interviews previously covered (eds Gubrium et al., 2012; Yin, 2003). The differences and characteristics of the three types of interviews are shown in *Table 7*.

Table 7: Characteristics and Use of Interview Types with Mixed-Method Design (eds Gubrium et al., 2012 p.196)

Type of interview	**Unstructured interviews**	**Semi structured interviews**	**Structured interviews (quantitative questionnaires)**
Domain	Not known	Known	Known
Direction of inquiry	Inductive	Deductive or inductive	Deductive
Approach	Investigator learns about phenomena during the course of the inquiry. Investigator assumes listening mode	Investigator knows the questions that need to be asked but not all the possible responses	Investigator knows that questions and responses are necessary
Questions	Not planned in advance but developed during the course of the inquiry	Questions stems (and sometimes prompts) planned in advance	Questions and response choices planned in advance
Responses	"Long responses" conducted with minimal interruption. Interviews not equivalent	Unscripted (free) responses to set open-ended questions. All respondents are asked the same questions	All respondents are asked the same questions in the same order. Participant selects responses
Sample	Sample changes according to the informational needs of the emerging analysis	Sample characteristics identified	Sample randomly selected from the selected population
Sample size	Depends on the scope and complexity of the phenomena	If data are to be numerically transposed, at least 30 participants are required	Large: size determined by number of questions
Analysis	Concurrent with collection	Analysis at end of data collection	Analysis at end of data collection

The initial interviews were conducted in a semi-structured way and contained the purpose of a short case study interview. This choice of interview method was based on the main purpose of these interviews, i.e. enabling the depiction of the value stream onto a VSM. Martin & Osterling (2014) states that questions regarding issues of the process should be asked to operators or other personnel during the gemba walk, therefore unstructured interviews will also be present during the case study.

3.6.2 Observations

Observations is another data collection method, i.e. the researcher is observing one or several employees who perform a task. There are two main types of observations: participant and direct observation (Yin, 2013). Participant observation can be described as:

"the researcher attempts to participate fully in the lives and activities of subjects and thus becomes a member of their group, organisation or community. This enables researchers to share their experiences by not merely observing what is happening but also feeling it" (Gill & Johnson 2002 p.144, cited in Saunders et al. 2007 p.283-284).

Direct observations could be observing behaviour or environmental conditions, such as meetings, working methods in factories and other activities. The method can provide the researcher with information that cannot be found in any other source of data, such as how technology is used. To ensure a greater reliability, it could be helpful to use more than one observer (Yin, 2013).

Both direct and participant observations were used to gather data in this thesis. This was required due to the character of the gemba walks performed in the packaging facility of the company.

3.6.3 Secondary data sources

Secondary data includes raw documents and published summaries and could be both quantitative and qualitative. It is data that have been gathered for other purposes. Such data is commonly used in case studies. Secondary data could e.g. be documentary data, survey-based data and multiple-source data (Saunders et al., 2007; Yin, 2013).

Secondary data has been gathered from the company's information system and from the vast amount of information available from various log books and other cGMP related documentation available.

3.7 How the case study was performed

The goal of this section is to give the reader a clear overview of how the case study was performed. It aims to clarify for example how data was gathered, why it was gathered and how it was used. The process of conducting the case study was transposed from the general case research process presented by Stuart et al. (2002), but has been altered to fit the characteristics present in this thesis. The structure of the case study conducted in this thesis is shown in *Figure 17* below.

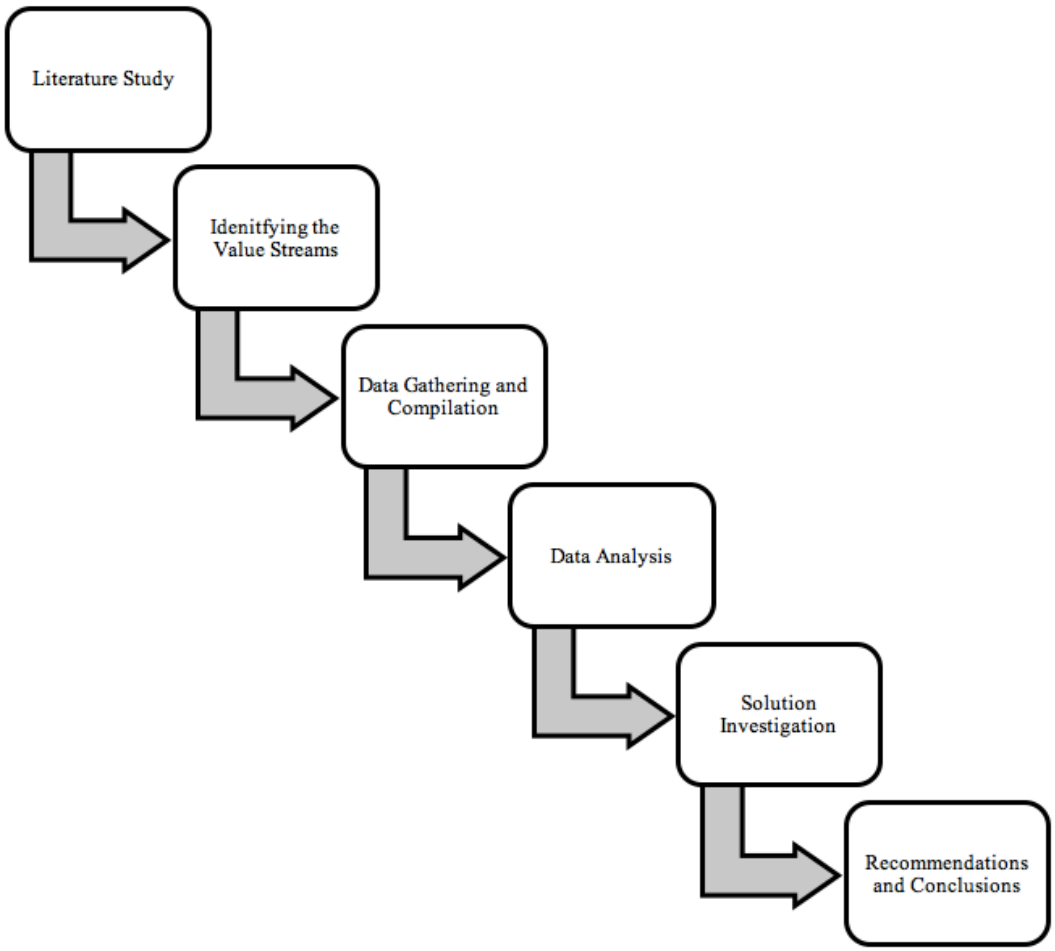


Figure 17: Structure of the case study

Since the choice of methodology already has been covered in the previous sections of this chapter, it will be given no further attention.

3.7.1 Literature study

As previously concluded, the research approach will be deductive. Therefore, the first step was to perform a literature study. Worthwhile noting is that although the major part of the theoretical foundation was laid during this phase, some additional theory had to be added ad hoc as the research progressed, i.e. an iterative approach had to be used.

A great part of the theory found in this thesis was accessed through internet sources. Search engines such as Google scholar and LUBsearch, Lund University's libraries search engine were used to access peer reviewed journals and books. In addition to internet sources, the authors also gained access to literature at Malmö Stadsbibliotek, Malmö University Library and Lund University Library. Some of the keywords that were used when finding suitable literature were: *lean manufacturing, value stream mapping, pharmaceutical industry, warehousing, warehouse operations, cGMP* and so forth. Various synonyms were also used in the process of finding suitable literature. The journals and books that were chosen as the theoretical foundation in this thesis were considered to be relevant in the sense that they enabled the authors to; understand relevant theories in order to gather and analyse data, understand the contextual limitations in the pharmaceutical industry and ultimately giving recommendations that were based on prior knowledge, thus satisfying both the company and contributing to academia. The information gathered from literature was merged into a theoretical framework which summarizes the different disciplines and theories that are necessary to resolve the research questions of the thesis.

Initially, the literature study only covered the topics *lean manufacturing, VSM* and *cGMP.* After the data gathering it became apparent that a section on *warehousing* would be necessary, and was therefore added.

3.7.2 Identifying the value streams

The initial activity of this phase was to set the scope, i.e. choosing product families, identifying the value streams and triggers, et cetera. Specific conditions and limitations were also clarified. In order to set the scope, several employees from different departments at the company were consulted. Help was also received from one of the employees with learning the information system used at the company. Three product families and their respective value streams were ultimately chosen.

The first step in creating the VSMs was conducting gemba walks. The gemba walks took place in the packaging facility as well as the warehouses. Visits were also made to the all relevant departments of the company to get a view of how the daily work was conducted. The result of the first gemba walks was an outline of the entire process. The first gemba walks were non-participatory and supervised by the production manager.

In order to refine the initial outline of the process, a set of semi-structured interviews were conducted. An interview guide was created in advance in such a way that the person being interviewed could answer freely. One or more employees from each of the following

departments were interviewed: the logistics department, the quality assurance department, the packaging department. One person from the warehouse was also interviewed. The underlying reason of the interviews was to understand the processes as well as gaining other insights regarding the value streams. A summary of the interviews is found in *Table 8* and the interview guide can be found in Appendix **B**.

Table 8: Summary of semi-structured interviews

Concerned department and title	**Date**	**Time**
Logistics department/ Logistics Manager 1	2017-02-21	1,25 h
Logistics department/ Logistics Manager 2	2017-02-13	1 h
Quality assurance department/ Quality Coordinator	2017-02-21	1 h
Packaging department/ Production Manager	2017-02-09	1 h
Packaging department/ Team Leader	2017-02-10	1 h
Warehouse/ Warehouse Operator	2017-02-20	1 h
Quality Control department/ Quality Analyst	2017-02-18	1,5 h

As the interviews progressed the mapping of the processes was conducted simultaneously. An outline for each one of the three chosen product families value streams were created in the business graphic tool ConceptDraw PRO 11.

3.7.3 Data gathering and compilation

The next phase consisted of data gathering with the purpose of filling the VSMs with information. The data gathering was initiated by gemba walks. This time, data was gathered through participatory observations and by measuring the time it took to perform certain activities. Unstructured interviews and questions that arose during the gemba walks were also present at this stage. The gemba walks were initially performed in the packaging facility. Each product family was "followed" through all the process steps in connection to the packaging facility. Through following this procedure, the lead times

could be broken down, recorded and understood. This meant that value adding times, change over times, line clearance and so forth could be measured with a stopwatch.

Next, gemba walks were performed in both warehouse A and B in order to measure the time for e.g. palletizing a finished order. A gemba session was also performed in the quality assurance department to record the flow of documentation.

After the initial gemba walks, it became apparent that it was hard to measure the overall lead times in an efficient manner, i.e. lead times between process steps. Due to the nature of the pharmaceutical industry and the regulations on traceability, the documentation is rigorous. In the packaging facility, there are books which are continuously updated with lead times, i.e. how long time the different steps of the process took, number of defects et cetera. One book is present at each room or station in the packaging facility. Through following an order, the lead times and defects present in each process in the packaging facility could be calculated. This also included the time each order spent idle between the process steps. This was done for all the product families at a sample size of 25 orders per product family. The data was transferred from the books into MS Excel manually where the lead times could be calculated.

Again, due to the strict regulations on traceability, the orders have to be signed throughout the entire process starting from when an order is printed and sent down to the packaging facility. This means that by examining the paperwork that an order contains, lead times across department borders as well as the date and time when all controls were performed could be extracted. Again, 25 orders per product family were examined and the data was transferred into MS Excel. The data that was accessed from the orders was used to calculate the lead times between process steps.

In some cases, lead times and other data had to be acquired through unstructured interviews. The unstructured interviews aimed at clarifying certain lead times and facilitate the gathering of information. In certain cases, the interviewees were asked where certain information could be found. *Table 9* summarizes the unstructured interviews conducted.

Table 9: Summary of unstructured interviews

Concerned department and title	**Date**	**Time**
Logistics department/ Logistics Manager 1	2017-02-29	0,5 h
Logistics department/ Logistics Manager 2	2017-02-23	0,5 h
Packaging department/ Team Leader	2017-02-27	1 h
Packaging department/ Team Leader	2017-02-24	0,5 h
Quality assurance department/ Quality Coordinator	2017-03-04	1 h
Warehouse/ Warehouse Operator	2017-03-09	1 h

The company's information system was also used to gather data. Information regarding order frequency, picking history from the warehouses and other data that was seen as necessary for carrying out the case study was extracted from the information system into MS Excel.

The next step in the process of gathering data was finalizing the three VSMs, i.e. adding the lead times and other data to the maps. The data was first processed in MS Excel. Lead times were calculated as well as up time, rejection percentage, changeover time et cetera. The data was added to the maps in ConceptDraw PRO 11.

The final data gathering was conducted through gemba walks in the two warehouses. Drawings of the warehouses was created where the various pallet positions and shelves were marked out. Sketches and photos taken during the gemba walks were used as a basis for the drawings. No previous drawing of how the racks were organized was present at that time. The information from the information system regarding picks from the different pallet locations were applied to the drawings in the form of a heat map. The number of storage positions as well as the number of occupied storage positions were also counted.

This data could not be gathered from the information system and therefore had to be counted manually.

3.7.4 Data analysis

The initial phase of the data analysis was conducted through studying the VSMs. The goal was to identify a number of discrepancies; waste, long lead times and non-consistent flow of both products and information. When identifying waste, consideration was taken to the nature of the process, that is if the process was value adding, necessary but non-value adding or non-value adding. Hines & Rich's (1997) definitions of waste were used in order to understand what activities or circumstances that create waste. All process steps in the VSMs were studied, first with a holistic approach, then more in detail. Several instances of waste were found through utilizing this procedure. In some cases, issues had to be broken down using the 5 why's method.

Next, the lead times depicted in the VSMs were studied. Lead times that seemed too long or just irregular were analysed in detail and once again the 5 why's method was used to find the root cause of the long lead times. An example of a lead time that was considered too long was the time between when an order was finished and the debriefing and documentation was conducted. This was true for all the three product families. The 5 why's approach revealed that the long lead time was the result of the allocation problem as well as unclear working tasks. The team leaders in packaging department are responsible for the debriefing and documentation but had to prioritize other tasks, thus the long lead times. This also lead to an inconsistent flow of information.

In order to fully grasp the underlying reasons for why certain activities took time or were performed like they were, a workshop was held. The workshop included people from the concerned departments, i.e. that had touchpoints with the considered value streams. *Table 10* shows which departments that were represented at the workshop. The workshop lasted for roughly two hours. The VSMs were presented for the attendants, accompanied by an explanation of the flow and the lead times. A group discussion followed where the lead times and wasteful activities were analysed to find the root cause of the issues.

Table 10: Summary of the workshop

Concerned department and title	**Date**	**Time**
Logistics department/ Logistics Manager 1	2017-03-28	2 h
Logistics department/ Logistics Manager 2	2017-03-28	2 h
Quality assurance department/ Quality Coordinator	2017-03-28	2 h
Packaging department/ Production Manager	2017-03-28	2 h
Packaging department/ Team Leader	2017-03-28	2 h

3.7.5 Solution investigation

Once the analysis was conducted, root causes to issues such as various forms of waste and long lead times had been identified. The next step to follow was investigating how the found deficiencies could be improved or mitigated. A distinction was made between short term and long term solutions. The short term solutions that were investigated were considered to be fairly uncomplicated to implement and did not require capital intensive investments. The time frame required to successfully implement these solutions was also considered to be significantly shorter than the solutions that were considered as long term solutions. Long term solutions were on the other hand considered to be more complicated to implement, required more capital support but could also ultimately be seen as strategic investments for the company. The underlying reason for proposing both long term and short term solutions was the company's current growth phase. While the short term solution might be easier to implement in a short term, the growth could make them insufficient when considering a larger timespan of continued growth.

Two phases of the solution investigation can be distinguished; identifying solutions and evaluation of the solutions feasibility. The identifying of solutions was conducted through studying the result of the analysis. Solutions to the cases of unnecessarily long lead times, wasteful activities and other deficiencies were distinguished and concretized. The second phase, i.e. the evaluation of the solutions feasibility was then initiated. A series of unstructured interviews were held with representatives from each affected department in order to see if the solutions were executable and how they would affect the concerned departments.

3.7.6 Recommendations and conclusions

The improvement proposals were screened, and the ones which would make the largest impact and at the same time were considered feasible were chosen as the final recommendations for the company. Worthwhile noting is that the feasibility of implementing the long term solutions is highly ambiguous. Nevertheless, the choice of recommending a new information system and a relocation of the entire company was made. The reason behind this choice was that the issues regarding capacity and the information system was presumed to become aggravated in the future, thus making these recommendations inevitable in the long run.

Finally, the research questions were answered. In order to answer the research questions, a triangulation between the theoretical framework, the analysis and the recommendations was made. In other words, the research questions were answered through the findings of the case study and the reasoning was strengthened through previous findings found in literature.

3.8 Credibility

A certain level of uncertainty will almost always be present in research. It is therefore important to reduce the level of uncertainty of the research. In order to reduce the uncertainty of getting the wrong answers, researchers must pay attention to two factors regarding the case design, namely reliability and validity (Saunders et al., 2007). Yin (2013) mentions four strategies that can be used in order to assure that the case study will rest on a solid foundation of quality and credibility. The strategies are displayed in *Table 11*.

Table 11: Case study tactics for four design tests (Yin, 2013, p.45)

Tests	Case study tactics
Construct validity	use multiple sources of evidence
	establish chain of evidence
	have key informants review draft case study report
Internal validity	do pattern matching
	do explanation building
	address rival explanations
	use logic models
External validity	use theory in single-case studies
	use replication logic in multiple-case studies
Reliability	use case study protocol
	develop case study database

A review of the concepts reliability and validity is appropriate before addressing how the authors chose to tackle these issues.

3.8.1 Reliability

Reliability relates to the degree to which the results of the research can be duplicated (Yin, 2014). Four threats against the reliability of a research can be identified (Robson 2002, cited in Saunders et al. 2007). *Subject or participant bias* can be experienced in for example authoritarian organisations. An example could be an interview where the interviewee is not telling the truth due to insecurity. A way of reducing the risk of bias is to make the data gathering anonymous. Similar to the subject bias, the occurrence of *observer bias* might be present.

Errors are also a threat to the reliability. Saunders et al. (2007) describes how *subject or participant errors* can occur when data gathering is done at a time when the subjects or participants might be on a "high, thus giving incorrect answers. In the same manner, *observer errors* can be a problem. An example of this may be that different formulations of the same question can generate different answers.

To assure the reliability of the research conducted in this thesis, a case study database was developed to gather all research information and data.

3.8.2 Internal validity

Internal validity refers to the degree of randomness of a result, i.e. if it is a casual relationship or not. Major threats to the validity of a relationship regard history, testing, instrumentation, mortality, maturation and direction ambiguity (Robson 2002, cited in Saunders et al. 2007). Yin (2013) points out that that internal validity is of little concern when dealing with descriptive or exploratory studies. Since no casual relationships are examined in this thesis, no active measures were taken to increase the internal validity.

3.8.3 External validity

External validity, or generalisability is concerned with whether the research is situation specific or if the results can be said to be universal. The latter being the goal if the research's goal is to develop a general theory (Saunders et al., 2007).

As pointed out by Yin (2013), single-cases studies should be supported by theory. The literature review functions as a supporting pillar to the case study. Further, the research questions were formulated before the research design phase, which Yin (2013) claims increases the external validity.

3.8.4 Construct validity

Yin (2013) presents two steps that need to be followed in order to the meet the test of constructing validity:

1. Define neighbourhood change in terms of specific concepts and relate them to the original objectives of the study.
2. Identify operational measures that match the concepts, preferably citing published studies that make the same matches.

In this thesis, the neighbourhood is the investigation of a production process within a pharmacy company focusing on value stream mapping. Operational measures are coherent with VSM measures suggested in literature, see *Section 2.5*.

As seen in *Table 11*, three case study tactics is presented to construct validity. Firstly, collecting data from multiple source that measures the same factor is implying a higher rate of overall quality of the study. A chain of evidence refers to an increase of reliability of the reader, in terms of presenting a clear path from derivation of data to the conclusion of the study. The final tactic involves a participant or informant of the case to review the

study. It is a matter of courtesy, but new material can emerge which the participant or informant earlier had forgotten.

4 Identifying the current state

4.1 Introduction to case

The company is mainly acting as a contract manufacturer, although development and production of one in-house pharmaceutical is present. The owner situations have reformed in terms of breakout of ownership to a new Asian owner. This change of owner structure led to development of own pharmaceuticals. Further, the company is also validating and testing various products but this is seldom affecting the actual production due to small batches.

The customers of the company are spread all over the world, including e.g. the United States and the company is hence approved by the federal agency Food and Drug Administration. Different regulations apply in different countries, making the manufacturing process complex since it has to comply to all standards and regulations of the countries that the company ships to. This also affects the variability of the products and subsequently the components.

Put simply, the company operates a bulk production, a packaging facility, two warehouses and a quality department. The entire organizational structure of the company is showcased in *Figure 18*. As previously mentioned, the bulk production will not be considered at all. The packaging facility consists of a number of rooms designated for various tasks. Some of these rooms or stations are automated, i.e. occupied by machines while others are appropriated for manual labour. The labelling and testing of syringes are conducted automatically with the help of an operator. The actual packaging of e.g. syringes, list of contents et cetera are done completely manually. So is also the folding of the packages.

The company operates two warehouses, from this point referred to as warehouse A and B. The smaller of the two, warehouse A, is situated within the premises of the packaging facility. Due to the nature of some of the substances, there are cool areas as well as locked racks located within the warehouse. This also applies for the larger warehouse, warehouse B, which is situated approximately 8 km from the packaging facility. The variability of the products previously mentioned means that there are many analogous articles, with only country specific differences that are distinguishing them, stored in the warehouses. The vast number of articles needed for the products results in that the warehouse B is crowded and problems with finding empty racks for some articles occur.

Product family C differs from the A and B in two aspects; the expiration dates of all the components must be longer than the final product and two different orders containing the

same product and with the same destination cannot be produced together. This results in even more trouble with the allocation within warehouse B. *Figure 19* shows the entire floor where the packaging facility and warehouse A is situated. The rooms marked with blue depicts where the warehouse premises and red depicts the rooms used by the packaging facility.

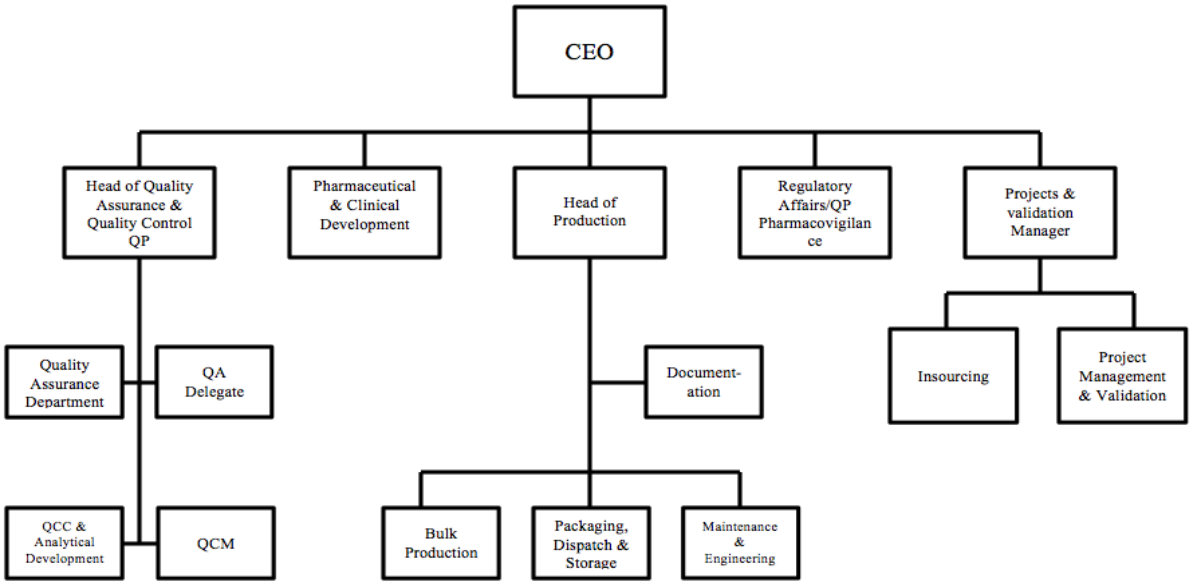


Figure 18: The organisational structure of the company

Due to the nature of the pharmaceutical industry, quality is of uttermost importance. There are two departments concerned with securing the quality of the final products. Since these two departments are so interconnected with the value stream due to the many and rigorous controls, a short introduction to their respective main area of responsibility is required. The quality control department is responsible for controlling paperwork such as packaging orders while the quality assurance department is responsible for conducting tests on material and the active substances. Worthwhile noting is that these two departments have additional responsibilities, but these have no touch points with the considered value stream.

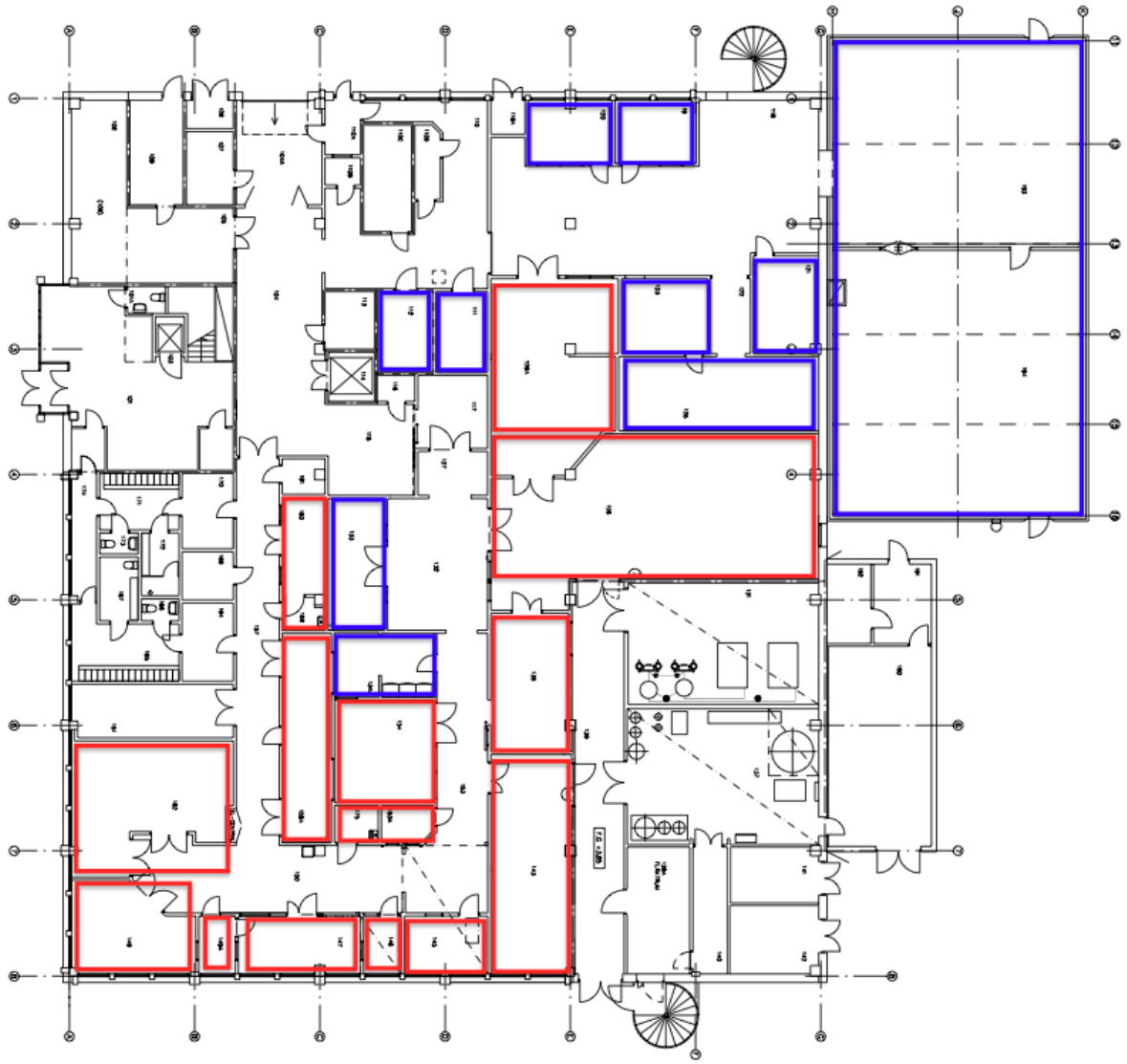


Figure 19: Layout of warehouse A and the packaging facility

4.2 Scope

The first step of creating a VSM is to define the context and the parameters that will characterize the current state map. It will also define the outline of the value stream that is supposed to be mapped. The scope was defined in accordance with the view given by on how to set a scope in the process of making a VSM, which is described in *Section 2.5.1.1.*

4.2.1 Value Stream

From the definition of a value stream, i.e. a chain of activities that a firm operating in a specific industry performs in order to deliver a valuable product or service for the market, the following activities have been identified in the value stream that will be mapped and

analysed. The activities in the list are not arranged in chronological order, since some of the activities occur several times between other activities in the value stream.

- Quality controls
- Official inspections
- Internal communication
- Briefing
- Packaging operations
- Printing labels
- Labelling of components
- Manual folding of primary and secondary packages
- Assembly
- Planning
- Documentation
- Line clearance
- Transport operations
- Warehouse operations

4.2.2 Specific Conditions, boundaries and limitations

Three major specific conditions have to be clarified since these conditions have a great impact on how the value stream is investigated. Firstly, the SOPs regarding official inspections are governed by cGMP and can therefore not be altered. This argument applies for a great deal of the operations conducted in connection to the concerned value stream. The specific influence of cGMP is in this state of the study is unknown because of the current early phase in the mapping process.

Secondly, some of the product variations, namely the country specific differences of the secondary package and list of contents, are not considered. Some of these variations are affecting the operational procedures, but the level of influence is considered negligible.

Thirdly, the entire production process will not be included. The bulk production, i.e. the production of the drug substances is not included in the value stream that is investigated. The underlying reason for it has previously been described. It does however have a great impact on the view upon the value stream and therefore it is important to remind the reader of this condition.

4.2.3 Trigger, first and last step

The chosen product families (see *Section 4.2.5* for the selection) were all found to have similar activities that initiate the first step of the value stream. The trigger, last- and first step of the value streams connected to respective product family are shown in *Table 12* below.

Table 12: Trigger, first and last step

Product family	Trigger	First step	Last step
A	Order is received	Inventory check	Delivery note
B	Order is received	Inventory check	Delivery note
C	Order is received	Inventory check	Delivery note

4.2.4 Improvement Time Frame

The improvement time frame was set to a maximum of one year. This number was set through consulting one of the managers at the company. Since this thesis does not cover the actual implementation of the proposed changes, the time frame will function as a delimitation of the extent of improvement suggestions.

4.2.5 Product families

The company produces a few number of products, but the product variability previously discussed is high. A product that is destined for a large number of countries can in some cases be customized for each country. The customization is however almost exclusively limited to the list of contents and the secondary package. The processes will thus look the same from a VSM point of view.

Some of the products that the company produces are sold in bulk, i.e. they are not affected by the packaging process. These products are not considered since it is outside the limitations given by the company. Consequently, only products that are subjected to processing within the packaging area were considered. By not taking account to the product variation as well as the bulk products, the choice of product families was narrowed down to just a few candidates. When the products respective value streams were studied in detail, significant differences were found compared between vital process steps. Further, due to the limited process, i.e. bulk production not being considered, and the few products available to study, it was concluded that a product family matrix was redundant. By

grouping products, the problem could be oversimplified and a risk that vital process steps could be overlooked would be present.

A Pareto diagram was created through extracting sales orders for the remaining products dating from 2016-02-01 to 2017-02-01. The diagram is shown in *Figure 20*.

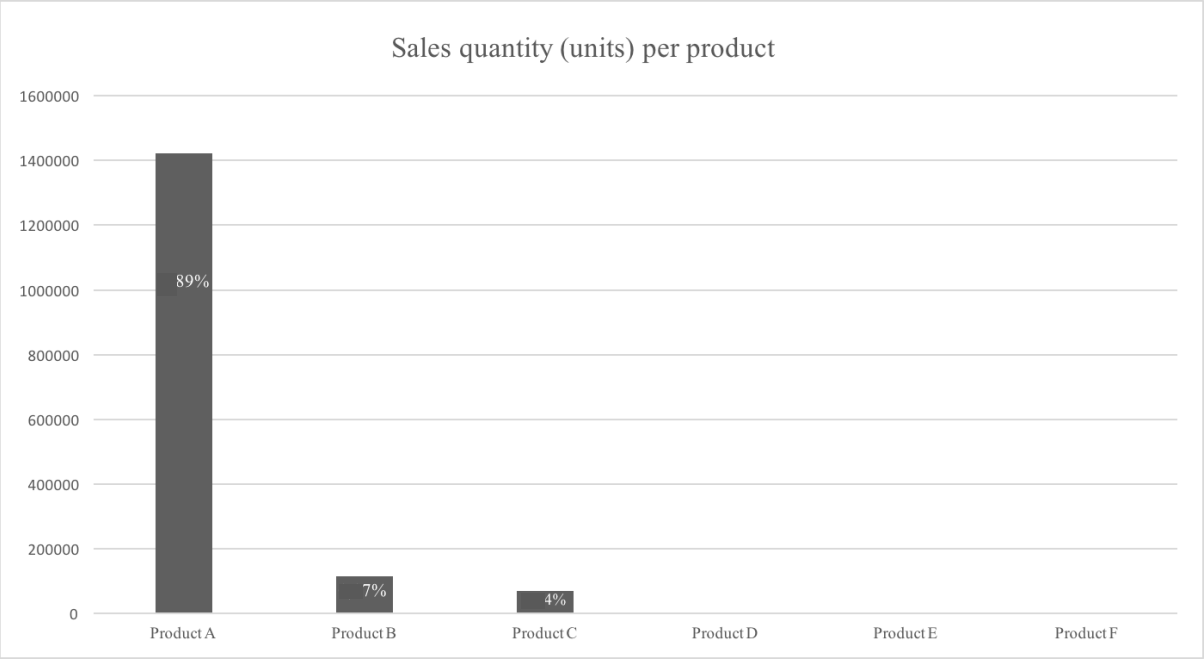


Figure 20: Sales quantity for each product. The percentages correspond to the share of the total volume

Accordingly, to an ABC analysis, product family A, B and C are corresponding somewhat to the principles of such an analysis. Given the limitations by the company and the Pareto analysis above, product family A, B and C will be comprised in the further investigations. Products D, E and F had no, or very small order quantities over the chosen time period. This was also confirmed by the employees of the logistics department. Because of the low sales volume for these products and consequently low impact on the company's revenue, these products are left outside this study.

4.2.6 Mapping the current state

The mapping of the current state was conducted in two major steps. The first step included information gathering through interviews with employees of each department of the company that has touch points with the value streams of the concerned product families. Information was also extracted from the internal information system. The second part of the mapping was done through conducting gemba walks in the packaging facility as well as the warehouses. During the gemba walks, questions were asked to the employees to clarify certain steps of the processes. The VSM for each product family were then created from the information gathered.

The VSMs depicts the flows from a medium detailed perspective. The purpose of the VSMs are to provide a holistic overview of the processes. This overview can then be used as a basis for strategic decisions. Next, the responsibilities of the departments that have touch points with the topical value streams are clarified. An extended explanation of some of the process steps are also necessary to give the reader a more comprehensible view of what the lead times are comprised of.

4.2.7 Logistics department

The logistics department, situated on the third floor, are responsible for a number of activities. The department is comprised of three employees. One of the employees are more involved in order receiving and outbound logistics. The other two employees are more focused on placing orders, forecasting et cetera. One of their main tasks is also to maintain contact with the customers and establish a foundation for the relationship between the company and its customers. This includes receiving forecasts, orders and also to update forecasts and orders to give their customers flexibility.

Further, the logistics department places internal and external purchase orders and plans the availability of material. All of the internal orders are placed in an information system and thereafter printed and delivered in person to the packaging department which is situated on the first floor of the building. Some of the components in the pharmaceutical products are managed by the customers, i.e. a form of vendor managed inventory. Other materials are purchased by the employees in the logistics department. These external purchase orders are also registered in the information system.

While the logistics department are monitoring all material flows, internal purchase orders are placed. Based on stock levels of the components and semi-finished products, three different kinds of internal orders are placed; mounting orders for product family C, packaging orders for product family A, B and C, and eventually a pack order for all products families. When an internal purchase order is placed, components like list of contents, boxes, syringes, labels et cetera are allocated in the information system. The information system shows on hand quantity at all the pallet positions in the two warehouses. The allocation of material is locked to a pallet position, i.e. moving a pallet from one warehouse to the other will not change the allocation position, but the on hand quantity will change.

The logistics department have touchpoints with the following functions of the company in connection to the considered value streams; quality assurance, quality control, packaging department and the warehouse employees. A lot of intra communication within the

logistics department also take place. The communication mainly takes the form of e-mails and phone calls. Two of the employees of the logistics department have a pulse meeting which lasts 30 minutes with the head of the packaging department and members of the quality department every week. The reason for this meeting is to resolve issues and coordinate the status of the packaging efforts as well as the approval of certain material and orders. In addition, a pulse meeting is scheduled every day at 14:00 between two members of the logistics department and the team leaders in the packaging department. This meeting is due to report the status of batches and to report issues.

A generalised picture of the logistics departments work tasks are shown below in *Figure 21.*

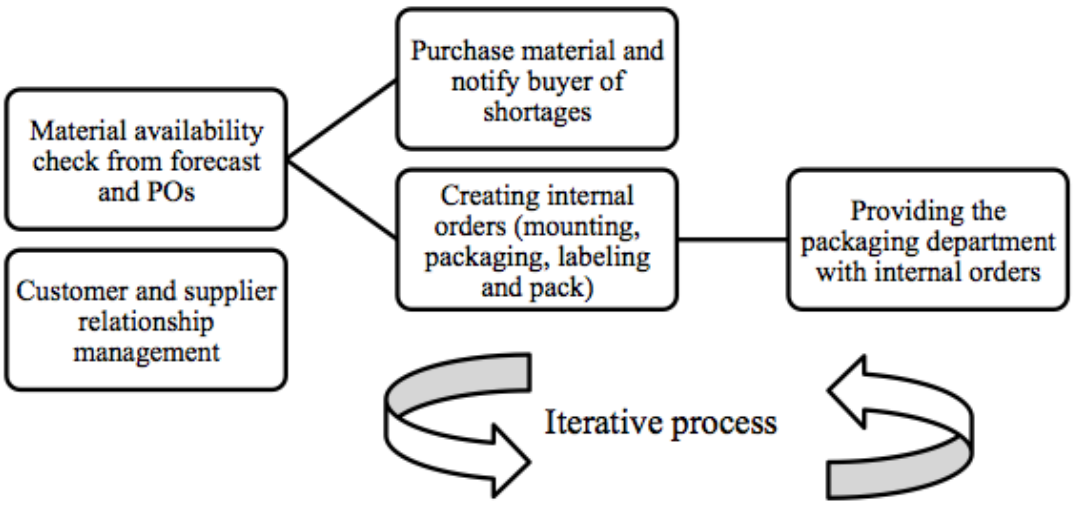


Figure 21: The logistics departments work tasks

4.2.8 The packaging department

There are 23 people working in the packaging department. Apart from the head of the packaging department, the production manager, there are three team leaders that coordinate the work of the operators. Since the activities performed in the packaging facility differs between the three product families, a description of the activities will be formulated for each of the three. The planning and confirmation of orders are however conducted in the same way for all product categories.

When the order arrives at the packaging department, one of the team leaders will receive it. If the packaging facility has available capacity, the packaging order will be initiated immediately. If no capacity is available, a team leader will plan for when the packaging order should be carried out. The orders with the closest delivery date are prioritized. When the packaging order is to be carried out, the team leader starts out by examining the

order, i.e. checking that the documentation is correct and that the right items are listed. The team leader then hands over the packaging order to a member of the quality assurance department for approval. While the packaging order is examined by the quality assurance department, the team leader prints out a picklist which he then hands over to the warehouse employees. Sometimes, the machines used has to be adjusted. If this is the case, the team leader has to call a technician who comes down and adjusts the machine properly. Once the order is approved and all material is transferred to the small warehouse, the actual packaging can begin.

When a packaging/mounting order is completed, the operators will return documentation in accordance with a number of SOPs. One of the team leaders will then go through the documentation, debrief the material and approve the order. This task takes roughly 2,5 hours. The documentation will be handed to the quality assurance department for further scrutiny.

4.2.9 Quality assurance department

The quality assurance department will have two touch points within the value streams. First, an approval of all packaging/mounting orders are required. This is conducted in the packaging facility where the quality assurance department has a designated room for controlling orders. A member of the quality assurance will be present at 10 A.M every day and control all orders that has been handed to them by the packaging department. This process takes roughly 15 minutes per order.

When an order is finished, i.e. the finished products are moved to warehouse A and the documentation is controlled by the packaging department, the quality assurance department has to approve the batch. This is conducted in a similar manner as controlling the orders. The paperwork is however more extensive and the process of approving a batch therefore takes roughly 30 minutes.

When the quality assurance department approves an order or a batch, it has to be registered in the information system. Before an order or batch is approved, it will have status Q. This means that the order cannot be initiated or that the finished products cannot be the subject of transaction within the system. Once the quality assurance department has approved an order, it can be given two different statuses, namely QP and A. Both of these statuses will make it possible for the packaging department to start the packaging process. The status QP however indicates that for example the bulk product, i.e. the active substance, might not have been approved yet and the packaging process is conducted with the risk of a deficient bulk product. If the order is given status A,

everything is approved and no risk of deficient material is present. A batch can only be shipped if it receives the status A.

4.2.10 Warehouse activities

4.2.10.1 Warehouse A

Warehouse A is located within the same premises as the packaging facility. It holds roughly 250 pallet positions and 130 shelf storage positions. Around 150 of the pallet positions and 60 of the shelves are located inside a freezer. The pallet locations have a single deep rack design and all pallet positions are shared. Just as in warehouse B, the storage follows a FIFO principle.

Almost all material that enters warehouse A is shipped from warehouse B. Once the packaging department receives confirmation from the warehouse operators that all material is in warehouse A, the packaging operators can pick the material. Once the material is picked, a packaging department team leader is supposed to change the status of the material to work in progress in the information system.

Due to the limited amount of storage positions in warehouse A, the packaging department must have forward planning when ordering material so that the warehouse operators are able to get them the material in time from warehouse B. If the packaging department orders material too early, warehouse A will become full. If no planning is done, the risk of waiting for the material to arrive is imminent.

As only pallets or boxes can be picked from warehouse B, there will be broken cartons present at warehouse A. These small quantity boxes are either shipped back to warehouse B or left in warehouse A.

4.2.10.2 Warehouse B

Warehouse B, situated 8.5 km from the production facility, is the company's largest material storage centre, containing approximately 1300 location of which a majority (1000) is pallet positions and a minority (300) shelf storage places. A heat map is presented in *Figure 22*. The figure demonstrates the most visited sections of warehouse B. All the pallet locations have a single deep rack design and all pallet positions are shared. Additionally, the warehouse facilitates a cooling room for raw materials that require a low temperature to avoid being obsolete. Except for some smaller components such as labelling material, all inbound logistics from suppliers are being handled at warehouse B. Special outbound activities regarding only one product for the American market occur at this facility. As a consequence of cGMP, every article and every unique batch of each article must have an

own location. Further, there are some left over machinery stationed at warehouse B which takes up some of the pallet positions.

All material handling in warehouse B involves cartons of different sizes or full pallets. Two counterweight forklifts are available for picking. The pallet used are EU-pallets and the most common height of the pallet racks are three pallets. However, a few racks have one or two additional levels and can thus fit four to five pallets in height. Each transaction, i.e. each pick and put away, is recorded manually by the warehouse operators in the information system.

Today, the picking lists are handed over from the packaging department to the warehouse operators after they have received a packaging order from the packaging department. Almost all material is picked according to a FIFO-principle due to the strict requirements on expiration date. However, the customers can sometimes specify a batch of a material for production. The packaging order is first approved by the packaging department and later the quality department. When it is approved by both parts, the packaging department hands the picking list to the warehouse operators. The warehouse operators receive the picklists on a daily basis but they are handed over at random moments and often with urgent delivery schedule. The material is moved from warehouse B to warehouse A where the material can be picked by the packaging department employees. It takes roughly 30 minutes for the operators to drive to the warehouse and another 30 minutes to finish a picklist.

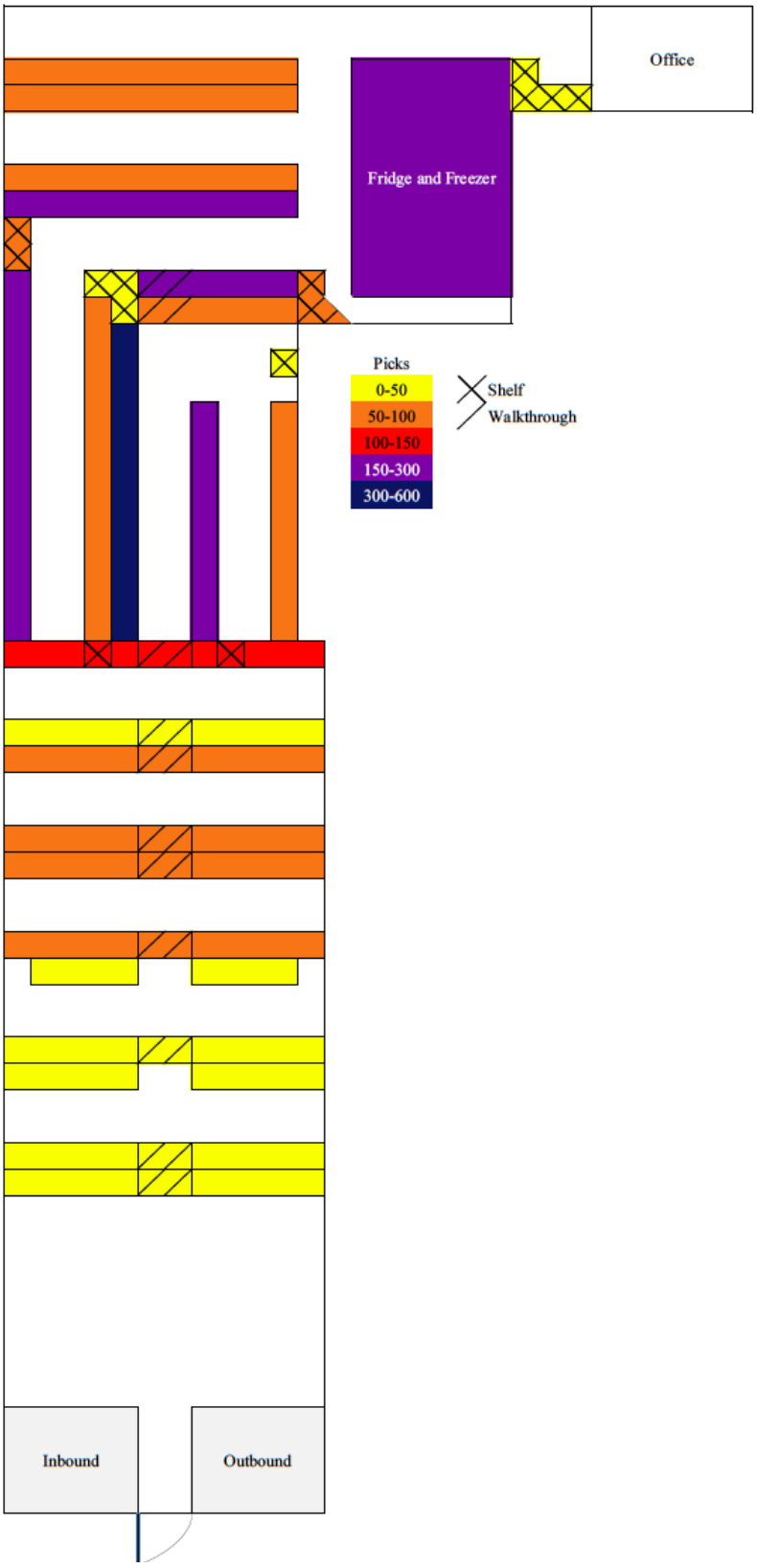


Figure 22: Heat map over Warehouse B

4.2.11 Product family A

Once a packaging order for product family A is triggered, the products will be refined in the different process step. Product family A is produced based on a six month forecast with a three-month frozen period. However, changes within the frozen period often occurs.

The first packaging process, i.e. labelling of syringe shown in *Figure 26*, starts with a line clearance SOP which is presented on the packaging order. The line clearance is done for each of the three packaging process steps. Once the line clearance activity has started, the second operator go to warehouse A and collect all the material for the packaging order. The other two processes are then initiated; labelling of secondary package, printing batch information and the final packaging. The processes are conducted in the order presented above, but occasionally labelling and printing are executed in parallel, i.e. overlapping. In some instances, the labelling of secondary package process precedes the labelling of syringes. The intention of the production of product family A, is to have these processes overlapping as often as possible. As products get ready during the final packaging process, they are transported in boxes á 1760 syringes, to warehouse B. In *Figure 23, 24* and *25*, the three packaging processes for product family A are further explained.

Once the batch is fully produced, the operators compile documentation and performs a count of the remaining material. The left-over material is returned to warehouse B and the documentation is handed over to the team leader who then debriefs the material from the information system. The documentation is eventually handed over to the quality assurance department for approval. The VSM of product family A is presented in *Figure 26*.

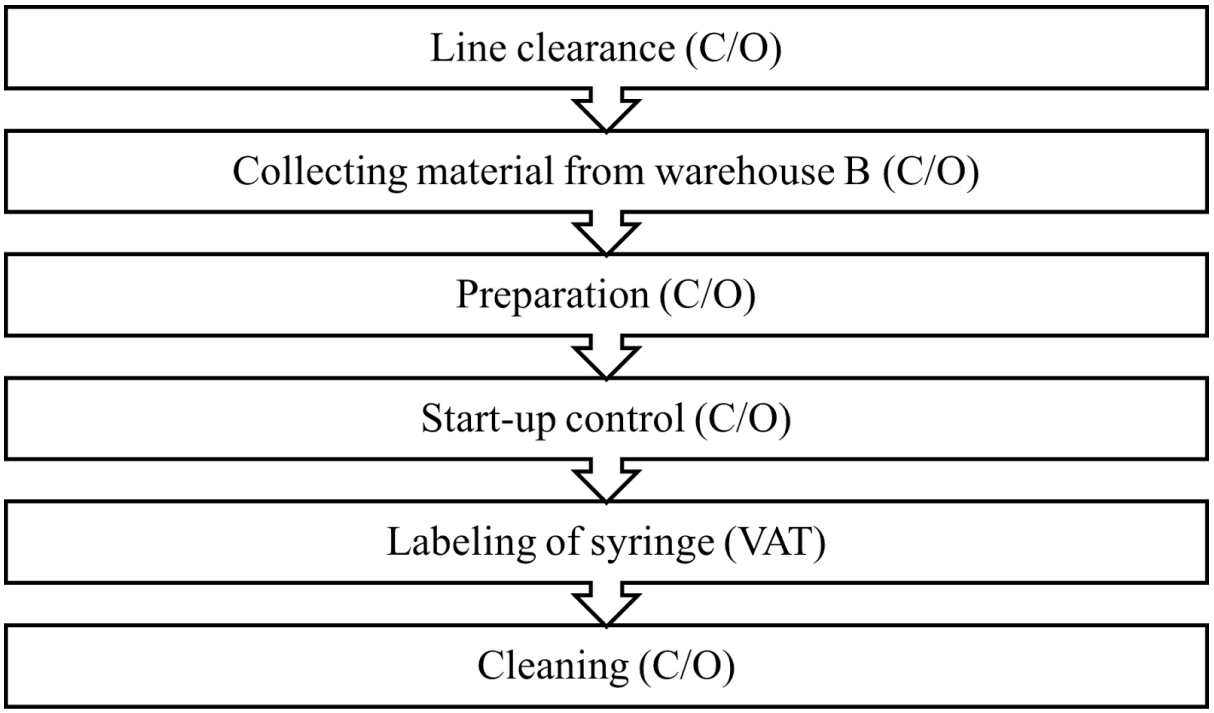


Figure 23: Labelling of syringe for product family A

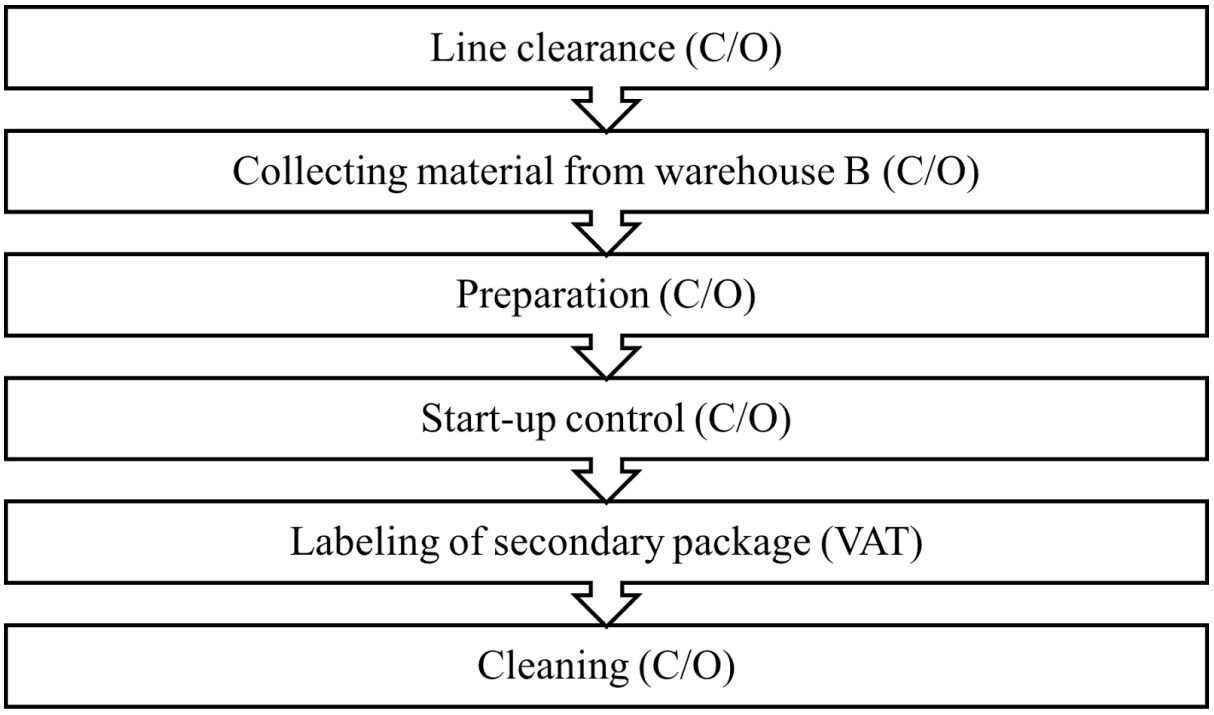


Figure 24: Labelling of secondary package for product family A

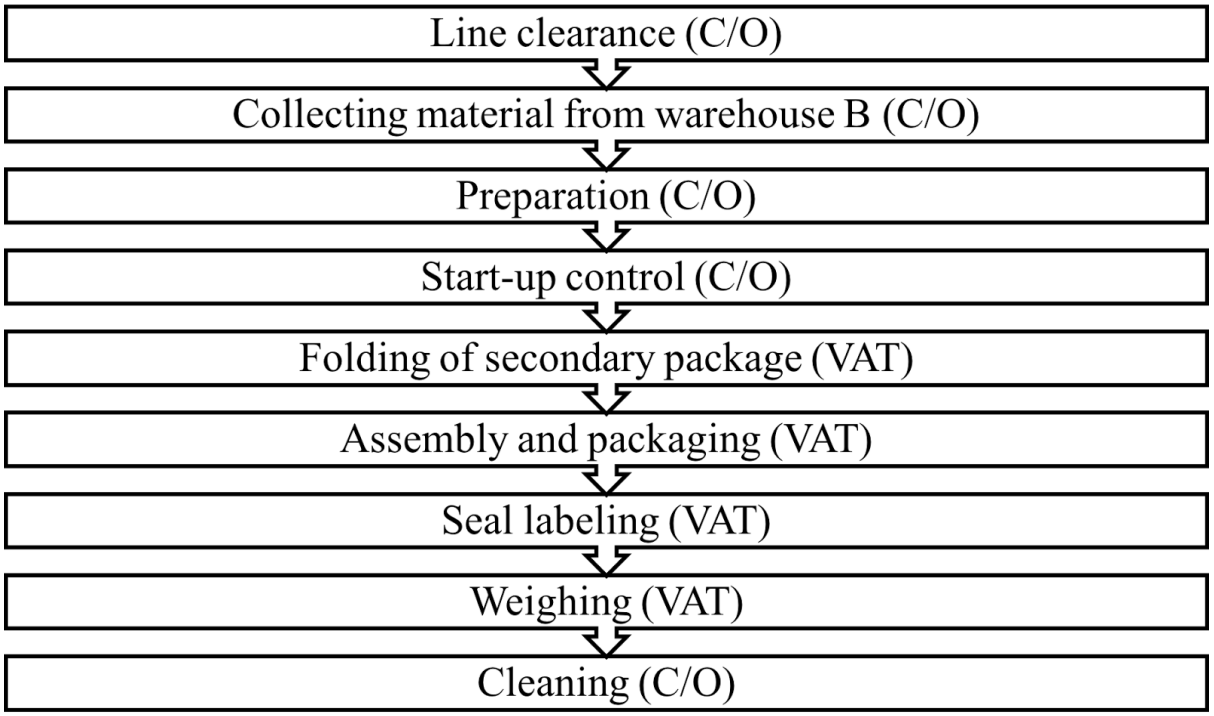


Figure 25: Final packaging for product family A

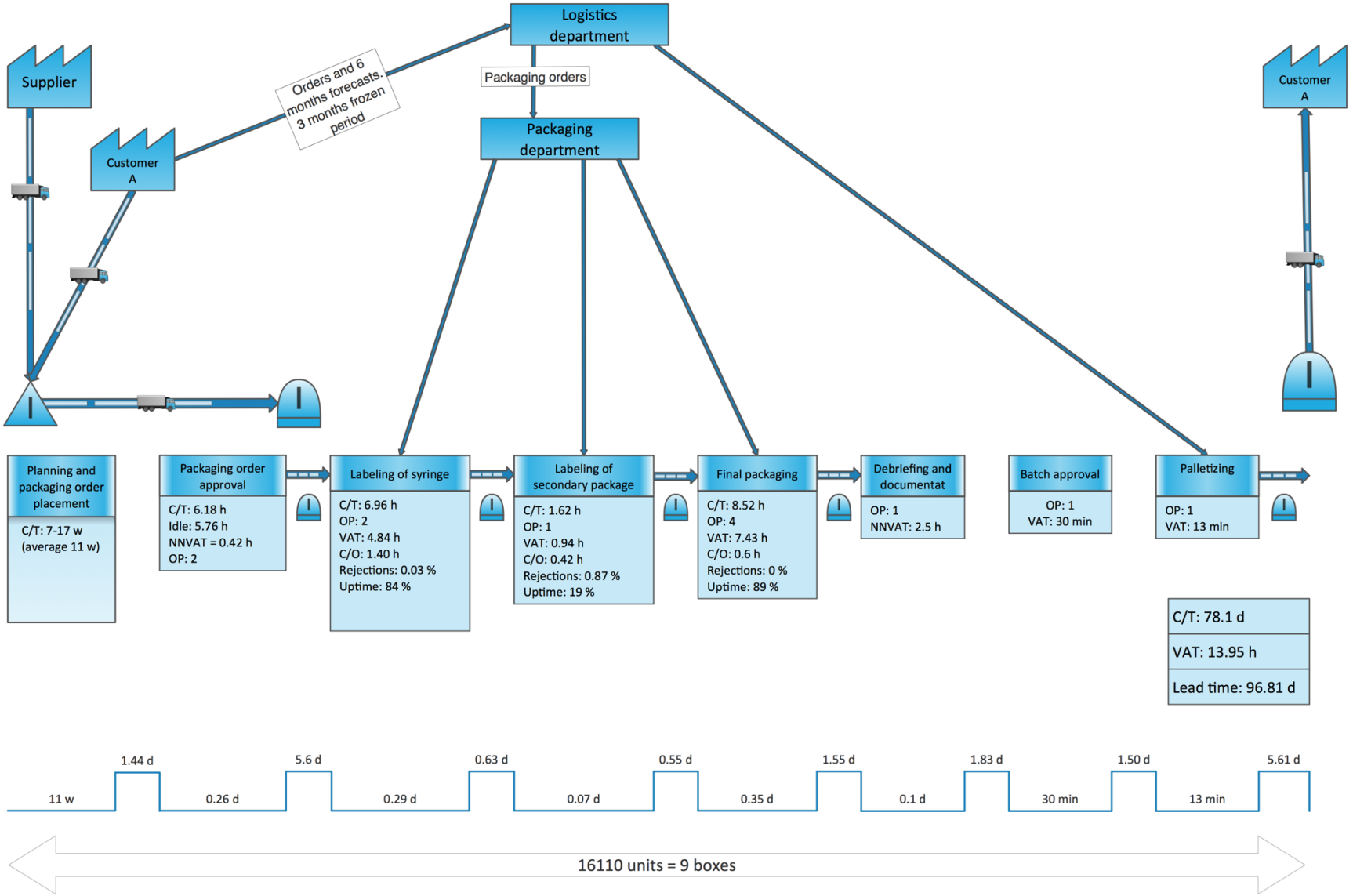


Figure 26: VSM of product family A

4.2.12 Product family B

Product family B is finished in two different steps. First, an internal labelling order is issued by the logistics department which is based on a forecast stretching six months. The process of approving the order, line clearance, et cetera is exactly the same as for product family A and B. Once the syringes are labelled, the operators compile the documentation, count the material, move left over material out to warehouse A and delivers all documentation to the team leader who forwards it to the quality assurance department. However, since the labelling order are not triggered by a customer order and the fact that it is only executed approximately two times per year, this process is not considered.

The second step is initiated by a packaging order. The pre-packaging process looks exactly the same as for product family A and B. Product family B goes through a two-step packaging process; labelling of the vials and assembly of belonging accessories and finally the packages are labelled in a machine, see *Figure 27* and *28*. As the products get finished, they are moved out to warehouse A successively. When each step of the process is finished, a line clearance is initiated and the operators compile documentation and performs a count of the remaining material. The material is returned to warehouse A. The complete documentation is handed over to the team leader when the order is fully produced, who then debriefs the material from the information system. The documentation is handed over to the quality assurance department for approval. The VSM of product family B is shown in *Figure 29*.

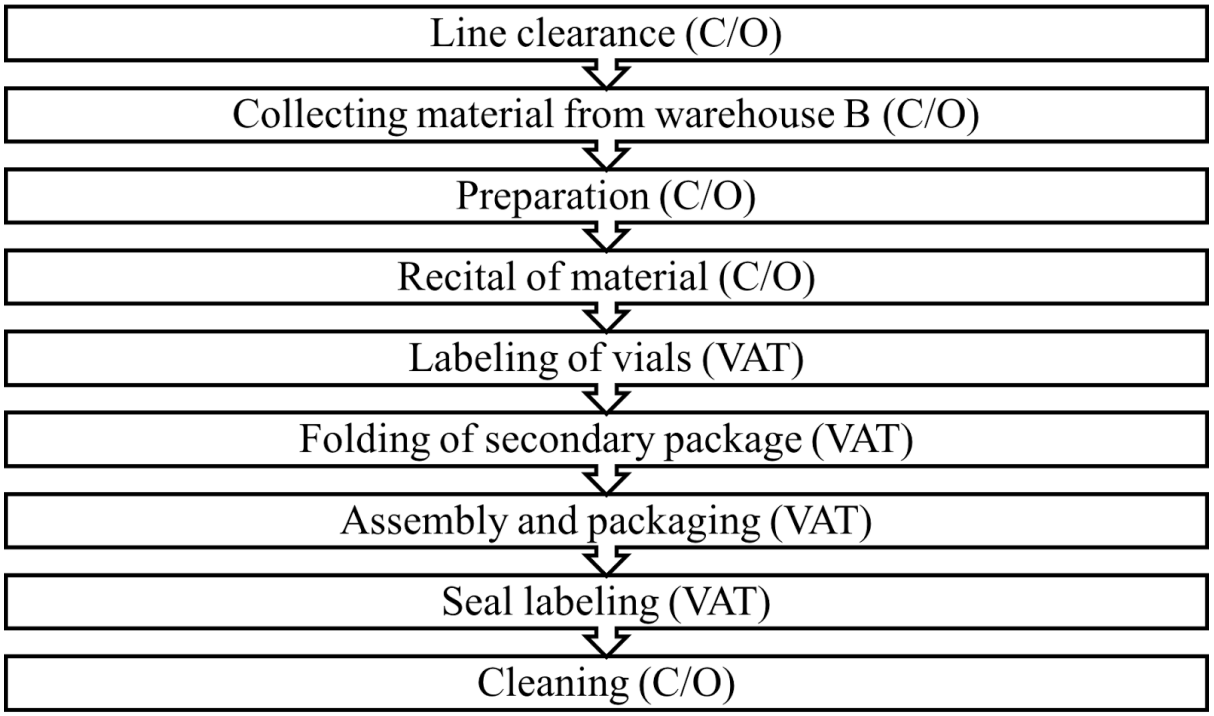


Figure 27: Labelling of vial and assembly for product family B

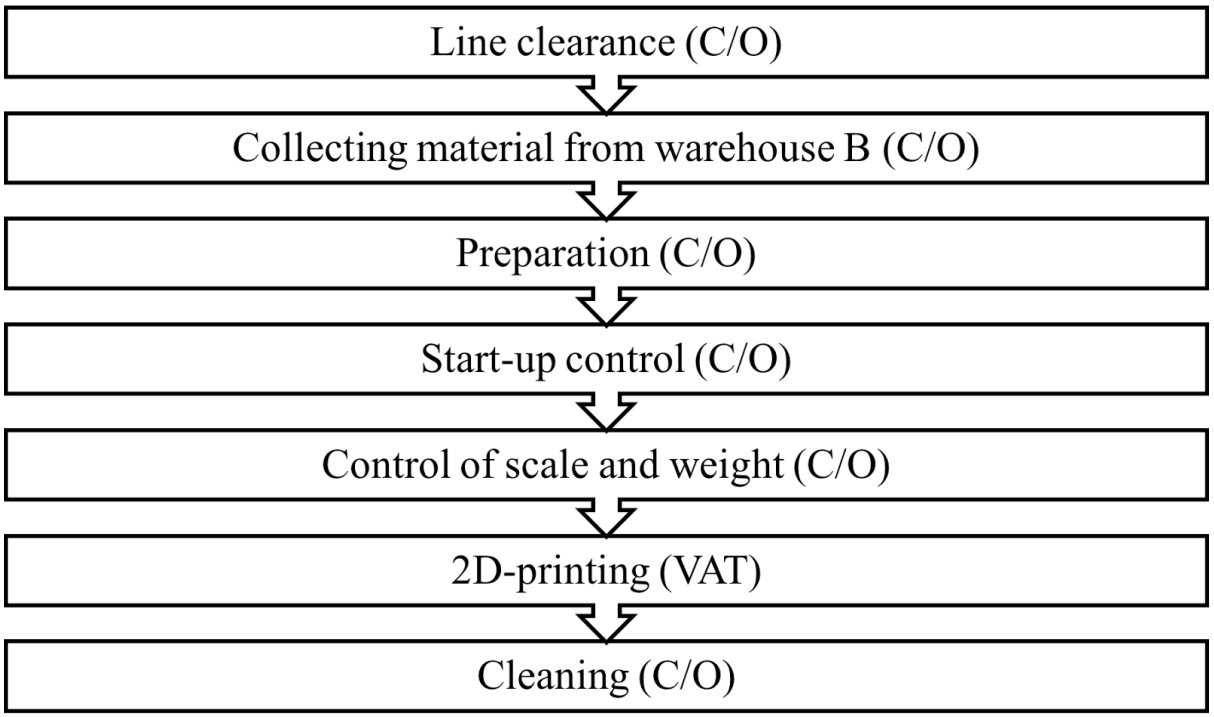


Figure 28: 2D-printing for product family B

Figure 29: VSM of product family B

4.2.13 Product family C

Product C is finished through two internal packaging orders, instead of one as for product family A. The first step is the mounting of an auto injector. The mounting is initiated by a mounting order, based on customer orders, issued by the logistics department and handed to a team leader at the packaging department. A mounting order can be done for several batches regardless of unique country specifications. If the packaging facility has available capacity, the mounting order will be initiated immediately. If no capacity is available, the team leader will plan for when the mounting order should be carried out. The team leader proceeds with examining the mounting order and handing it over to the quality assurance department for another examination. The team leader hands over a picklist to the warehouse employees. Sometimes, the machines used has to be adjusted. If this is the case, the team leader has to call a technician who comes down and adjusts the machine properly. Once the order is approved and all material is transferred to the small warehouse, the actual mounting can begin.

The mounting process starts with a line clearance SOP. Once the line clearance is finished, the operators go to warehouse A and collect all the material for the mounting order. The mounting is most often conducted by two operators who control two machines. When the order is finished, a cleaning procedure is initiated and the auto injectors are moved to the warehouse. Compilation of documentation and a material count is initiated before handing over the documentation to the team leader and returning the remaining material to the warehouse. The team leader sends the documentation to the quality assurance department and debriefs the material from the information system.

The first of the two steps is now finished. For a full content of the mounting process, see *Figure 30*. Once the quality assurance department has examined the documentation, the auto injectors are approved. Before the approval, the auto injectors cannot be accessed in the information system. This means that the logistics department cannot initiate the second step, namely a packaging order, before the quality assurance has approved the documentation.

In like manner as the mounting order, the packaging order is approved by a team leader and the quality assurance department at the packaging facility once capacity is present. Picklists are printed and handed to the warehouse employees and once material is on hand, line clearances are initiated and operators ventures to warehouse A to collect the parts needed for the order. The auto injectors now move through the final packaging process, see Fig*ure 31*. The packages are folded simultaneously or before the process starts. As the

products get finished, they are moved out to warehouse A successively. When the last step of each process is finished, a line clearance is initiated and the operators compile documentation and performs a count of the remaining material. The material is returned to the warehouse; the documentation is handed over to the team leader who then debriefs the material from the information system. The documentation is sent to the quality assurance department for approval. The VSM of product family C is shown in *Figure 32.*

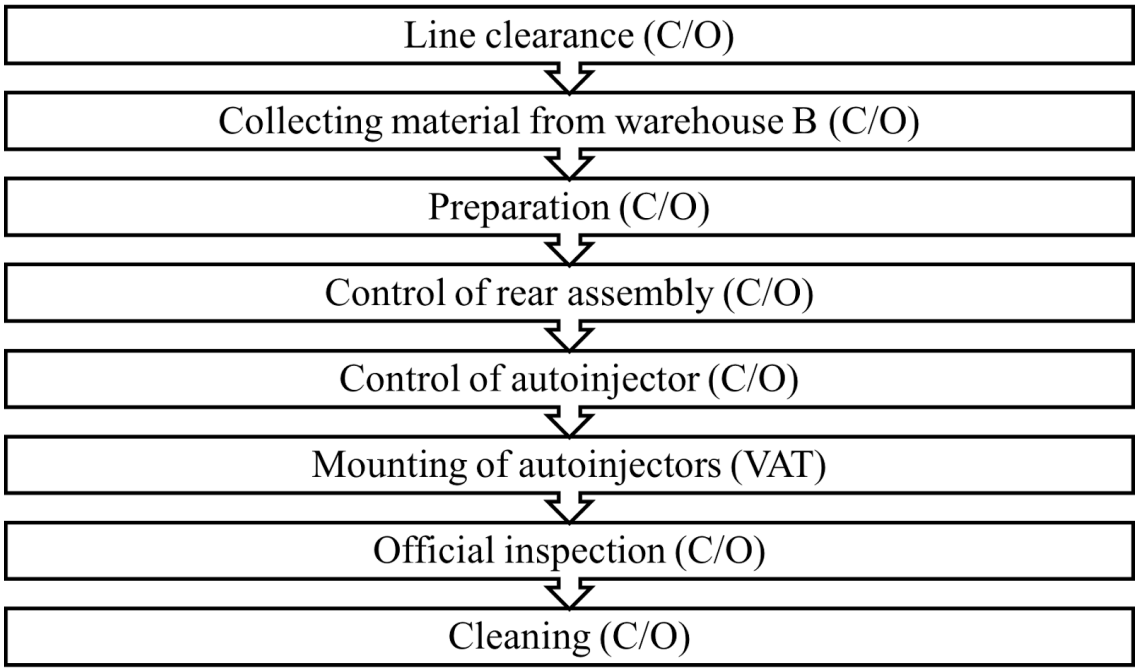


Figure 30: Mounting for product family C

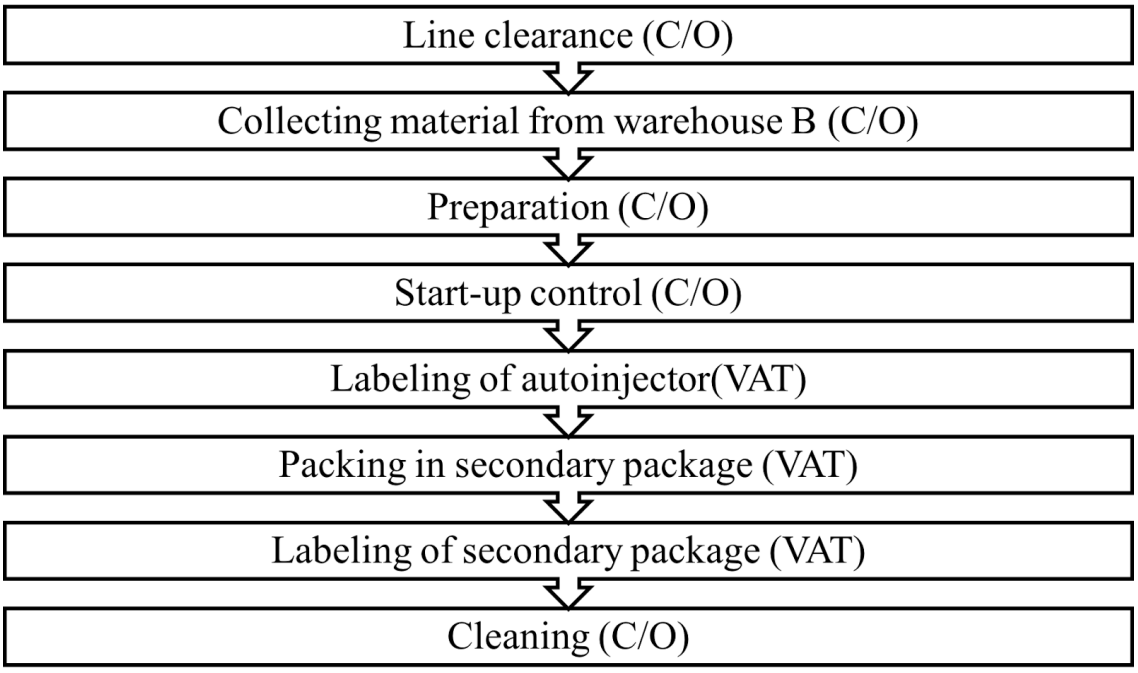


Figure 31: Final packaging for product family C

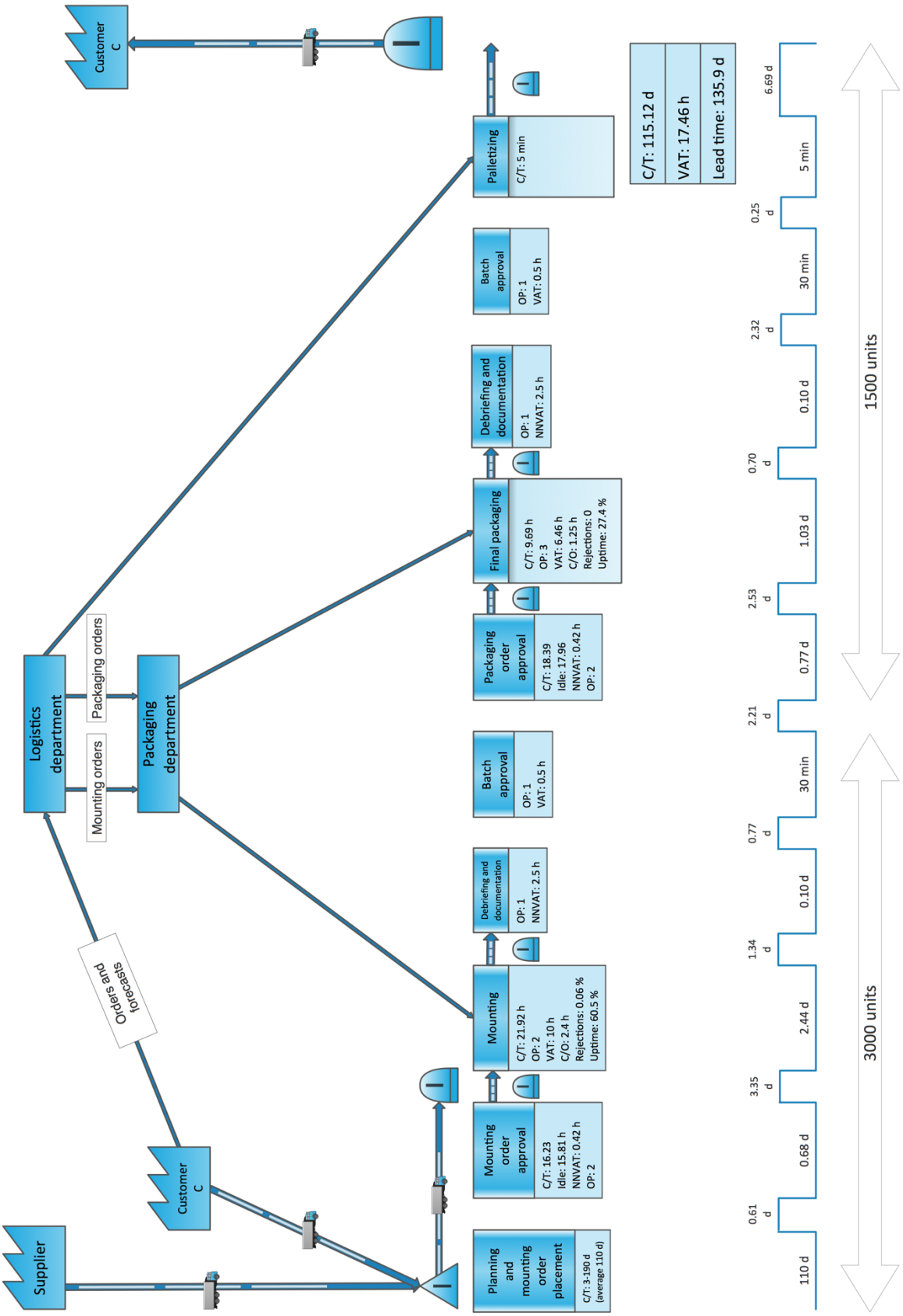


Figure 32: VSM of product family C

5 Analysing the current state

The VSMs presented under *Section 4.2.11-13* were analysed as well as the data regarding picking history and the heat map over warehouse B. The analysis of the value stream maps was almost entirely based on problem identification and the adaption of various lean tools. The warehouses were analysed in a similar manner; however, a more statistical approach could be utilized due to the data that had been gathered.

The discrepancies and areas which were found to have contingent improvement potential were identified as areas where different kinds of waste occurred. Consideration was taken to if the operation or process was value adding or not, i.e. the nature of necessary but non-value adding activities were considered. This does especially apply to the contextual limitations of cGMP. For example, both the packaging department and the quality assurance department has to approve the documentation when a batch is finished. This could be considered as a wasteful activity, however it is necessary according to cGMP. The identification of waste was conducted with the help of *Table 4*. Next, all the wasteful activities are described. The type of waste present is clarified in the description of the problem.

5.1 Unnecessary occupation of space

During the gemba walks in the packaging facility and warehouse B, two cases of unnecessary occupation of space became apparent. The inefficient usage of space is wasteful considering the issues that the company has regarding limited space in the first place. This applies to both warehouse B and the packaging facility. The two cases of unnecessary occupation of space will now be further explained.

5.1.1 The packaging department

The packaging departments unnecessary use of space is especially unfortunate. The situation regarding limited floor space is most urgent here. Due to cGMP regulations, only one order or batch can be processed in each room. The room used for the final process step, *Labelling of vial and assembly* (*Figure* 29) for product family B boasts both a machine which is used to print a label on the vials as well as a designated hand-packing area. The machine, which covers a large part of the room is only partly in use. The rest of the machine is not used but is still kept in the room. This can be seen as waste since it takes up valuable space and therefore acts as a bottleneck for the production capacity labelled as "waiting" in *Table 4*. *Figure 33* shows the room in question. The green marking depicts

the part of the machine that is in use, while the black marking shows the rest of the machine that is not used.

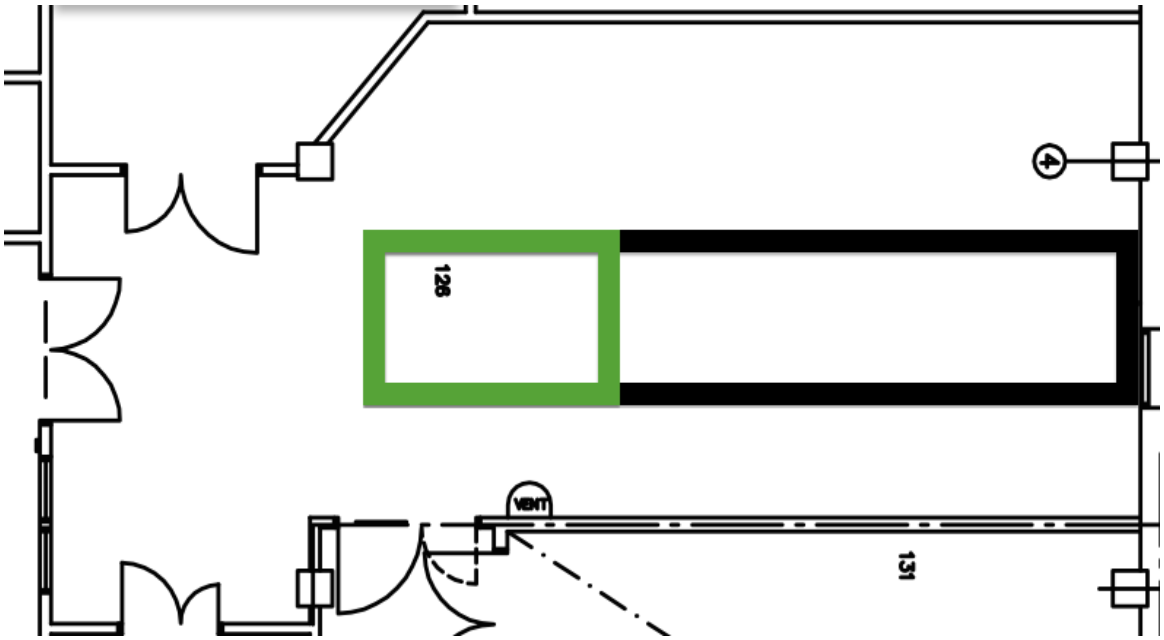


Figure 33: Machine position in the packaging department

5.1.1.1 Warehouse B

The utilization rate in warehouse B is currently high and the warehouse operators was also pointing this out as an issue. The utilization rate was calculated to 84,6 percent which shows a snapshot from the warehouse. According to the warehouse operators, the data was collected on a day when the utilization rate was relatively low. As the company is growing, the utilization issue will probably increase over time. The snapshot of the utilization in warehouse B is shown in *Table 13*.

Table 13: Snapshot of the utilization in warehouse B

Type of storage	**Total number of storage positions**	**Number of storage positions occupied**	**Utilization rate (%)**
Pallet positions	1000	846	84,6 %
Shelves	300	254	84,6 %
Grand total	1300	1100	84,6 %

There are two cases of unnecessary use of space in warehouse B. Firstly, the area behind the outbound area in the warehouse is currently used to store various old machines that are no longer in use. *Figure 34* shows the approximate space occupied by the machines which is marked in black.

The second case of unnecessary space usage also relates to outdated equipment. Again, old machines are stored on pallet positions in one of the sections of the warehouse. *Figure 34* highlights the sections where the machines are stored with black colour. The first black area is denoted with "1" and the second with "2".

Both cases of unnecessary space usage presented in this section were considered to be of the type "waiting" found in *Table 4*. This is because the unnecessary space usage ultimately will lead or leads to bottlenecks. It could arguably also be classified as a "transport" waste since it can lead to double handling in the warehouses due to lack of storage units.

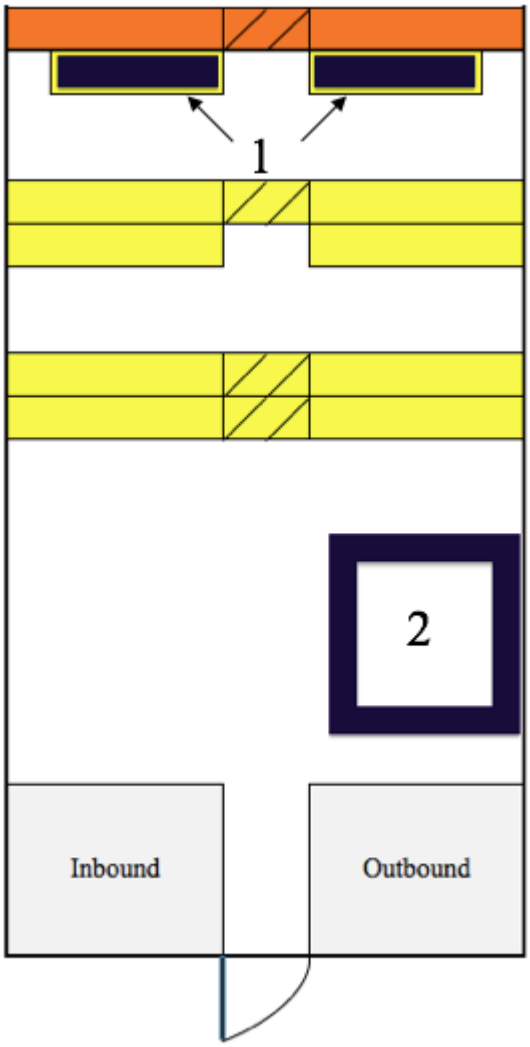


Figure 34: Unnecessary usage of space in Warehouse B, marked in black

5.1.2 General about the packaging facility

The packaging facility's current layout is well planned when considering the perimeter. The floor that is occupied by the packaging facility is also shared by warehouse A and a number of service rooms. As previously mentioned, the issue with increasing order quantities and little free capacity has to be resolved. Therefore, it is questionable if some of the service rooms really has to be located on the same floor and thus take up valuable space that instead could be used by the packaging facility. The service rooms were thus also considered as waste in the form of a bottleneck connected to the production capacity, i.e. waste classified as "waiting".

5.2 Allocation of material

The allocation issue was considered as a waste since it creates bottlenecks and double handling of both material and information, i.e. "waiting" and "transport" waste. To begin with, this problem originates from a lack of sufficient data support. The root cause of the problem is the system's tendency to allocate warehouse locations instead of the material that is on that location. Subsequently, if a location is allocated, implicitly the material on that location, and the material is moving to another location - the allocation of the first location is released and the material appears in the system as unallocated. One example of the problem is visualized in a process map, see *Figure 35*. This unfortunate issue is most apparent when material is transported from warehouse B to warehouse A for production.

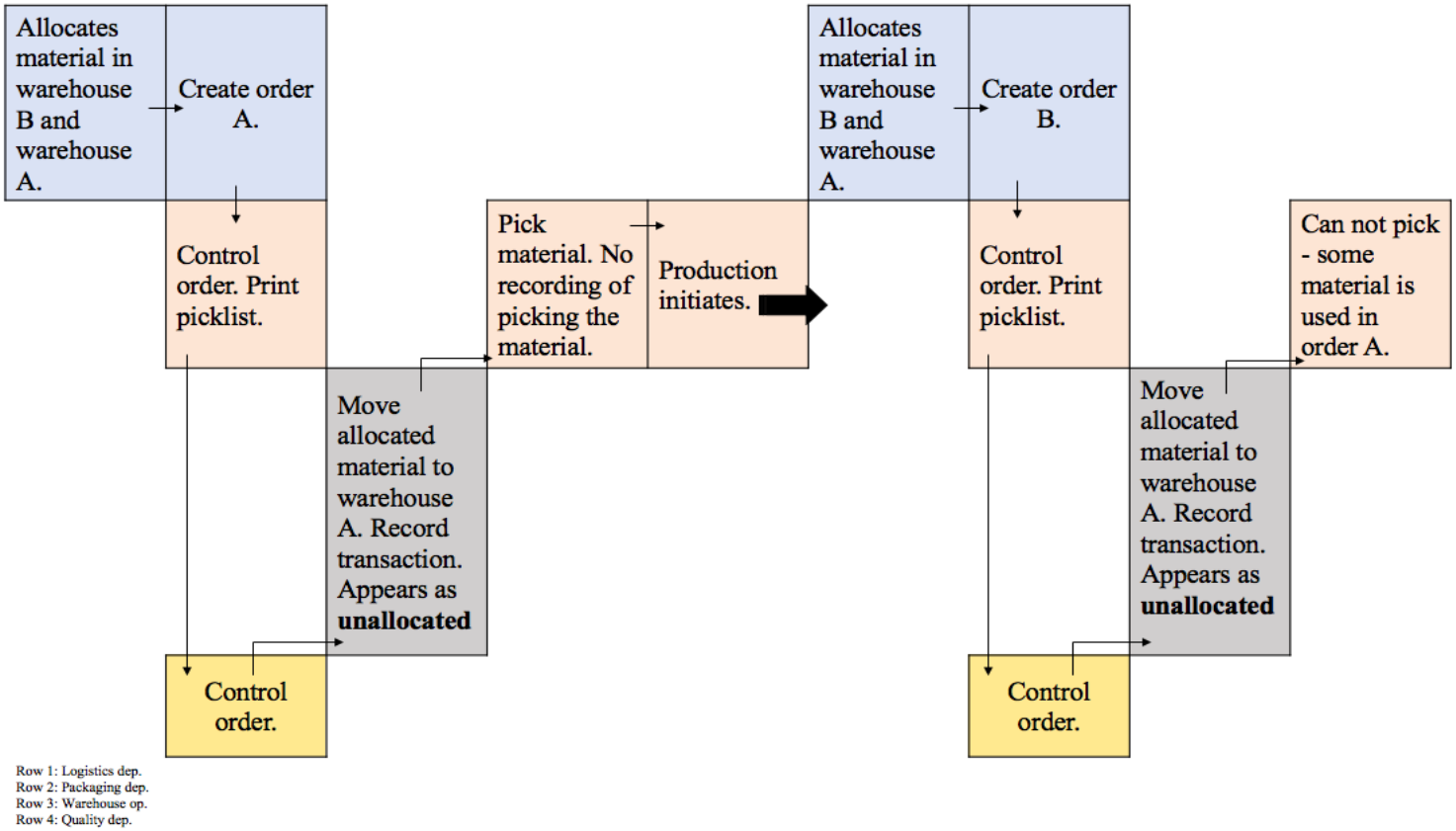


Figure 35: Example of a result of the allocation problem

To further clarify what is happening in the figure above, the logistics department has mistakenly allocated the same material twice, i.e. a double allocation of material. This consequence is not the only problem that occur because of this issue. In the process of placing a packaging order, the logistics department have to double check previous orders to be fully sure of what material is available. Obviously, it is not enough to just check the stock levels, i.e. it can be unallocated material but used for another order, but also track exact amounts of material that was allocated weeks ago. It is a time consuming procedure and the flaws in the system are not adjusted by this double checking - the double allocation is still happening over and over again.

It is the packaging department's responsibility to create and print picklists, as demonstrated in *Figure 35*. It has earlier been stated, but the picklists concern material flow between warehouse B and A. The team leader in the packaging department have to assure what material in warehouse A is available before creating a correct picklist. This is a very time consuming procedure, partly responsible for the long lead time from order placement to the actual beginning of the production. The team leader in turn also perform a double check, i.e. controlling what unallocated material in warehouse A that actually is available. The final step for the team leaders in the production process is the debriefing of material. The debriefing activity is prolonged due to the allocation problem. The

information system proceeds from the moment the material was allocated, i.e. when the order was made by the logistics department. Since the allocated material has been moved, and also transacted in the information system but as unallocated material, the team leader need to look up the correct location where the material was picked before entering the production.

The first result of those frequent occasions when unallocated but not available material is used for production is an immediate contact with a warehouse operator. The operator is often forced to let go of the current activities and drive the total time of an hour to retrieve the material from warehouse B. Even this material movement suffers from the allocation problem. The waste of time in all concerned departments was retrieved through observations and surveys. It is presented in the *Table 14* below, as minimum time per month. Note that the times are excluding the most time consuming incidents. An example of an excluded incident is the time required when information needs to go back and forth between departments. It is difficult to quantify and trace the exact waste in time per month, but the presented times are considered ambiguous.

Table 14: Time waste per month due to the allocation problem

Packaging Department	**Logistics Department**	**Quality Department**	**Warehouse Operators**
2 h	22 h	3 h	3 h
Total time per month: 30 hours			

Ultimately, the allocation problem leads to a minor quarrel between the logistics and the packaging department. Both parts are aware of the problem, but in stressful moments with planning deviations it is a problem that indirectly could create quarrel.

5.3 Information flow

Several indications of an ineffective internal information flow emerged when the value streams were mapped. This can indirectly be identified in the VSMs as long cycle times between certain process steps. The internal communication is carried out through mail, phone calls and in some instances meetings. This way of communicating has however proved to be insufficient and lacks structural mechanisms for assuring that the right information reaches the right person in time.

Due to the nature of cGMP regulations, the departments that are closely interconnected by overlapping work tasks throughout the production process in a pharmaceutical company are very dependent on each other to ensure a smooth flow of information.

Documentation travels along the actual products, and validation of both documentation and the products needs to be carried out at several instances. The employees at the different departments generally had little knowledge of exactly what the other departments work tasks were comprised of and how their workload looked like. The previously described issue regarding material allocation is a good example of how the lack of transparency across functional borders creates interdepartmental quarrel which was an apparent issue when the study was performed. Since the allocation did not function and created double work for both departments, quarrels often emerged between the departments. However, no one really knew what the actual problem was but rather assumed that it was the other departments fault.

The warehouse operators who often had to make emergency runs to collect material is also a telling example of where the information sharing was ineffective. The orders which contains a pick list is sent from the logistics department to the packaging department. The packaging department then prints the pick list and hands it to the warehouse employees. As shown in the VSMs (*Figure 26, 29* and *32*), this generally takes a couple of days. During this time, the material might already have been used in the production. Thus, a gap can be seen. Through sharing information directly to whom it concerns instead of making it go through another instance might increase the chance that the information is up to date.

The logistics department handles all the forecasts and orders that are received from customers. The packaging departments then receives internal packaging orders from the logistics department with a deadline at which the order must be packed. As seen in the VSMs (*Figure 26, 26* and *32*), the logistics department generally knows approximately what orders that are needed to be produced many weeks in advance. This information is often not shared in due time and as a result material planning, capacity planning et cetera becomes difficult for the packaging department. The only scheduled meeting between the packaging department and the logistics department is a short pulse meeting every day at 14:00 and a longer one that is supposed to take place every week. The quality assurance department is also represented at this meeting.

The waste that occur due to issues regarding the information flow can be characterized as "waiting" and "transport" due to bottlenecks and double handling of information and material. Further, the inefficient information sharing is also contributing to a lack of transparency that could lead to uneven flow in the packaging department as well as between interdepartmental deliveries of documentation. This could be characterized as "waiting" waste in the form of idle time between processes as described in *Table 4*.

5.4 Prioritization of work tasks

One of the main reasons behind long lead times in between certain process steps presented in the VSMs are that certain tasks often gets a lower priority. An example is the debriefing and documentation, which lay under the packaging departments area of responsibility. During interviews it became apparent that debriefing material from the information system as well as completing documentation often fall between the cracks due to lack of time. This will in turn lead to pressure on the quality assurance department which consequently will have less time to finish the batch approval. The same issue, which has been previously discussed, concerns the logistics department which currently sends the orders to the packaging department in something that can be described as a JIT manner.

The lack of a holistic attitude towards the entire process obstructs a smooth cross functional teamwork. This is in some cases evoked by a lack of manpower but in other cases, the prioritization of tasks is unclear and no directives are present The previously described ignorance regarding other departments responsibilities and work tasks further aggravate the situation. A certain resistance to change has also been distinguishable. Instances where employees perform tasks without knowing why they do so have also been discovered. A strong “we do as we always have done” mentality is latent within certain parts of the company.

Another issue regarding the prioritization of work tasks are unclear responsibilities. The team leaders and the operators share the responsibility to gather material for the orders as well as transporting left-over material to the warehouse when a batch is produced. The operators are superior as far as number goes, but still the team leaders complain that the task of moving material often ends up on their desk. One reason behind this is that some operators lack a forklift license, which at sometimes might be required to place boxes on pallet positions that cannot be reached by hand.

Further, it is the team leader's responsibility to register the movement of material in the information system. The operators can however leave a special note to the team leaders which describes what material is moved where. Signing batch documentation during the packaging process is another area where unclear responsibilities were considered to be problematic. Line clearance, frequency controls, label controls are some examples of various controls that are conducted during the packaging of a batch. The documentation of these controls are to be signed by two operators. There are no pre-assigned “signers”, but the signing is rather done by the randomly chosen persons that conduct the controls. The team leaders control the documentation after the batch is finished before sending it to the quality assurance department for a final approval. The team leaders claim to see a negligent

attitude towards signing the controls amongst the operators and occasionally has to correct the inaccuracies found on the controls. This is according to the team leaders a time consuming activity. To summarize the unclear responsibility distribution, the physical activities connected to the packaging processes are lacking process owners.

The issues described in this section could be derived from the lack of clearly defined tasks, i.e. lack of standardized work which is one of the approaches to become more lean. The waste that occur due to the lack of standard work were classified as "waiting" and "transport".

5.5 Warehouse location

The problems arising from having such distance, i.e. 8 km, between warehouse A and B are many. Not to mention that warehouse B is far larger warehouse A, which puts the dependence of warehouse B in an even greater position. It is a warehouse setup that cause wasteful and time consuming operations and it simultaneously triggers a great many of other issues. The company is naturally fully aware of the problems related to this setup and the difficulties arising from it. It can however not be disregarded in the analysis, even though it is an obvious concern. In *Table 15*, which displays identified issues arising from the warehouse setup and what waste or consequence that the issue leads to.

Table 15: Problems arising with the current location of warehouse B

Issue	**Type of waste/consequence**	**Comment**
Long lead times regarding material movement	Transportation and waiting	Picklist from packaging department to warehouse operator. 1 h to 28 h lead time
Traffic delaying movement	Transportation and waiting	Primarily in the morning and in the afternoon
Double handling	Unnecessary motion.	A component is being handled in both warehouse B and A. All movements are handled manually in the information system
Environmental stress	Greenhouse gas	Average 20 km per day
Delay in the information system	Waiting and double handling	Double effect caused by the allocation problem
Constrained to a warehouse operator.	Waiting	It is only the two warehouse operator who can pick from warehouse B
In- and outbound operations	Time	Needs traveling to warehouse B
Reverse logistics	Time, double handling and space (in warehouse A)	The need of having a system for returning material that cannot be stored in warehouse A, because of space limitations
Risks with moving valuable goods back and forth.	Risk-taking	Unexpected incidents can occur
Dependence on one vehicle	Risk-taking	Only one truck is available for hauling

5.6 Serial processes

This identified issue regards the packaging process for product family B. As presented in the value stream map for product family B (*Figure 29*), the lead time between *Packaging order approval* and *Labelling of vial and assembly* has been confirmed to 6.25 days. These days are made up of waiting time, that is to say that nothing is happening to that particular order during this period. Moreover, it is the longest lead time identified apart from the order planning. The *Labelling of vial and assembly* step is containing vial labelling, folding of secondary package and assembly. All these three activities are executed in the same room in the packaging facility. To be able to get a clearer understanding of the nature of this issue, some earlier described but also new prerequisites will hereby be explained.

Each production room in the packaging facility can only be constituted by one order at the time due to cGMP regulations. For product family B, this regulation is accompanied with a requirement from the customer that further prevent the flexibility. The requirement states that even if the exact same product is to be produced on two separate orders, these orders have to be produced one at the time, i.e. they cannot be produced in one single batch. It results in one extra round of changeover activities. This requirement is only applied to product family B. There is simultaneously a significant increase in orders for the next 12 months and even a continuous increase after that, based on forecast and signals from customer B.

For product family B, in the *Labelling of vial and assembly* step, the vials are naturally being labelled before all the components can be assembled. In the beginning of this process step, the vials are being labelled in parallel with the folding of the secondary package. The total VAT for the labelling, folding and assembly for 600 units is 3.8 hours, i.e. 228 minutes. The figure below demonstrates the distribution of the total VAT on these three activities, i.e. labelling, folding and assembly.

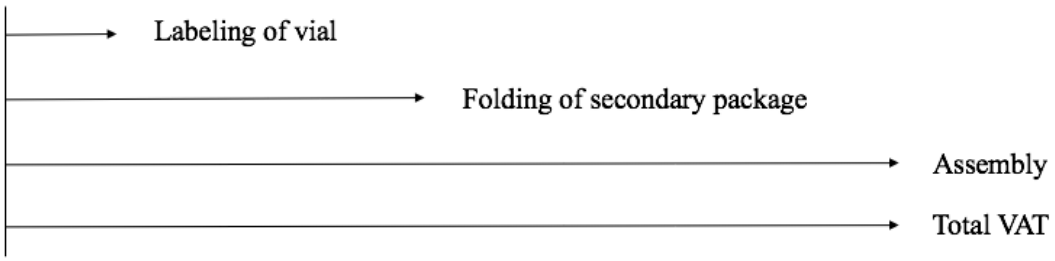


Figure 36: VAT distribution for Labelling of vial and assembly step

As *Figure 36* visualizes, both labelling of vial and folding of secondary package are two activities that are being locked to one order until the assembly of all units is complete. Nevertheless, *Figure 36* does not the comprehend the full picture. The changeover time is

not included and if it was, the time these activities are being locked to one order would be even more significant. So, the utilisation rate for these two activities are unnecessary low with respect to the long lead time, the number of orders in progress and the upcoming larger orders. The flexibility for a company whose production is MTO-based, with an ambition to be as responsive as possible, this serial process structure is contradictious. This issue can be derived from placing the entire process in one room and not spreading out the activities such as labelling of the vial and the folding of the secondary packages.

By not having the opportunity to conduct activities in parallel due to the allocation of designated rooms, waste which can be characterised as "waiting" occur. This waste is mainly occurring because of large variations of cycle times between activities, as shown in *Figure 36*.

5.7 No monitoring of performance

This section is complementing the information flow issue with another information sharing topic, i.e. no monitoring activities of performance are in place. The identified trouble areas are regarding the production activities within the packaging department. Today, all on going activities are kept out of the information systems. The only information retrievable for the logistics department are the batch approval. However, this information is not easily accessible and the extraction requires several steps in the information system. Additionally, the importance of this information regarding the performance status is quite insignificant.

The lack of support for monitoring the performance prevent the logistics managers to plan the upcoming orders and to report customers about the status of delivery. Additionally, the logistics department do without an overview of what orders are produced and how far gone the manufacturing process has progressed.

As for a strategic purpose, the company cannot establish performance targets without having specific lines of actions for monitoring the performance. The value stream maps reveal that the company are struggling with long lead times. The lead times are made up by long waiting times in which the concerned orders are in idle and nothing happen to them.

There have been identified a willingness to improve and some actions have been taken. Though, the effect of the changes has not been followed up properly. A sign of success after a change is based on feelings of a smoother operation mode instead of supportive data that actually demonstrate an improvement. Lastly, incentives for employees to gain from an improved performance is impossible if the performance cannot be measured.

Further, by not monitoring performance, the company will never know if certain projects actually are prosperous or if they instead lead to waste. The non-existent monitoring itself could potentially be a catalyst of wasteful activities.

5.8 Information system

The information system that the company currently is utilizing was found to have a number of flaws. This is not necessarily because the system is incapable in general, but rather designed for purposes or situations which diverge from the business that the company conducts. The information system is basically designed and optimized for handling the production of large batches. Since the company often aims to be flexible and generally can be said to manufacture small batches, there is a tactical mismatch between the company's objectives and the capabilities of the information system.

The mismatch is visible throughout the entire company. Due to the information systems original design towards producing large batches, there is an apparent lack of efficiency when conducting certain activities or tasks. Moving material in the information system is a telling example of an inefficiency which is very time consuming. Since at least a few different batches are started in the packaging facility each day, it quickly becomes an issue. The team leaders in the packaging department, whom are responsible for moving the material from the warehouse into the production area in the information system, does not have time to do so. This displacement shall be executed because of traceability due to cGMP and as a confirmation for work-in-progress for the logistics department. From a long term perspective with rising number of orders, this way of work is not feasible. All material that is going to be used for an order has to be moved individually, i.e. the team leaders cannot just transfer the entire order. The allocation of material is another aspect of the system that does not align with how the company's daily operations function.

Due to specific events in the company's past, the information system is in some instances attuned to settings which are no longer up-to-date. This has led to confusion to why certain activities in the information system are performed. Further, only a few people seemingly knew how to handle the system and no proper education have been given to new employees. The ones who knew the settings and how to interpret the non-topical descriptions of certain activities learned new employees how to handle the system rather than requesting that the system should be updated to fit with the company's current situation.

The issues with the information system seems to be one of the root causes to why long lead times can be seen between process steps in the VSMs (*Figure 26, 29* and *32*).

Another example of a seemingly unnecessary and time consuming activity emerge in the debriefing of material, i.e. when an order is fully produced and all components shall be debriefed and turned into a finished product. *Figure 37* demonstrates when the issue arises. Even if the material has been recorded in warehouse A, the packaging department need to make the movement of material yet again in order to be able to debrief the material. The debriefing module is not registering that material has moved and only notes where the material was the first the time the order was created. Subsequently, the packaging department need to find the material in warehouse B and move it to warehouse A, even if it already has been moved physically and in the system.

The issues that come with the information system creates waste in the form of "waiting" and "transport" much like the allocation issue, which generally speaking can be derived from deficiencies of the information system. Other examples of waste can be found in the attuned to settings which are no longer up-to-date which confuses the employees, thus the tasks take longer time to perform than they should.

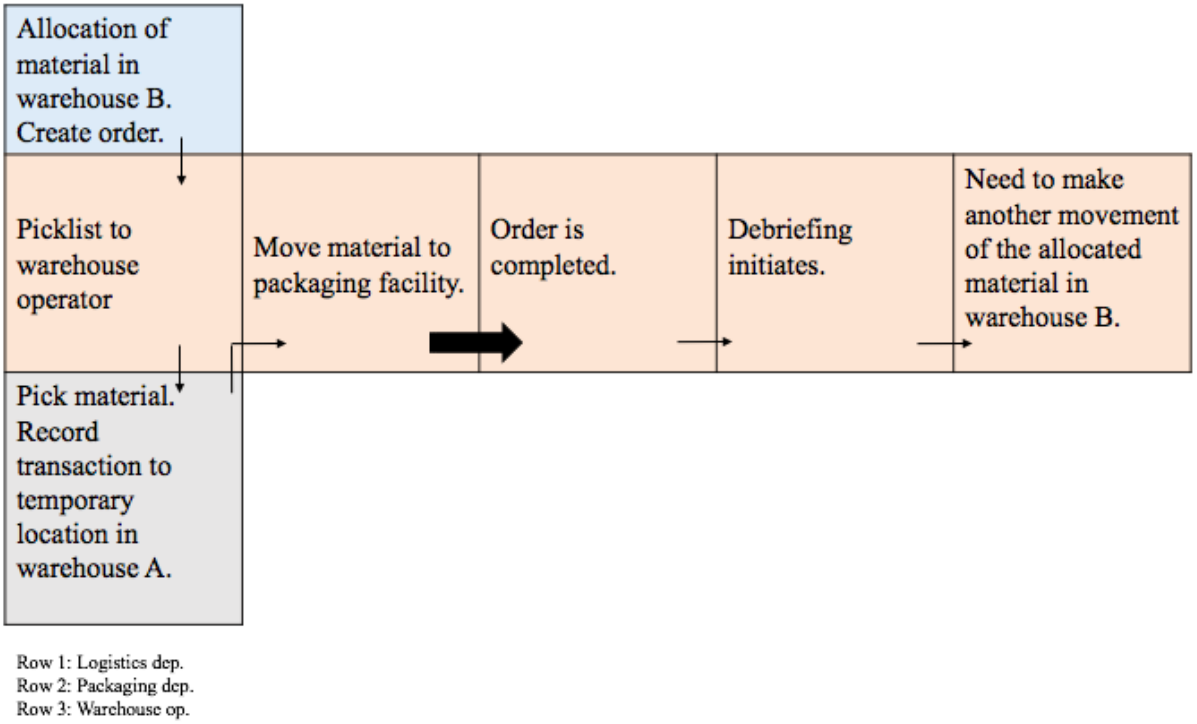


Figure 37: Flaw in the information system

6 Recommendations for the future state

In this section, recommendations are given that will guide the company towards an improved future state. Recommendations towards eliminating the problems found in *Section 5* are presented from both a short term and long term perspective. The need for long-sightedness is stressed by Sörqvist (2013), who points out that lean is synonymous with being long term. As the company is currently in a position where firefighting and ad hoc solutions often occur, a short term perspective to balance the operations was also considered important.

Through following the approach described by King (2009), namely picturing an ideal state without waste, the improvement proposals were identified. The conceptual framework developed in this thesis was used as a general frame of reference when developing the solutions, i.e. consideration was taken to the four different theoretical components. The most influential and necessary components were lean and cGMP. Below follows a short motivation of this statement.

The underlying reason for lean's importance when developing improvement proposals were the waste identified in *Section 5*. In almost all instances, the waste types "waiting" and "transport" could be identified. By studying *Table 4*, it becomes clear that these two types of waste can be derived from an insufficient flow, either of material or information. As continuous flow is central in lean thinking (Rother & Shook 1998, cited in Serrano 2008, p.41), the usage of lean thinking to mitigate the identified categories of waste becomes apparent.

As already mentioned several times in this thesis, cGMP governs achievability of actions due to its regulating nature, therefore it was a vital part when developing improvement proposals.

This chapter will start with a presentation of the short term recommendations, followed by the long term recommendations. As the problems identified in *Section 5* often were interconnected, one recommendation might mitigate several problems. In order to facilitate the reader's ability to comprehend the link between a specific solution and the problems it seek to mitigate, feedback will be given to the topical problems.

6.1 Short term proposals

In this section, the short term improvement proposals are presented. The short term proposals are characterized by being not very capital intensive and considering the needs of a company in a shorter time horizon.

6.1.1 Introducing packaging assistants

As mentioned in *Section 5.4*, unclear responsibilities were found to be a contributing factor to the idle times that obstructed a continuous flow. One of the main problems that could be derived from the issue related to unclear tasks was the errors that occurred when the operators in the packaging department signed the batch documentation. In order to minimize the occurrence of incorrect signing of documentation which can be very time consuming during the debriefing and documentation task conducted by the team leaders in the packaging department, packaging assistants should be introduced. The packaging assistants should also be assigned to picking material, and putting away finished goods.

The role as packaging assistant should be assigned to a number of operators in the packaging department, preferably one or more per product family. The idea is that the packaging assistants should have an expanded area of responsibility and therefore improve the quality of the documentation and be assigned with a number of other tasks which will improve the flow and decrease the lead times between certain process steps. Three extra tasks should be added to the tasks of an operator, so that when he is done with an extra task, he continues performing as an operator. This means that no extra work load is added per se, thus the expanded work tasks will not contribute to a stressful environment for the affected operators. *Table 16* below describes the expanded job assignments that comes with and explains how it will affect the company's operations.

Table 16: New job assignments

Assignment	Description	Improvement
Gathering material for the order	The packaging assistants should gather the material for the order	Reduces the workload of the team leaders. Reduces certain lead times.
Documentation	The packaging assistants are responsible for signing all documentation in connection to the production	Decreases the amount of errors, thus also reduces certain lead times
Putting away finished products	The packaging assistants should put away the finished products	Reduces the workload of the team leaders. Reduces certain lead times.

By assigning packaging assistants, waste can be removed. Having the packaging assistants signing and checking the documentation will result in less errors. This will primarily lead to a lowered lead time in the process step *Debriefing and documentation* for all product families. The team leaders have complained that their workload is heavy, and this could also be seen in the VSMs. By releasing time from e.g. occasionally having to carry out the time consuming correction of the inaccuracies found on the controls, more time will be available for conducting other tasks. This is important since the team leaders were found to be somewhat of a bottleneck and contributing to a lot of idle time between process steps. The lead times that will be positively affected are shown in *Figure 39*.

Today, both the operators and the team leaders are allowed to gather material for an order. The same applies for putting away the finished goods. Through moving the responsibility entirely to the packaging assistants, i.e. operators, waste in the form of "waiting" can be removed, thus shortening lead times between the process steps. The lead times that will be positively affected are shown in *Figure 38* below, which applies for all product families.

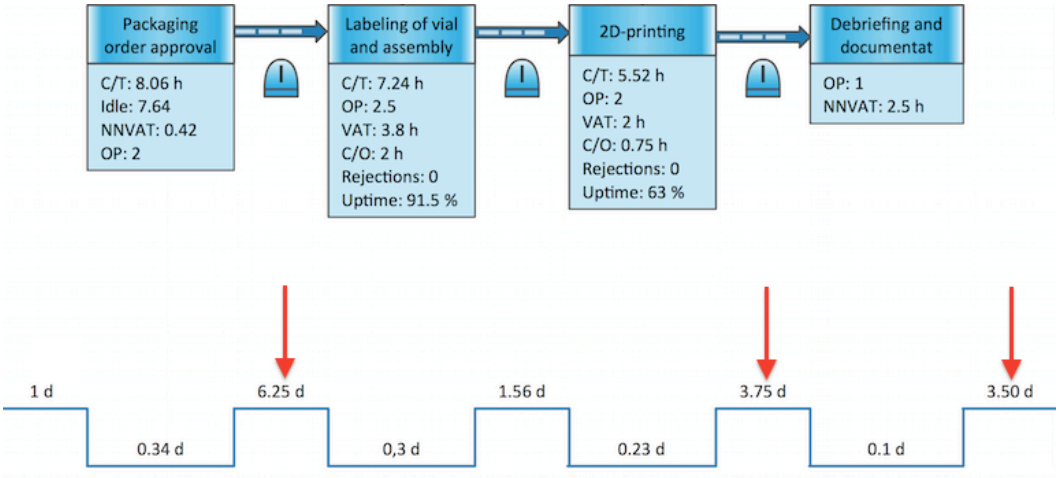


Figure 38: Affected lead times

Further, other benefits could potentially be seen with the introduction of packaging assistants. When the team leaders no longer will be having to switch tasks, i.e. go to the warehouse et cetera, there is a possibility that they can conduct their work even more efficiently. An in depth focus on the debriefing, control and order approval could thus lead to shorter lead times in these processes. There is also a possibility that the packaging assistants will adapt a kaizen-like mind-set due to their expanded responsibilities. Moreover, by eliminating shared processes and assigning process owners, the company will

move towards a more lean way of work with standardised tasks and a more continuous flow.

6.1.2 New allocation process

The problem with allocation of material results in numerous time consuming activities in several departments of the company. The logistics department as well as the packaging department double checks the availability of material which eventually leads to an unplanned trip for one of the warehouse operators. The fundamental reason behind this is obviously the limitation in the information system. Consideration was taken to a short time horizon when proposing this improvement suggestion. Apart from a long term solution, the following suggestion was derived from investigating what and in what sequence actions were taken as a result of the allocation problem. The proposal is depicted in *Figure 38*. In order to make a clear description of the proposal, the changes are denoted with a number and described after the figure.

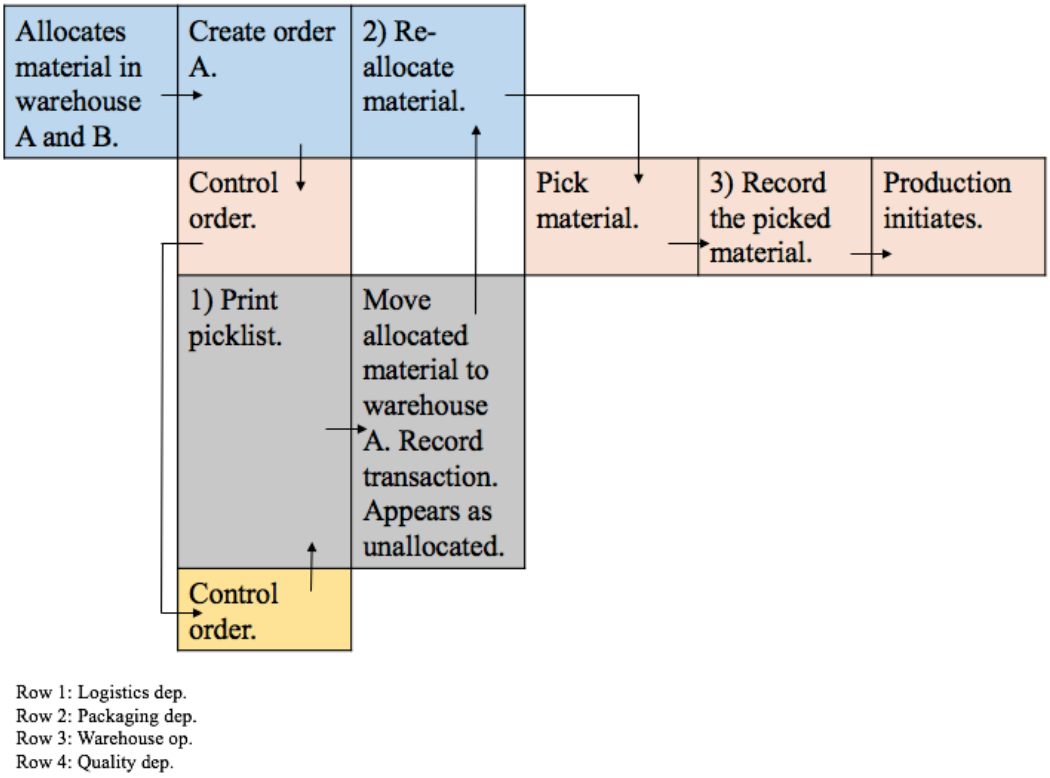


Figure 39: New allocation process

1. The picklist is reflecting the current stock levels the moment the picklist is created. The picklist returns a zero if the location is empty. Today, the team leaders print the picklist and hand it over to a warehouse operator. It can be up to a 24 h delay before the warehouse operator picks the material, occasionally resulting in an

unexpected empty location. If a warehouse operator prints the picklist himself when he is about to pick the material, the accuracy of the picklist increases immensely, especially in combination with the two upcoming changes in this section. It will decrease the risk for potential errors.

2. Both number 2 and 3 are activities that are totally new, compared to number 1, which is a switch in a work task. The allocation problem originates in the impossibility to trace where material is and if it is in progress. The proposal is to let a warehouse operator notice the logistics department when allocated material has been moved and to what location. It enables the logistics department to reallocate the material to its current location. As they reallocate, double allocations will not occur and the double checking before allocating material will disappear. The reallocation will also make contribution to the team leaders, as they do not have to double check in the debriefing activity since the material has been picked by the packaging operators from an allocated location. It is recommended to perform this activity as soon as possible.
3. Even though the reallocation will prevent the logistics department to double allocate material, this extra recording will improve the flexibility for unexpected circumstances. Situations occur when the logistics department need to use allocated material for an urgent order. Today, the material can be allocated in warehouse A and at the same time being used in a packaging process. It is therefore unclear for the logistics department what material is available. The proposal is to assign the team leaders, or possibly also a packaging assistant, to record in the information system if material has been brought into the packaging facility in order to increase visibility. As for number 2, this activity is also recommended to be performed in the quickest of manners.

6.1.3 Release tied up space

In section 5.1, unnecessary occupation of space, two different areas were identified as waste in terms of space. Firstly, in the packaging department, *Figure 33* and later also in warehouse B, *Figure 34*. Because two cases of unnecessary space were identified, each will be handled separately.

6.1.3.1 Unnecessary space in the packaging department

As a reminder, the area highlighted in bold black is occupied of a large machine out of use. The machine will never function as a production tool again for the company. Attempts have been made to sell it, but it is not an easy task to sell a highly customized machine. The advice given is to make a final attempt to sell it. If the attempt fails, the last resort

is to simply recycle the machine. As freed up space will emerge, some actions must be taken to utilize the new opportunities for managing a better flow. However, these actions are presented in *Section 6.1.4* because the nature of the actions can more appropriately be derived to the serial processes issue.

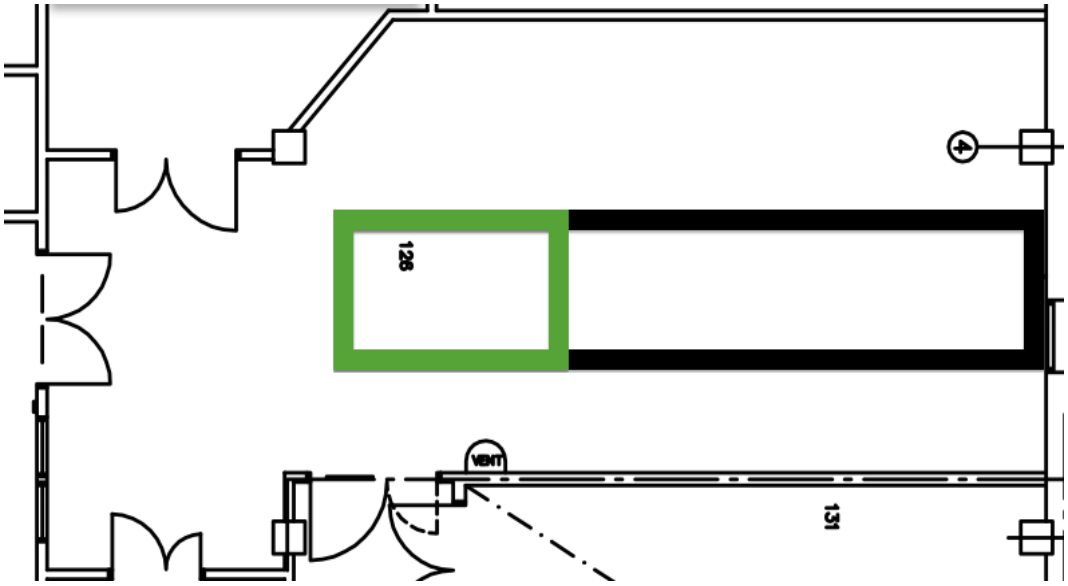


Figure 40: Machine position in the packaging department

6.1.3.2 Unnecessary usage of space in warehouse B

The same advice regarding the unused machinery in the packaging department applies to the unused machinery in warehouse B. The premises are also the same, i.e. highly customized machinery that is hard to sell without future usefulness.

The utilisation rate within warehouse B is in *Table 13*, at a rather optimal level. However, this is just a snapshot and as the study has progressed, the utilisation rate has increased. New products will soon be launched and one new product in particular will stress the warehouse situation even further. This new product will come in 80 different variations, with regard to country specifications resulting in approximately 400 unique articles. In addition, the cGMP regulation stating that each unique batch of a component needs a unique warehouse location. The company is approaching a real challenge in releasing enough space for all components.

The recommendation for the company is to install additional shelves and pallet locations in section 1 and 2, see *Figure 34*. In section 1, ten additional pallet locations are available. For convenience, this section is recommended to use pallet locations because they are already installed but occupied with unnecessary material. Section 2 however, can make room for between 150 - 300 new shelf locations. The lower boundary concerns the larger size of shelf based on existent model of shelf and the upper for the small dito.

As new products are emerging, a ramp up phase is typically initiated for the company. The order size is starting low and is intended to grow successive during a period of one to two years. These new shelves can constitute a basis for storage components of new products.

Another field of application is for the reverse movement of goods, i.e. left over material from the production that does not grant a place in warehouse A. These new shelves are located in the nearest possible spot from the inbound area. This is possible since the company use shared locations. But, if the location where the component was initially picked in warehouse B is not empty, i.e. the same component already employs a location, it is more beneficial to put the leftover material in that location.

6.1.4 Adding an additional room

In order to increase the capacity of the packaging facility, the company is suggested to transform a room that currently is occupied by air compressors in to a packaging station. This would grant the company additional capacity and availability to scale their operations further, an imperative considering the current growth. The recommendation is to move the compressors to an adjacent room, thus clearing up space of roughly 60 square meters and commit it to packaging operations. The room in question is marked in green in *Figure 41*. The purple markings show the air compressors and the arrow indicates where they should be moved.

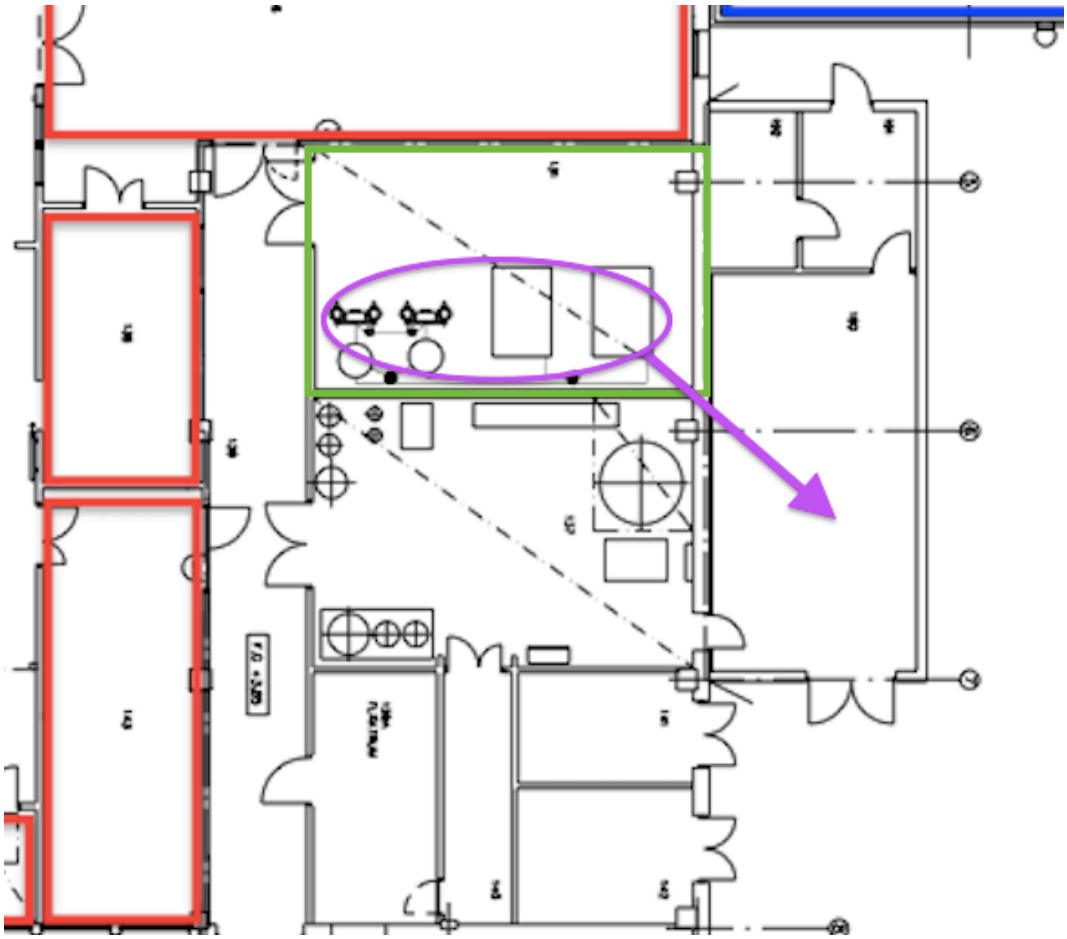


Figure 41: Location of new room

6.1.5 Introducing dividing walls

As described in *Section 5.6*, the current serial character of processes within the packaging facility was found to be somewhat of a bottleneck. As cGMP regulates that only one batch can be produced per room, the current utilization of the rooms in the packaging facility was found to be far from optimal. With the changes described above in Section 6.1.3 and 6.1.4, more space will be available for the packaging department, thus an increase in production capacity. However, by introducing dividing walls, the potential capacity will increase. It will also grant the company flexibility. The recommendation builds on the prerequisite that the improvement proposals in presented in Section 6.1.3 and 6.1.4 are carried out. *Figure 42* depicts how the affected area of the packaging facility would look like after the changes where the green square indicates the new position of the labelling machine.

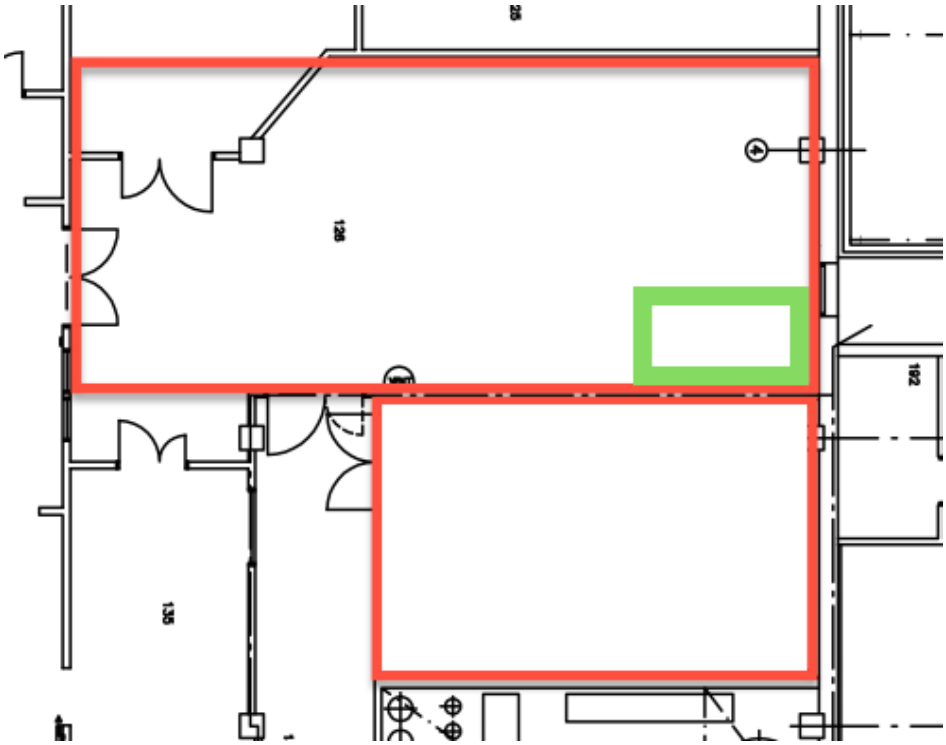


Figure 42: New layout

If dividing walls are added, processes can be carried out in parallel. This would solve the current problem presented in *Section 6.1.4*. The packaging process of product family B is currently experiencing a bottleneck in the step *labelling of vial and assembly* step, where the vials are being labelled before all the components can be assembled.

Consider two batches that are supposed to be produced, e.g. 400 units of product family B to two different countries. In the current layout, the second batch can only be started when the first batch is finished as described in *Section 6.1.4*. By adding a dividing wall, see the new layout in *Figure 42* above, between the vial machine and the rest of the room, the vials for batch number two can be labelled immediately once the first batch is labelled and a line clearance is conducted. The labelling of the second batch is thus conducted at the same time as the first batch is packed and assembled. If the new room is added, both batches can be assembled simultaneously. If a dividing wall is set up in the new room, a total of three batches could in theory be assembled simultaneously, depending on the size of the batches. *Figure 43* shows the new layout where two dividing walls are present, marked with purple.

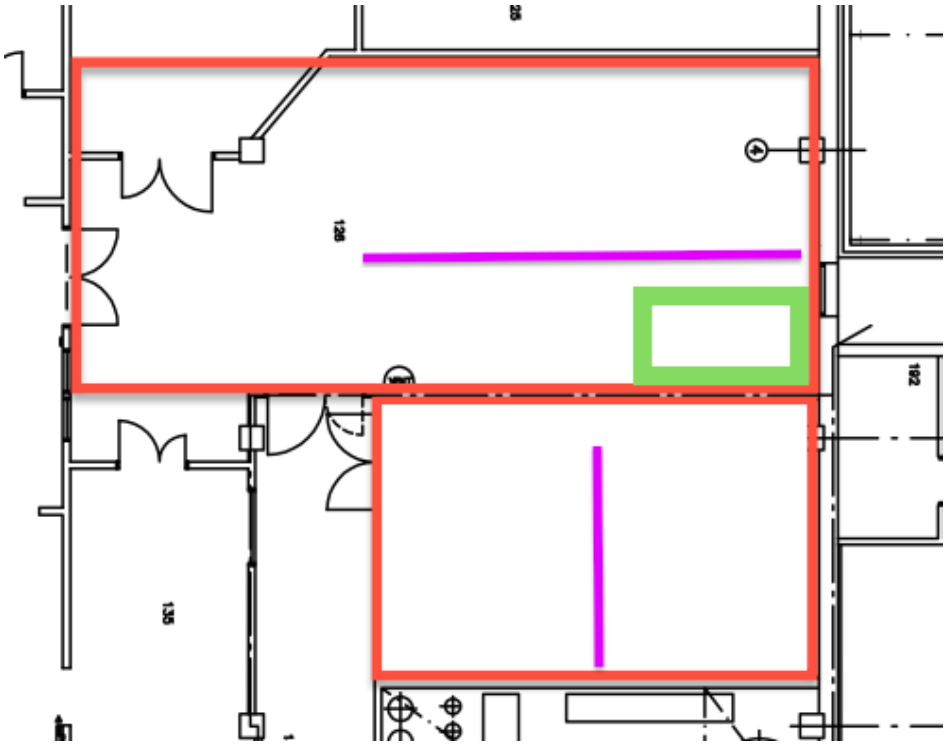


Figure 43: The new layout with two dividing walls present

The nature of dividing walls, i.e. easy mounting and dismantling, makes them ideal for delimiting rooms so that the rooms can be adapted to situational factors regarding order size, number of orders and so forth. The introduction of dividing walls will also reduce waste in the form of "waiting" and contribute to a better flow due to the ability to produce several batches of product family B in parallel, thus also shortening the overall lead time of the entire value stream.

6.1.6 Measuring performance

One of the core components of the lean philosophy is having a long term perspective. As Sörqvist (2013) points out, continuous improvement is central in the lean philosophy. The company has launched a number of improvement projects in the past, but done so without any clear way of benchmarking whether the implementations were successful or not. The recommendation is thus that the company here from should follow a PDCA-cycle when considering any new projects or improvement connected to the value streams. The PDCA-cycle that the company should conform to follows (Sörqvist, 2013):

1. Plan: A plan of action is developed in which the change is thoroughly planned. Consideration is also taken to possible hurdles and how risks can be mitigated.
2. Do: The changes proposed in the plan are implemented.
3. Check: The implementation is evaluated through benchmarking or other techniques.
4. Act: Any improvement suggestions that occur during the check-phase is acted upon. It could for example be rectifications of machine settings et cetera.

Point number 3 in the PDCA-cycle, namely *Check* is the point where the company was found to be lacking initiatives. An example will therefore be given below that will guide the company on how to measure the impact of a change. Due to the limitations in the information system, the proposal is to conduct the measurement manually.

This example will clarify how the measurement of the impact that the introduction of packaging assistants should be conducted. Before the introduction, the number of errors occurring on orders in the process step *debriefing and documentation* shown in the VSMs should be measured during a limited time period. The time it takes to correct the errors should also be recorded. This could be done through handing the team leaders a formulary which they should fill in. *Table 17* below gives a simple example of how a formulary could look like.

Table 17: Example of measurement formulary

Number of errors per order	Type of errors	Accumulated time needed to correct errors

Once a satisfactory set of data has been collected, the introduction of packaging assistants should be initiated. Once the packaging assistants are acclimatized, a new formulary should be handed to the team leaders. It should be designed like the previous formulary. When a new data set has been gathered and compiled, it should be visible to see if the number of documentation errors has been decreased or not. Using metrics to evaluate change initiatives can be valuable in order indicate that a certain project has been successful and can thus be used as a foundation to gain top management support for e.g. further improvements within a specific area. It can also help to elucidate why issues occur in an Ishikawa styled manner. For example, by measuring and specifying what kind of

errors that are present in the documentation, it could be possible to identify where a certain error occur in the processes.

6.1.7 Introducing improvement meetings

As one of the key success factors of becoming lean is continuous improvement, the company should introduce meetings with continuous improvement on the agenda. These meetings should be viewed upon as kaizen events, i.e. team activities that focus on continuous improvements. At least one representative from each department should attend the meeting, that as a suggestion should take place every fortnight. The meetings should follow the PDCA-cycle described in *Section 6.1.6* in order to ensure a systematic approach to improvement activities and the possibility to monitor the success of the same.

Many benefits can be seen from having meetings that focus on continuous improvement. Firstly, the meetings can help the company overcome some of the issues regarding cross-functional information flow. As different improvement proposals will be discussed, the diversity of the attendees will ensure that important information will be shared across functional borders. Further, the issue regarding a resistant attitude towards change which was discussed in *Section 5.1.4* could possibly be improved by arranging the meetings. Since the improvement proposals could affect several departments, a deeper understanding of the other departments responsibilities and work situation could also be an outcome.

6.1.8 Introducing scanners

An efficient and effective way of becoming more lean for the company, would be to introduce scanners for all material handling. Scanners are already in place, but only used to check whether a material or finished product is approved by the quality department. In comparison to the present complete manual handling activities, scanners would reduce the risk for mistakes and improve accuracy in several occasions;

- Secure correct put aways when new goods arrive and when material is moved between warehouse A and B
- Secure correct picks when picking in both warehouses and when the packaging facility move material from warehouse A in to the production facility.
- Improve traceability because of more accurate movements. It is in line with cGMP regulation of full traceability. The scanners most however be verified to meet all requirements.

As all picks and put aways have to be made manually, unnecessary time waste occurs. The time for the team leaders to move material from warehouse A into the packaging facility

when an order is to be made, is so time consuming that the activity very seldom happens. The result is as earlier mentioned, confusion regarding what material is available. By introducing scanners, this operation could be executed instantly without any significant time waste.

The presumably most significate improvement area is the allocation problem. New scanners could solve that issue, with allocations that are reallocated each time an allocated material is moved.

The largest challenge with implementing scanners is to get them verified by cGMP and to integrate and implement them with the current information system.

6.2 Long term proposals

The long term improvement proposals given are considering the company's situation from a more strategic perspective and builds on the assumption that the current growth rate will continue. The solutions were also considered to be more complex to implement and higher investments are needed to actualize these improvement proposals.

6.2.1 Moving to a new location

The company is currently experiencing a period of growth, with an increasing number of orders and quantities. In the long term, the company will be forced to move their operations to new premises. This is due to the issues regarding the already non-existent capacity in warehouse A and the packaging facility, but in the extension this would also include warehouse B. If the company for example would introduce new products to pack, the capacity issues would lead to unpredictable events. Warehouse A is already almost running at full capacity, and so does the packaging facility. It is hard to see how the company could continue its expansion without moving their operations to new premises. Further, the current set-up with two warehouses where one acts as a fast-pick area would become even more problematic. A large amplification of the allocation issue would follow the wake of new products, thus making the choice of staying within the same premises even more doubtful if the company wants to continue to grow.

The solution to these inevitable issues is to move the entire company to new premises. There are two possible solutions; moving to a location where the entire company and warehouse can fit or moving to a location which can hold the company and a warehouse which is larger than the current warehouse A. In choosing the first solution, the company would also terminate the contract for warehouse B whereas in the second scenario, warehouse B would be kept. The second scenario might be advisable if considering

spreading risks, but implies that the on-site warehouse has to be sufficient in terms of storage positions to obtain a reasonable scalability. If the company would choose the second scenario, the position of the new premises would also be a factor that should be considered, i.e. not placing production too far away from warehouse B.

6.2.2 New information system

The current information system was one of the first identified areas where the support was considered low and the modernity was outdated. Many complains have been intercepted from each involved department. The general consensus regarding the flaws within the information system is the feeling of incapacitation. Regardless of the limitation, i.e. that no proposal of a new information system shall be given, many of the issues can be derived from the flaws in the information system to a such extent that it is inevitable to exclude. The complexity of an information system is high and the most apparent flaws that need correction will only be mentioned, in order to fit within the size of the other recommendations.

The cross functionality has been proven to be insufficient considering the information exchange between departments, in terms of convenient information channels. Most apparent is the production planning process, where information is stored outside the information system in Microsoft Excel sheets. The sharing of significant data, such as production schedule, forecasts and available capacity is confined to irregular occasions. It would require a new IT structure that can support e.g. a future sales and operation planning process without storing data on several locations. This would additionally mitigate the double usage of software applications when placing e.g. internal packaging orders.

Apart from the allocation problem, which obviously is one of the greatest bottlenecks with the current information system, a concern has been identified through observations and opinions from several employees regarding the user friendliness of the system. Each action is demanding several interactions for executing a relatively simple operation, such as the debriefing of material activity. On top of that, the system is slow and as an example to demonstrate that; to get an overview of the stock levels can take up to 90 seconds of waiting time. There is a great deal of time that potentially could be saved just by highlighting the number of unnecessary interactions and the slowness of the information system.

The company has in one module got stuck in an old operative system (OS). The OS cannot be updated due to the modules lack of support for a newer system. It is one example of

the importance of looking into future needs. The current system is made for large and few batches, but is used for many and relatively small batches. As previously mentioned, the number of batches continues to increase and will increase even more with the new product introductions. Without implementing new IT support, the current flaws will take a form of a more severe character.

7 Conclusion

This section will cover the findings from the case study and connect the analysis to the posed research questions. All three research questions will be subjects to general discussions which aims to further clarify the situational factors and concretize relevant material found in the analysis. Research question number two has partly been answered in the previous chapter, but a short summary will be given to concretize the findings from the case study.

7.1 Answering the research questions

RQ1 What deficiencies are affecting the processes and in what way do they affect the business?

During the study, several deficiencies connected to the processes were found. The present deficiencies could be categorized into three groups; waste, available capacity and cross-functional communication issues. The different kinds of waste that were identified were classified in accordance with Hines & Rich's (1997) definition of waste. Two types of waste were found to be commonly existent within the process, namely waiting and transport. The reason for this could be that cGMP focuses mainly on quality as Chowdary & George (2012) points out, and not so much on improving flow. *Table 1* which displays inter alia the objectives of lean and cGMP, combined with *Table 4*, which shows the different types of waste gives a clue to why flow related waste is present in the company's processes, while quality related waste is not.

The company's general business strategy is being responsive. In the context, this means being able to accept orders on short notice and being able to produce them in a just-in-time manner. Although most orders are placed in accordance with the predestined time-limit, the company claims that their current growth phase partly can be described by their responsiveness to just-in-time orders.

The occurrence of waste such as waiting and transport in the form of double handling of information affects the company's ability to be responsive in a negative way since. Wasteful activities are extending the lead times in the process from order to dispatch, and thus aggravate the company's ability to pack orders in a timely manner. This has led to that orders do not always get delivered on time. Apart from the waste, the company is experiencing capacity issues. By squeezing orders into an already packed schedule makes planning more complicated due to the limited capacity. The lack of cross-functional communication between the departments is further obstructing the planning and execution of orders as well as prolonging lead times between process steps. This has previously been

addressed as an issue commonly found in the pharmaceutical industry by Green & O'Rourke (2006), and the company is no exception. Further, the information system was also found to be a touchstone in that it generated double handling of information and was not aligned with the company's strategy. The design of the information system also created issues regarding the material allocation which generated a lot of extra work in planning for orders.

The apparent and regulated focus on quality which is a consequence of cGMP can clearly be seen when analysing the processes from a lean perspective. To conclude, the deficiencies were not found to affect the company's business greatly in the current state, seen from an external perspective. The internal efficiency is however affected greatly. Double handling of material and information as well as idle time do indeed cost the company resources and money. Further, a lot of time is being spent on the allocation issue. The occurrence of late delivery of orders has however seemingly not yet lead to any deteriorated relationship to their customers.

As the orders and order quantities are currently increasing and have done so over during the past years, the situation could quickly change. The conclusion that can be made is that if nothing is done to reduce the waste, reduce the lead times, releasing capacity and improve the communication, the company will not be able to serve their customers in the impending future.

RQ2 *How can the deficiencies be improved through lean thinking with consideration taken to the contextual limitations given by cGMP?*

An investigation of the root causes of the identified deficiencies was initiated. The 5 why's method was the main tool for creating an understanding of the origins to each identified deficiency. A workshop was held in order to attain a higher detail level of the root cause and to give additional input from employees. As the root causes to the deficiencies were identified, an ideal state was considered and solutions were designed. Some solutions were cross-functional in the sense of mitigating more than one deficiency. Certain solution proposals were dismissed due to limitations given by cGMP; double quality and documentation controls could not be altered, attempts to optimize stock levels and material distribution was aggravated due to cGMP and vendor managed inventory plus customer specific batch decisions and country clusters.

Table 18 summarizes all given recommendations. Each proposal is connected to one or more deficiencies. Further, the waste mitigation is also highlighted in order to derive what improvement contribution each recommendation has and finally what time horizon is suitable.

Table 18: Summary of recommendations

Recommendation	**Identified problem mitigated**	**Waste mitigation**	**Time horizon**
New allocation process	Allocation process/Prioritization of work tasks	Waiting/Transport	Short
Introducing packaging assistants	Prioritization of work tasks/Information flow	Waiting/Transport	Short
Release tied up space	Unnecessary occupation of space	Waiting/Transport	Short
Adding an additional room	Serial processes	Waiting/Transport	Short
Introducing dividing walls	Serial processes	Waiting/Transport	Short
Measuring performance	No monitoring of performance/Information flow	*	Short
Introducing improvement meetings	No monitoring of performance/Information flow	**	Short
Introducing scanners	Allocation problem/Prioritization of work tasks	Waiting/Transport	Short
New location	Overall	Waiting/Transport/Unnecessary motion	Long
New information system	Allocation problem/Information flow/No monitoring of performance	Waiting/Transport	Long

Measuring performance (*) and introducing improvement meetings (**) can not be derived to a specific kind of waste. Both recommendations can however be derived to lean, in the sense that they are both focusing on a long term perspective in a continuous improvement domain.

As Chowdary & George (2012) showed in their case study, pharmaceutical companies that are complying to cGMP can successfully adopt a lean perspective in order to improve their operations. A pattern of waste type is as already described, more particularly 'waiting' and 'transport'. The introduction of a lean philosophy is therefore appropriate in terms of aligning both cGMP's focus on quality with lean's focus on quality, cost and continuous improvement. Through merging the objectives of both lean and cGMP, most of the waste types showed in *Table 18* can be mitigated through appropriate means of action.

A mutual aspect of the deficiencies identified is the need for improved information flow. Information sharing has been pinpointed by Green & O'Rourke (2006) as an area where lean and cGMP can be aligned. It is confirmed by the analysis in this thesis. Overall, the analysis also pointed out that flow related issues and wasteful activities, which is not one of the focal areas of cGMP can be brought into the light by utilizing VSM as a tool of analysis. Further, by applying lean tools and methods in order to mitigate the flow and waste related deficiencies can be improved. The conclusion is that focus should be concentrated on supporting activities around the actual packaging process to improve the flow, remove wasteful activities and cut down idle times, i.e. the activities between process steps. The steps between and around the actual packaging also proved to be less regulated by cGMP, and thus also easier to adapt to a lean state.

RQ3 *Does VSM constitute a good foundation for process optimization within the pharmaceutical industry?*

The actual construction of VSM in a context characterized by the regulatory nature of cGMP was found to be facilitated by the cGMP itself. As cGMP presents strict rules upon traceability, comprehensive documentation is available. This documentation makes it possible to follow the actual value streams and in many process steps, valuable information that can be used in the construction of a VSM is added. This could for example be quantity, rejects, when a process started and when it ended and so forth depending on the type of process. The availability of documentation makes it relatively simple to follow an order through the entire value stream, since all the process steps in the value streams are documented. The information gathered from the documentation naturally needs to be complemented with information from observations and interviews since numbers on VAT and other data is not included in the cGMP documentation. Further, gemba walks are

needed to actually understand the processes, but the cGMP related documentation gives a clear and initial understanding of the flow and lead times in the value streams.

Without the cGMP related documentation, it would have been a much more time-consuming and complex task to map the value streams. 25 orders per product family could be followed through their respective value stream in this thesis, a number which would have been significantly lower if the cGMP related documentation would not have been present. The documentation should be considered as secondary data, and the validity can therefore not be guaranteed. However, without the documentation, only a few orders per product family could have been traced. This means that the VSMs would have been created from a significantly smaller data set, thus making it less statistically valid due to the impact of variations.

As shown in this thesis, VSM can successfully be used to pinpoint areas of improvement within the pharmaceutical industry. Since no implementation has been made yet, no improvements can actually be proved. However, as the VSMs were used to highlight areas with unjustified long lead times and wasteful activities, the conclusion is that VSM does constitute a good foundation for process optimization within the pharmaceutical industry. The deficiencies within the processes were also most often actionable, meaning that VSM can be used successfully to create an environment where lean and cGMP can coexist in symbiosis. The cGMP regulatory framework was also as already mentioned found to facilitate the actual construction of VSM, which could be argued to further strengthen the conclusion of VSM as a good foundation for process optimization within the pharmaceutical industry.

7.2 Theoretical contribution

Previous research related to VSM in the pharmaceutical is limited, but Chowdary & George (2012) presented a case when positive results had been reached. The thesis has further strengthened the perception that VSM is applicable in a cGMP governed environment within the pharmaceutical industry. Despite the absence of a follow up procedure, which partly is based on time constraints and the fact that a few proposals have yet been actualised, the thesis indicates a positive co-operation between VSM with additional lean tools and a manufacturing process within the pharmaceutical industry.

In this thesis, eight issues have been identified as problematic. The analysis reveals in what way these issues affect the business and what type of waste each issue can be categorized as, according to Hines & Rich's (1997) waste categorisation, *Table 4.* The characteristics and the common denominator of the identified waste turned out to be *waiting* and

transport. This finding can represent an indication of what type of waste that is most likely to be discovered within the pharmaceutical industry. Further research is absolutely required in order to generalize the result, but the finding in this thesis could be used to confirm such a statement in future research. The types of wastes identified can also directly be correlated to material and information flow and it confirms that a lean approach in a cGMP governed environment is applicable and useful for process improvements.

7.3 Contribution to the commercial and industrial life

Several deficiencies that were affecting the manufacturing processes within a pharmaceutical company were found in this thesis. Some of the deficiencies, like inadequate information sharing, had previously been brought up in literature. This thesis will further stress the need of actions taken to improve information sharing in companies operating in the pharmaceutical industry. Further, this thesis has pointed to that certain types of waste seem to be present within the pharmaceutical industry, and can therefore give managers an understanding of in which areas improvement actions could be focused.

Ten improvement proposals were presented. Managers can use these recommendations as a guideline of how to eliminate or reduce the effects of certain types of waste or deficiencies. Further, as the improvement proposals are presented with an outline that summarizes what deficiency or waste that it seeks to adjust, managers gain a deeper understanding of how certain issues can be resolved. The theoretical summary presented in the thesis can also be used by managers to gain understanding of which different tools and philosophies that can be adapted when transforming the operations towards a future state.

7.4 Future research

As this thesis is limited by both time and the nature of the research questions, there are additional areas that possibly could be investigated further in the name of academia. In this thesis it was concluded that VSM can be used successfully to pinpoint areas of improvement. Another finding was that that certain waste types seemed to occur more often than others. It could therefore be interesting to further investigate if the occurrences of certain waste types in the pharmaceutical industry are characteristic for the same.

Another area of possible future research could be to further investigate how to optimize a warehouse in the pharmaceutical industry. Due to the lack of data and partly by the time constraints, the authors were unable to analyse the warehouse operations sufficiently to propose any substantial recommendations to the company. The regulatory nature of cGMP, e.g. one batch per storage position, and the many product variations that are

present due to country specific regulations regarding documentation, can be further investigated in order to find improvement strategies in connection to warehouse operations.

In this thesis, information sharing was found to be an issue for the company. This issue is seemingly not unique for the company, but is rather found elsewhere in the pharmaceutical industry as some authors have pointed out. Therefore, another area that should be subjected to intensive research is improving information sharing and communication within a pharmaceutical company.

References

Bartholdi, JJ, & Hackman, ST 2010, *Warehouse & distribution science:*, Atlanta, GA: The Supply Chain and Logistics Institute, School of Industrial and Systems Engineering, Georgia Institute of Technology, 2010, viewed 9 March 2017.

Bolten, EF 1997, 'Chapter 6: Other Warehouse Operations', *Managing Time & Space in the Modern Warehouse* pp. 58-83 n.p.: American Management Association International Business Source Complete, EBSCO*host*, viewed 9 March 2017.

Burke, K 2016, 'The use of statistics in understanding pharmaceutical manufacturing processes', British Library EThOS, EBSCO*host*, viewed 18 January 2017.

Chowdary, B, & George, D 2012, 'Improvement of manufacturing operations at a pharmaceutical company: a lean manufacturing approach', *Journal Of Manufacturing Technology Management*, 23, 1, pp. 56-75, Inspec, EBSCO*host*, viewed 19 January 2017.

Chronéer, D, Wallström, P, 2016 'Exploring Waste and Value in a Lean Context' , *International Journal Of Business And Management*, 10, p. 282, SwePub, EBSCO*host*, viewed 18 January 2017.

Čiarnienė, R, & Vienažindienė, M 2012, 'LEAN MANUFACTURING: THEORY AND PRACTICE', Economics & Management, 17, 2, pp. 726-732, Business Source Complete, EBSCOhost, viewed 11 May 2017.

Golicic, S. L., Davis, D. F. & McCarthy, T. M., 2005. A Balanced Approach to Research in Supply Chain Management. In: H. Kotzab, S. Seuring, M. Müller & G. Reiner, eds. Research Methodologies in Supply Chain Management. New York: Physica-Verlag, pp. 16-27, viewed 24 January 2017

Greene, A, & O'Rourke, D 2006, 'Lean manufacturing practice in a cGMP environment', *Pharmaceutical Technology Europe*, 18, 10, pp. 33-39, CINAHL Complete, EBSCO*host*, viewed 1 February 2017.

Grosfeld-Nir, A, Ronen, B, & Kozlovsky, N 2007, 'The Pareto managerial principle: when does it apply?', *International Journal Of Production Research*, 45, 10, pp. 2317-2325, Business Source Complete, EBSCO*host*, viewed 2 February 2017

Gubrium & J. A. Holstein (Eds.). (2003). Thousand Oaks,CA: Sage. 981 pages. ISBN: 0-7619-2850-2. $39.95 (paperback)', *Human Resource Development Quarterly*, 17, 1, pp. 125-129, Business Source Complete, EBSCO*host*, viewed 6 February 2017.

Gubrium, JF, Holstein, JA & Marvasti, AB 2012, 'The implications of interview type and structure in mixed-method designs', in *The sage handbook of interview research: the complexity of the craft*, 2nd edn, SAGE Publications, Inc., Thousand Oaks, CA, pp. 193-205, Viewed 6 February 2017

Hines, P, Holwe, M, & Rich, N 2004, 'Learning to evolve: A review of contemporary lean thinking', International Journal Of Operations & Production Management, 24, 10, pp. 994-1011, Business Source Complete, EBSCOhost, viewed 20 December 2016.

Hines, P, & Rich, N 1997, 'The seven value stream mapping tools', *International Journal Of Operations & Production Management*, 17, 1, pp. 46-64, Business Source Complete, EBSCO*host*, viewed 20 January 2017.

Ibon Serrano, L, Carlos Ochoa, L, & Rodolfo de Castro, V 2008, 'An evaluation of the value stream mapping tool', *Business Process Management Journal*, 14, 1, pp. 39-52, Business Source Complete, EBSCO*host*, viewed 19 January 2017.

Jasti, N, & Kodali, R 2015, 'Lean production: literature review and trends', International Journal Of Production Research, 53, 3, pp. 867-885, Business Source Complete, EBSCOhost, viewed 21 December 2016.

Jasti, N, & Sharma, A 2014, 'Lean manufacturing implementation using value stream mapping as a tool:A case study from auto components industry', *International Journal Of Lean Six Sigma*, 5, 1, p. 89, Publisher Provided Full Text Searching File, EBSCO*host*, viewed 23 January 2017.

Jeyaraj, K, Muralidharan, C, Mahalingam, R, & Deshmukh, S 2013, 'Applying Value Stream Mapping Technique for Production Improvement in a Manufacturing Company: A Case Study', *Journal Of The Institution Of Engineers (India): Series C*, 94, 1, p. 43, Supplemental Index, EBSCO*host*, viewed 23 January 2017.

Katarina, P, & Vojislav, B 2012, 'LEAN AND SIX SIGMA CONCEPTS APPLICATION IN PHARMACEUTICAL INDUSTRY', *International Journal For Quality Research, Vol 6, Iss 1, Pp 23-28 (2012)*, 1, p. 23, Directory of Open Access Journals, EBSCO*host*, viewed 19 January 2017.

Key2Compliance 2014, EudraLex: The rules governing medicinal products in the European Union, Key2Compliance, Lidingö

KING, P. L. (2009). Lean for the process industries: dealing with complexity. Boca Raton, CRC Press.

KRAM, M, TOŠANOVIĆ, N, & HEGEDIĆ, M 2015, 'KAIZEN APPROACH TO SUPPLY CHAIN MANAGEMENT: FIRST STEP FOR TRANSFORMING SUPPLY CHAIN INTO LEAN SUPPLY CHAIN', Annals Of The Faculty Of Engineering Hunedoara - International Journal Of Engineering, 13, 1, pp. 161-164, Academic Search Complete, EBSCOhost, viewed 11 May 2017.

Langstrand, J 2017,'An introduction to value stream mapping and analysis' 2016, SwePub, EBSCO*host*, viewed 19 January 2017.

Leopold, K, & Kaltenecker, S 2015, *Kanban Change Leadership : Creating A Culture Of Continuous Improvement*, n.p.: Hoboken, New Jersey : John Wiley & Sons Inc., 2015., Library catalogue (Lovisa), EBSCO*host*, viewed 31 January 2017.

Liker, J, Erkelius, L, & Hallberg, J 2009, *The Toyota Way : Lean För Världsklass*, n.p.: Malmö : Liber, 2009 ([Sverige] : Elanders), Library catalogue (Lovisa), EBSCO*host*, viewed 30 January 2017.

LUCA, L 2016, 'A STUDY ON QUALITY ANALYSIS MEASURING PROCESS', Fiability & Durability / Fiabilitate Si Durabilitate, 2, pp. 68-72, Academic Search Complete, EBSCOhost, viewed 11 May 2017.

Läkemedelsverket 2015a, *Svensk Lagstiftning.* Available from: <https://lakemedelsverket.se/overgripande/Lagar--regler/Svensk-lagstiftning/>. [12 March 2017]

Läkemedelsverket 2015b, *Tillverkning av läkemedel (GMP).* Available from:<https://lakemedelsverket.se/malgrupp/Foretag/Lakemedel/Tillsyn-och-uppfoljning---GMPGDP/Tillverkning-av-lakemedel-GMP/>. [13 March 2017]

Martin, K, & Osterling, M 2014, *Value Stream Mapping*, n.p.: New York, McGraw-Hill.

Michael, F 1999, 'Process improvement by poka-yoke', Work Study, 7, p. 264, Emerald Insight, EBSCOhost, viewed 11 May 2017.

Nolen, J, 'Standard operating procedure (SOP)', *Britannica Online*, Britannica Online, EBSCO*host*, viewed 1 February 2017.

O'Connor, M 2017 2015, *Product Family Analysis,* LeanMath. Available from: <http://leanmath.com/blog/2015/04/30/product-family-analysis/>. [15 February 2017]

Olhager, J 2013, *Produktionsekonomi : Principer Och Metoder För Utformning, Styrning Och Utveckling Av Industriell Produktion*, n.p.: Lund : Studentlitteratur, 2013 (Spanien), Library catalogue (Lovisa), EBSCO*host*, viewed 30 January 2017.

Omogbai, O, & Salonitis, K 2017, 'The Implementation of 5S Lean Tool Using System Dynamics Approach', Procedia CIRP, 60, Complex Systems Engineering and Development Proceedings of the 27th CIRP Design Conference Cranfield University, UK 10th - 12th May 2017, pp. 380-385, ScienceDirect, EBSCOhost, viewed 11 May 2017.

Patrocinio, E 2015, 'VALUE STREAM MAPPING: Operationalizing Lean Manufacturing', SMT: Surface Mount Technology, pp. 12-18, Business Source Complete, EBSCOhost, viewed 20 December 2016.

Pavnaskar, S, Gershenson, J, & Jambekar, A 2003, 'Classification scheme for lean manufacturing tools', *International Journal Of Production Research*, 41, 13, p. 3075, Business Source Complete, EBSCO*host*, viewed 18 January 2017.

Plakhotnik, M, & Rocco, T 2006, 'Handbook of Interview Research: Context and Method, by J. F. Gubrium & J. A. Holstein (Eds.). (2002). Thousand Oaks, CA: Sage. 981 pages. ISBN: 0-7619-1951-1. $155.00 (hardcover) Inside Interviewing: New Lenses, New Concerns, by J. A. Holstein & J. F. Gubrium (Eds.). (2003). Thousand Oaks, CA: Sage. 557 pages. ISBN: 0-7619-2851-0. $53.95 (paperback) Postmodern Interviewing, by J. F.

Pojasek, RB 1999, 'Poka-Yoke and Zero Waste', *Environmental Quality Management*, 9, 2, pp. 91-97, Business Source Complete, EBSCO*host*, viewed 1 February 2017.

Porter, ME 1985, *Competitive Advantage : Creating And Sustaining Superior Performance*, n.p.: New York : Free Press, cop. 1985, Library catalogue (Lovisa), EBSCO*host*, viewed 3 May 2017.

PwC 2015, *Are you unlocking the value of your supply chain?*. Available from: <http://www.pwc.com/gx/en/pharma-life-sciences/pdf/pwc-pharma-supply-chain-distribution.pdf>. [23 January 2017]

Rahman, N, Sharif, S, & Esa, M 2013, 'Lean Manufacturing Case Study with Kanban System Implementation', Procedia Economics And Finance, 7, International Conference on Economics and Business Research 2013 (ICEBR 2013), pp. 174-180, ScienceDirect, EBSCOhost, viewed 11 May 2017.

Ríos-Mercado, R, & Ríos-Solís, Y n.d., *Just-In-Time Systems*, n.p.: Dordrecht, Netherlands : Springer, ePublications, EBSCO*host*, viewed 2 February 2017.

Saunders, M, Lewis, P, & Thornhill, A 2007, *Research Methods For Business Students. [Elektronisk Resurs]*, n.p.: Harlow : Financial Times/Prentice Hall, cop. 2007, Library catalogue (Lovisa), EBSCO*host*, viewed 24 January 2017.

Schmidtke, D, Heiser, U, & Hinrichsen, O 2014, 'A simulation-enhanced value stream mapping approach for optimisation of complex production environments', International Journal Of Production Research, 52, 20, pp. 6146-6160, Business Source Complete, EBSCOhost, viewed 20 December 2016.

Southworth, T 2012, 'Gemba walks', *Label & Narrow Web*, 17, 2, pp. 38-39, Business Source Complete, EBSCO*host*, viewed 20 January 2017.

Stuart, I, McCutcheon, D, Handfield, R, McLachlin, R, & Samson, D 2002, 'Effective case research in operations management: a process perspective', *Journal Of Operations Management*, 20, pp. 419-433, ScienceDirect, EBSCO*host*, viewed 9 March 2017.

Sundar, R, Balaji, A, & Kumar, R 2014, 'A Review on Lean Manufacturing Implementation Techniques', Procedia Engineering, 97, "12th Global Congress on Manufacturing and Management" GCMM - 2014, pp. 1875-1885, ScienceDirect, EBSCOhost, viewed 11 May 2017

Swamidass, PM 2000, 'Encyclopedia of Production and Manufacturing Management', *Encyclopedia of Production & Manufacturing Management* p. 1 n.p.: Business Source Complete, EBSCO*host*, viewed 1 February 2017

Sörqvist, L 2013, *Lean: Processutveckling Med Fokus På Kundvärde Och Effektiva Flöden*, n.p.: Lund : Studentlitteratur, 2013 (Danmark), Library catalogue (Lovisa), EBSCO*host*, viewed 30 January 2017.

The European Commission's Directorate for public health and risk assessment 2017, 'EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines'. Available from: <https://ec.europa.eu/health/documents/eudralex/vol-4_en> [9 March 2017]

WHO 2017, *GMP Questions and Answers*. Available from: <http://www.who.int/medicines/areas/quality_safety/quality_assurance/gmp/en/>. [27 January 2017]

Wiljeana J., G, Wen‐Hsing, L, Jennifer A., F, & Eileen M. Van, A 2013, 'Characteristics of established kaizen event programs: an empirical study', *International Journal Of Operations & Production Management*, 9, p. 1166, Emerald Insight, EBSCO*host*, viewed 11 May 2017.

Yin, RK 2013, *Case Study Research: Design And Methods*, n.p.: London : SAGE, cop. 2014., Malmö University Library Catalogue, EBSCO*host*, viewed 25 January 2017.

Appendix

Appendix A - Interview Guide (Swedish)

- Hur personer många jobbar på den avdelningen du är på?
- Vad har din avdelning för roll?
- Vad är din roll och vilka arbetsuppgifter har du kopplat till produktionen?
- Kan du ge din bild över hur processen ser ut, från att order mottages till att order levereras?
- Vad initierar/avslutar dina respektive arbetsuppgifter?
- Vilka beröringspunkter har du med andra personer på företaget kopplat till dina arbetsuppgifter?
- Vad ser du för problem i produktionsprocessen?
- Vad ser du för problem med materialflödet?
- Vad ser du för problem med informationsflödet?
- Om du fick göra ändringar i processen, vad hade du gjort då?
- Vad begränsar dina möjligheter att utföra dina arbetsuppgifter?

Appendix B - Interview Guide (English)

- How many people are working at your department?
- What role do your department have in the company?
- What is your role and what work tasks do you have in connection to the production?
- Could you give us your view upon how the process from incoming order to shipment looks like?
- What activities trigger/terminate your respective work tasks?
- Which touchpoints do you have with other people in the company connected to your work tasks?
- What problems can you see in the production process?
- What problems can you see with the material flow?
- What problems can you see with the information flow?
- What changes would you make to the process?
- What delimits your ability to perform your work tasks?