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Understanding how contextual factors influence warehouse configuration in a pharmaceutical setting

A case study

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This master's thesis for the degree of Master of Science in Mechanical Engineering has been conducted at the Division of Engineering Logistics at the Faculty of Engineering, Lund University. Supervisor at LTH: Dr. Joakim Hans Kembro. Examiner: Prof. Jan Olhager

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Preface

This thesis was conducted during the last part of 2019 and during the spring of 2020 as part of the authors' master's degrees in mechanical engineering at Lund University, faculty of engineering. This thesis was conducted as a case study, in collaboration with a pharmaceutical manufacturer in Sweden.

First, we want to express our sincerest thanks to our supervisor Joakim Kembro, at the division of Engineering Logistics, that has provided useful insights as well as challenging us to create even better work. Without these comments and challenging propositions, the thesis would not have turned out the way it did.

We also want to express our gratitude to the case company for letting us explore and immerse ourselves in the interesting world of pharmaceuticals. We want to thank all the respondents for taking time to answer our questions and letting us visit them during the field visits. We also want to especially thank our company supervisor who has steered us in the right direction and made sure the project was a success.

Christoffer Maltesson

Victor Sandberg

Abstract

Title: Understanding how contextual factors influence warehouse configuration in a pharmaceutical setting.

Authors: Christoffer Maltesson and Victor Sandberg.

Problem description: The role of the warehouse has changed dramatically over the years, from being viewed as a necessary evil, to playing a vital or even critical role in the pursuit of business success. The growing importance of warehouse configuration has become evident and research on configurational considerations has been discussed in a broader range of literature. An area that has not received much attention, in regard to warehouse configuration, is the pharmaceutical industry. Since pharmaceutical manufacturers are required to operate in compliance with several regulations, it seems to be an interesting research area. To conduct this research, a pharmaceutical manufacturer who is in the process of building a new warehouse has been selected to study in depth.

Purpose and research questions: The study will investigate the interface between warehouse configuration and the pharmaceutical context. The purpose will be to fill in the gaps in the research by '*exploring the pharmaceutical context and understand how it influences warehouse configuration.*' Given this purpose, the following two research questions are formulated: *What are the contextual factors that influence warehouse configuration? and How do the contextual factors influence warehouse configuration?*

Methodology: An exploratory case study with a pharmaceutical manufacturer was conducted. Before collecting any primary data, a secondary data study was carried out. The aim of this study was to understand the implications of various pharmaceutical regulations. It was also helpful with decisions regarding what primary data to collect. The case study included multiple data collection methods and data was collected from multiple sources. The first and foremost collection technique used were interviews, a technique that was studied thoroughly before it was performed. The analysis of the collected data was conducted through multiple steps of pattern matching to fulfill the purpose.

Conclusion: From the secondary data study, along with the empirical findings, the study identified five contextual factors and their influence on warehouse configuration. The first and most significant factor is the regulatory aspect; there are multiple regulatory bodies monitoring the industry and there are specific regulations for configuration of storage areas and how materials are handled. Two other factors, closely related to regulation, are control and separation. Control is concerned with overall control of operations whereas separation entails separation of goods, flows and processes. The two last factors, with origins in the external environment, are product and customer characteristics. Another finding was the identification of two new ancillary processes: pre put-away and post-picking.

Keywords: Warehouse, Configuration, Pharmaceutical context, Contextual factor, Regulation, Production warehouse, Case study

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List of definitions

Starting materials
Any substance of a defined quality used in the production of a pharmaceutical product, but excluding packaging materials (WHO, 2014)

Qualified person
Every pharmaceutical company must have at least one qualified person that must have a formal scientific diploma in an appropriate field. This person is ultimately, and personally, responsible to ensure that all batches have been produced and checked according to the law. (Directive 2001/83/EC)

CFR
Code of regulations is the codification of general rules and regulations published by US government agencies. Title 21 covers rules and regulations of the Food and Drug Administration (Food and Drug administration, n.d.)

Eudralex
Is a collection of the rules that governs pharmaceutical products within the European Union. EudraLex volume 4 contains guidance for interpretation of principles for good manufacturing practices of medicinal products (European commission, n.d.)

Contextual factors
External factors that affect, or influence, different decisions and solutions for a company in a certain context (Norrman and Kembro, 2019)

Configurational elements
Decision elements such as choice of equipment or layout (Norrman and Kembro, 2019)

Orphan drugs
Drugs that are used as treatment for rare diseases or conditions that affect no more than five people out of 10'000 in the European Union (European Medicines Agency, n.d. a)

Active pharmaceutical ingredient
Any substance, or mixture of substances, that are to be used in the manufacturing of a drug. An API substance have a direct effect on the human body. For example, in Panodil® the API is paracetamol. (European Medicines Agency, n.d. b)

Temperature mapping
A procedure used to locate hot and cold areas and temperature distribution within a storage zone to ensure proper storage conditions. (WHO, 2019)

List of abbreviations

3PL	Third party logistics
API	Active pharmaceutical ingredient
CFR	Code of federal regulation
EMA	European Medicines Agency
ERP	Enterprise Resource Planning
FDA	Food and drug administration
FEFO	First-expiry-first-out
FG	Finished goods
FMD	Falsified medicines directive
GMP	Good manufacturing practice
KP	Key performance indicator
LV	Läkemedelsverket (Swedish medical products agency)
MHRA	Medicines and Healthcare products Regulatory Agency
MTO	Made to order
QA	Quality assurance
QC	Quality control
QP	Qualified person
ROI	Return on investment
SKU	Stock keeping unit
WIP	Work in process
WMS	Warehouse management system

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1. Introduction

1.1 Background and problem discussion

The role of the warehouse has changed dramatically over the years, from being viewed as a necessary evil, to playing a vital or even critical role in the pursuit of business success. Customers want great and swift service, and companies want to manage efficient and effective flows (Faber et al., 2013; de Koster et al., 2017). Today, the warehouse can be the key that ensures a competitive edge as well as serving as an integral part of any supply chain strategy (Kembro, 2016; Faber et al, 2018). In essence, a warehouse can be described as "…points in the supply chain where product pauses, however briefly, and is touched". (Bartholdi and Hackman, 2019) While this is true, it hides the underlying complexity. Warehouses are, in fact, complex systems in and of themselves, with processes and activities carried out to serve their purpose. Warehouses can serve many purposes such as matching supply and demand, act as a consolidation point or facilitate postponement strategies (Bartholdi and Hackman, 2019; Twede et al., 2000). While the purpose might differ from different warehouses, such as a retail warehouse serving private persons or a grocery distribution center serving stores, there are many commonalities to be found on how they are organized in terms of both material flow and general processes (Bartholdi and Hackman, 2019). A warehouse involves two groups of physical processes, namely inbound and outbound processes (Bartholdi and Hackman, 2019). Which in turn are broken down into; receiving, put-away, storage, picking, packing and shipping (Bartholdi and Hackman, 2019; de Koster et al., 2007; Rouwenhorst et al., 2000). Basically, the warehouse involves an array of resources to handle incoming goods and store it until it is needed. Then it is picked, sometimes sorted and packed, and shipped (Bartholdi and Hackman, 2019; cf. Rouwenhorst et al., 2000).

The competition that companies experience drives continuous improvements across the organization to provide better services while maintaining efficiency and effectiveness. For warehousing operation and design this is not an exception, on the contrary, it is of great importance. This changing environment will require warehouses to support and realize overall strategies (Gu et al., 2007). The growing importance of warehouse configuration becomes evident. Research on configurational considerations has been discussed in a broader range of literature. Market situation, product and order characteristics and several more are factors that influence considerations for warehouse design (Rouwenhorst et al., 2000; Gu et al., 2007). Configuration elements, as proposed by Kembro and Norrman (2019a), are present at all levels of warehousing operation and design decisions. For the warehouse this might entail decisions on aisle configuration, degree of automation, picking strategies, choice of material handling equipment, IT-support and more (Kembro and Norrman, 2019a; Rouwenhorst et al., 2000, Faber et al., 2018; cf. Gu et al., 2007). Literature has also discussed factors that affect warehouse configuration (Rouwenhorst et al., 2000; Gu et al., 2007) but this is not the complete story. An important part is the contextual setting that the warehouse operates in, and the contextual factors affect performance and use (Faber et al., 2018; Sousa and Voss 2008). These contextual factors have implications for considerations across the board. From this emerges an interesting field of research where different contextual settings influence configuration elements.

One field that has not received much research regarding warehouse configuration is the pharmaceutical industry. In 2018, the global market for pharmaceuticals amounted to $1.2 trillion and expects to exceed $1.5 trillion by 2023 (IQVIA, 2019). In response to rising global demand, the complexity of supply chains is exacerbated. The increasing complexity increases the risk of errors and therefore the risk of supply disruptions and drug shortages. A crucial part of these complex supply chains are effective and efficient warehouses that are operated by the pharmaceutical practitioners. Naturally, due to the limited attention to pharmaceutical warehouse configuration in general there is, to the best of our knowledge, no research regarding contextual variables affecting warehouse configuration.

An interesting part of the pharmaceutical context is that manufacturers are required to operate in compliance with the international rules and guidelines of 'Good Manufacturing Practice' (GMP). The prime purpose of GMP is quality assurance in order to prevent infliction of harm to the end user. Apart from guidelines regarding e.g. hygienic manufacturing areas and proper documentation procedures, GMP retains guidelines for storage, handling, labeling and distribution of pharmaceuticals (WHO, 2014). With regards to the limited research on the subject, as well as the regulations followed by GMP, researching how contextual factors influence warehousing configuration in a pharmaceutical setting certainly seems to be an interesting research area.

In order to conduct this research, a pharmaceutical manufacturer who can be studied in depth has been selected. The company is a developer and producer of pharmaceuticals who specializes in aseptic injectables and sprays for nasal and oral administration. In recent years, the company has experienced significant growth and the growth is expected to increase in the following years. Unfortunately, overall logistical processes and warehouse capacities are unable to cope with the substantial growth. To manage this situation, the company is building a new production site at a new location. Initially, this site will only operate as an external warehouse but in time, all businesses will relocate to this location.

The main goal and delivery to the selected company is to establish a complete warehouse configuration for the new warehouse. This configuration entails a design of the warehouse layout as well as enhanced warehousing processes in terms of effectiveness and efficiency. To reach this goal it is of utmost importance to understand the configuration elements and identify the contextual considerations in a pharmaceutical setting. By identifying the contextual variables and understanding how they influence the warehouse configuration, it will be possible to adapt existing warehouse design theory and apply it to establish the new configuration.

1.2 Purpose

While warehouse configuration and the pharmaceutical context have been well researched individually, there has been limited research that integrates the two. To be able to configure the case company's new warehouse, the study will investigate the interface between warehouse configuration and the pharmaceutical context, illustrated in figure 1.1 below. Therefore, the purpose of this thesis will be to '*explore the pharmaceutical context to understand how it influences warehouse configuration and to configure a pharmaceutical warehouse.*'

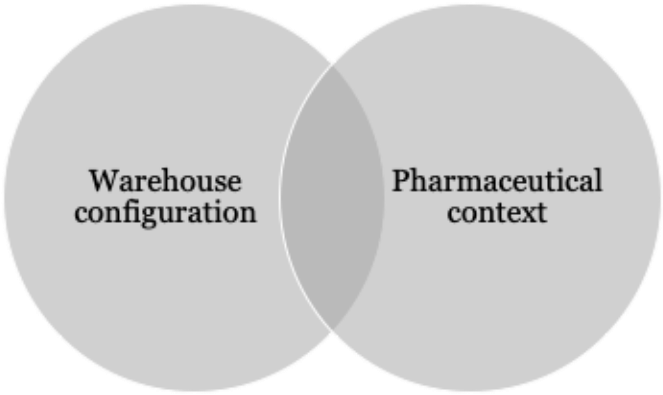

Figure 1.1 – Area of research, the interface between warehouse configuration and the pharmaceutical context

Given the purpose of this thesis, we want to gain more insights into how the pharmaceutical context influences design and configuration elements. Hence, we formulate the following research questions.

> *RQ1: What are the contextual factors that influence warehouse configuration in the pharmaceutical context?*
>
> *RQ2: How do the contextual factors influence warehouse configuration in the pharmaceutical context?*

Research question one seeks to fulfill the first aim of the research, namely, understanding the pharmaceutical context. The contextual factors will provide a means of conceptualizing the context and provide an overview of it. However, this is only half of the purpose which also seeks to answer how the context influences. Therefore, we also formulate the second research question.

1.3 Scope

This thesis will be conducted in collaboration with a pharmaceutical company and will focus on warehouse operations and configuration. As of today, the case company has two separate facilities in different locations. This current setup will be the entity on which the study will be conducted. However, the company is planning to build a new site that aims to consolidate all the activities performed in the company. Our configuration proposal will be limited to this new setup and location. To make it clear what the scope is, figure 1.2, illustrates what is regarded as the current setup and what is regarded as the new setup. It can also be noted, from the figure, that the external warehouse will be made redundant and consequently will be removed in the new setup.

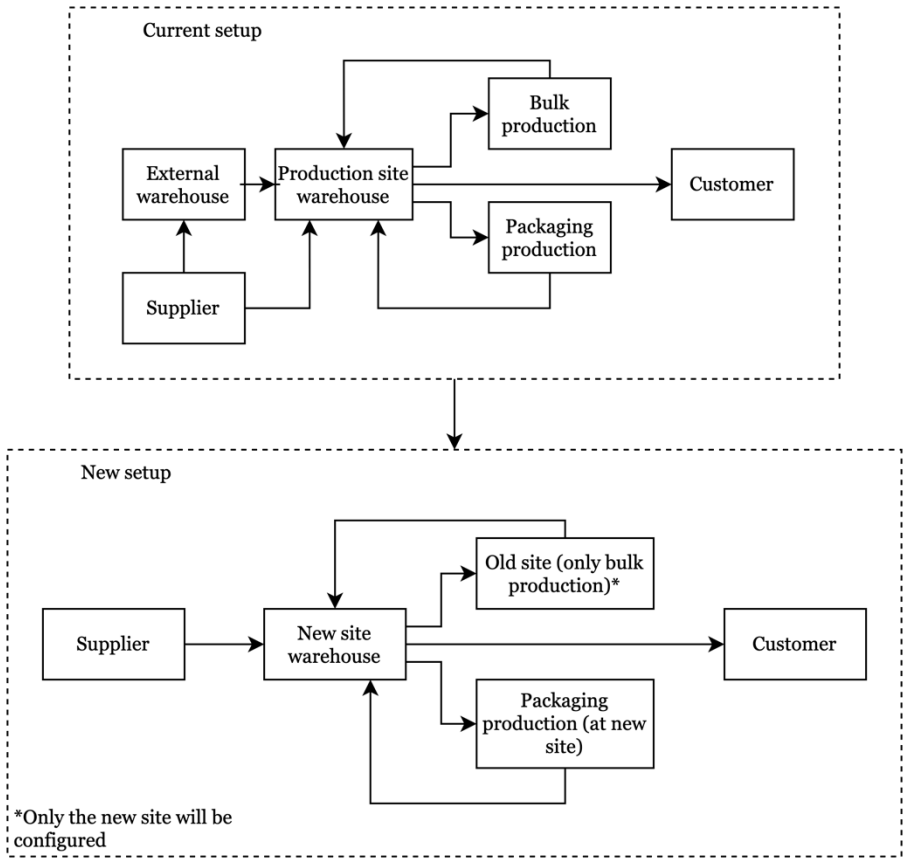

Figure 1.2 - Illustration of current and new setup for the case company

Furthermore, the complete warehouse process will be investigated and analyzed (cf. Bartholdi and Hackman, 2019) and will also be configured. Additionally, physical equipment such as palletizers, lift-trucks and more will be included in the analysis. Structural consideration on how to configure pallet racks is also included in the analysis.

In the medium to long term, the company will transform their business from a multi-site setup to a single site setup, which in turn will affect warehouse considerations greatly. While this thesis will focus on the new site that will end up as the single site, only the setup with warehouse and packaging at the new site, and bulk production at the old site will be considered. Future requirements will change and therefore the thesis will not consider the longer-term planning horizon (10+ years).

The new site is a new construction project and this thesis will consider the warehouse structure, as proposed by architects, as a fixed constant. Nevertheless, the proposal will include a fully fitted and configured warehouse that will make use of its full footprint. However, the configuration will fit the capacity needs in the short and medium term, including a timeline for expansion to the fully utilized space scenario.

Implementation of the proposed configuration will not be investigated. Also, the managerial aspects such as staffing, and LAS will be left outside the scope. Alongside this, the case company's supply chain setup and strategy will be viewed as a constant and the warehouse will be viewed as its own entity. Also, the case company's overall strategies will also be viewed as constants.

1.4 Thesis outline

This thesis will be built up by seven sections that all contribute to answer the posed research questions. The structure, or outline, is shown in figure 1.3. The three first parts, *introduction, frame of reference* and *methodology* will provide the foundation for the thesis. An introduction to the subject is given in this section, as well as positioning of the study. Also, the purpose and the research questions are defined. After, the frame of reference will provide an overview of the theoretical landscape of warehouse configuration as it is today. This will result in a conceptual framework that will be used throughout the study. This is also a reason why the next step, methodology, comes after the theory. The methodology guides the research and helps to ensure both research quality and trustworthiness. *Data aggregation* is just the empirical data section that is divided into two parts; *secondary data study* for explaining the context and *case study* for data from the single case study. The third part, analyzing and discussion, will provide answers to the posed research questions. This will be divided into two parts as well, one for each research question. The first part describes the contextual factors and the second part describes the influences of those contextual factors. After this, before concluding and reflecting upon the contributions and conclusions, the theory and the knowledge from the study is set in a practical setting - exploring a way to configure the case company's new warehouse. Lastly, the thesis will conclude the findings and answer the research questions clearly. It will also discuss limitations and opportunities for future research.

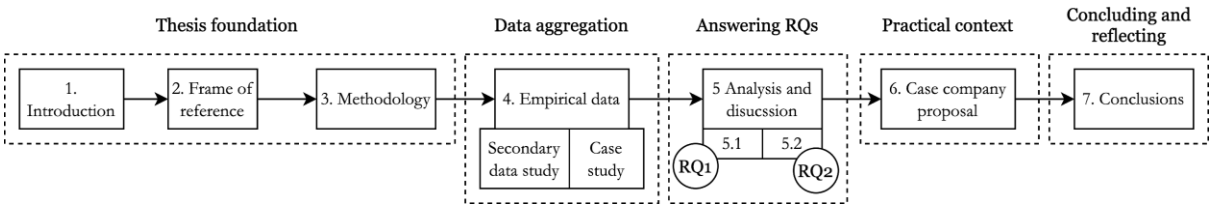

Figure 1.3 – Thesis outline

2. Frame of reference

This thesis seeks to explore and explain the pharmaceutical context. More specifically, it seeks to understand how the context influences warehouse configuration in a theoretical and in a practical sense. Given the purpose this requires a theoretical foundation to build a conceptual framework around which the thesis will be formed. Warehouse configuration is not a singular thing, it is made up of different important components that require attention and understanding. The goal of frame of reference is to provide those components and understanding. The main parts of what is being configured are operation aspects and, design and resources. These are the tangible things that often are connected to the warehouse and warehousing in general. On top of that, warehouse goals and types, as well as design approach explains the motivation behind why the warehouse exists. The design approach will provide a guide for how the actual process of configuring a warehouse works.

The conceptual framework that will be presented at the end of this section, as an amalgamation of all the components, will provide the thesis with structure and will help guide further analysis and discussion.

2.1 Warehouse types and goals

Warehousing control and operation has increased in importance and are essential parts of any supply chain (Baker and Canessa, 2009; Bartholdi III and Hackman, 2019; Gu et al., 2010). While also being an important piece that affects business success; getting warehouse operation and design right is not a trivial task (Baker and Canessa, 2009; de Koster et al., 2017). Different factors will affect how effective and efficient a warehouse will operate and complex decisions are the rule rather than the exception. Decisions and considerations on layout, storage policies, picking policies, equipment and many more are key to get right for a functioning warehouse (Bartholdi III and Hackman, 2019; Baker and Canessa, 2009). First of all, the type of warehouse impact considerations. Several authors have stated different types of warehouse and their function. According to Bartholdi III and Hackman (2019), warehouses can be categorized principally by their customers and they present retail DC, service parts DC, E-commerce DC, 3PL and perishables warehouse. Rouwenhorst et al. (2000) proposes a viewpoint that only two types can be distinguished; the distribution warehouse and the production warehouse. Frazelle (2015) suggests eight different warehouses and their roles: raw material, work-in-progress, finished goods, overflow, distribution center, bonded, public and contract warehouses. Frazelle (2015) also provides a more detailed description of the distribution warehouse and divides it into: home delivery, omni-channel, retail and cross-dock. Regardless of which author's viewpoint, different types of warehouses will have their own set of requirements. As an example, a perishable goods warehouse will need to ensure a cold chain and be able to handle products with short shelf life and this will greatly affect warehouse design and operations (Bartholdi III and Hackman, 2019). Additionally, each of the different types of warehouses will share the same goals of consolidation and matching demand (Bartholdi III and Hackman, 2019). However, many considerations will be different depending on the type, task and purpose (Bartholdi and Hackman, 2019; Frazelle, 2015; Rouwenhorst et al., 2000). The literature has provided a few different ways of describing this division, on purpose and task at least and table 2.1 shows a proposition on how to view and divide different warehouses according to their roles and customers they serve.

Table 2.1 - Warehouse types, their descriptions and goals

Type	Description	Goal	Sub types	Description	Goal
Distribution center	Distribution centers fulfills customer orders and are also placed closer to the customer. May store a large assortment of articles and order characteristics might differ depending on the customer type	To handle complexity material flows and picking activities. To provide maximum throughput with minimum investment and operational cost is also important	Brick and mortar (B&M)	Supplies to stores or retail outlets (e.g. brick and mortar). Likely to have regular shipments (receiving and shipping) where the customer might be captured. It is characterized by large product flows, large orders with many items. Orders are however known somewhat in advance	Need to support sales and marketing activities.
			E-commerce (E-com)	Fulfills online customer orders. Usually deals with smaller orders that requires short throughput times. The material flows are variable due to marketing activates and seasonality. Returns are also an activity that characterizes this subtype	Need to support sales and marketing activities. Providing fast handling whilst maintaining pick quality at lower cost. Also needs to handle reverse (return) flows efficiently.
			Cross-dock	A sort of terminal that does not store goods but only sort and mix incoming shipments	Needs to coordinate complex flows and to provide fast material handling
			Spare part	Stores spare parts, often with extremely large assortment and diversity of items. Handles stock orders as well as emergency orders.	To store goods cheaply and to provide flexible picking for different types of orders
			Omni channel	A distribution center that integrates physical store replenishment and, online and digital sales. Combining the characteristics of bricks and mortar and e-commerce	To manage complexity of B&M and E-com flows whilst maintaining quality, cost and support for sales and marketing activities.
Production warehouse	Production warehouses holds inventory in different stages of the production cycle as well as finished goods that is awaiting shipment to distribution centers. Some of the material may be stored for a longer period of time and may be stored in larger quantities to handle difference in purchase batch and production batch size	Being cost efficient and having enough storage capacity is important. Being able to provide shorter response times for production so to ensure production flow and avoid delays	Raw materials	A warehouse that holds unprocessed materials destined for production	Need to support timely production and assembly.
			Work-in-progress (WIP)	Material that is partly processed and that awaits further processing for completion is stored here	Serve as a buffer between production schedules and demand
			Finished goods (FG)	Holds large quantities of finished goods awaiting shipping to DC	Have enough capacity in both storage capacity and handling resources

2.2 Warehouse design and resources

2.2.1 Physical layout

One of the most crucial design considerations to be made is the one regarding layout. This non-trivial task has an effect on how the warehouse will perform and by extension, business success. There is no single right answer, the best or most optimized solution, the reality is a bit bleaker (Huertas et al., 2007). Warehouse type, role and user requirements all play a role in how the layout will be conceived and for practitioners this means putting pieces together to achieve their purpose and goals (Huertas et al., 2007; Hassan, 2010; Frazelle, 2002). Unsurprisingly, a warehouse needs to store things therefore capacity needs will be an important, if not the most important, requirement to be considered. Capacity is closely linked to productivity and safety in the warehouse, whilst it is desirable to have high storage utilization, too high utilization will result in a dramatic decline in productivity and safety. From figure 2.1 it can be noted that around 80% should be aimed for whilst utilization exceeding 85% will result in the dramatic decline (Frazelle, 2015). Besides the overall capacity needs, different processes will require enough space to function effectively and efficiently. Which in turn affects the capacity needs. Similarly, space requirements of different departments and zones in the warehouse will have the same effect.

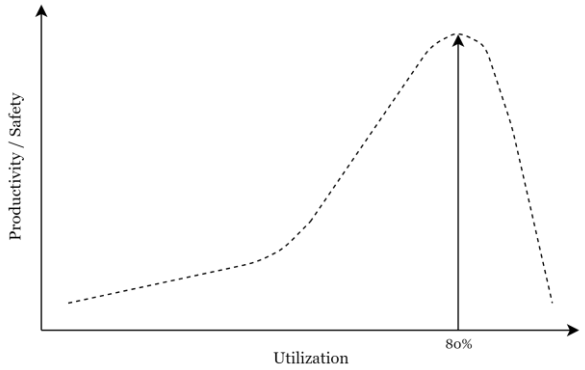

Figure 2.1 - Warehouse productivity and utilization, adapted from (Frazell, 2015)

Balancing optimal space usage and productivity whilst considering operational costs and minimizing them is the goal of the warehouse design (Eriksson, 2019; Hassan, 2010; Rouwenhorst et al., 2000; de Koster et al., 2007). The first problem to be solved, to achieve this goal, is the *facility layout problem* which means locating the different departments such as receiving, picking, storing, sorting, shipping and so on within the confines of the warehouse structure (de Koster et al, 2007). This will however be explored in the next section. Nonetheless, another important piece in the design problem is what de Koster et al. (2007) calls the *internal layout design* or *aisle configuration problem* which is the actual layout and how it is designed. The number of aisles, their length, width and orientation are a few of the considerations to be made (Gu et al., 2007; de Koster et al., 2007). There are different units of handling in a warehouse and this depends on what the company actually produces and who its customers are. One can handle pallets, cases and broken cases which all have different requirements. The storage of pallets can be handled with floor storage or with racks and there are both pros and cons with both. Also, floor storage or rack storage will affect calculations for optimal dimensions. To store pallets on the floor is a cheap alternative, as well as flexible

because you could always rearrange the stored goods. However, stackability will be a concern and if this is not possible much vertical space will be unutilized which of course is wasteful. Also, the safety aspect cannot be disregarded, and high stacks of pallets can pose a risk for warehouse staff. A racking solution could alleviate these problems while reducing labor requirements because of easier storage and retrieval of pallets. Additionally, more pallets can be stored in the same area due to the ability to store vertically. However, rack systems are costly and need to be installed which does not provide the same flexibility of floor stacking (Bartholdi III and Hackman, 2019).

Aisles in the warehouse needs to be accessible to staff which means that aisles for storage and retrieval equipment is required (Bartholdi III and Hackman, 2019). Adding too many aisles will decrease the warehouse space that can be used to store goods which, after all, is the main purpose of the warehouse (Hassan, 2002). The aisle consideration is coupled with lane depth and the number of pallets stored in front of each other. This will have to be decided together in conjunction with material flows and requirements (Bartholdi III and Hackman, 2019). Without careful consideration, you might think that the deeper the lane, the better. This might seem true, but the risk of multiple handling increases significantly which will incur cost for handling. There are, however, formulas that can be used to calculate lane depth to achieve space efficiency. One can employ different formulas depending on the type of storage mode; floor storage or pallet flow rack. Common for all calculations are the input data in the form of stackability, demand and order quantity (Bartholdi III and Hackman, 2019). Onwards, aisles need to be configured to fit in the warehouse building and other space requirements that are posed (Gu et al., 2007). Aisle orientation will be important to consider, not only for capacity concerns, but also for labor and cost. If the aisles are too long or too intricately placed, it will increase the length and time needed to travel within the warehouse to execute put-away and picking activities. This will increase the need for more resources and will incur higher labor cost (Bartholdi III and Hackman, 2019; Gu et al., 2007, Gu et al., 2010). To decrease the amount of travel that is needed aisle orientation and configuration will be key to review thoroughly. To reduce the travel, aisles should be configured parallel to material flow which favors straight uninterrupted aisles. However, it can be beneficial to introduce cross aisles to shorten the distance between storage locations. Moreover, there are concepts of angled aisles that increase the amount of aisle space but can reduce travel time up to 20% (Bartholdi III and Hackman, 2019). Figure 2.2 below shows cross aisles and angled aisles.

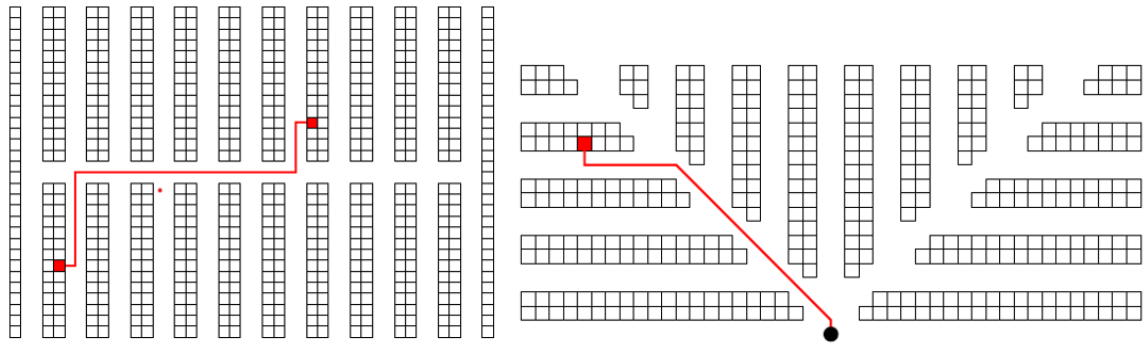

Figure 2.2 - Cross aisles (left) and angled aisles (right) (Bartholdi III and Hackman, 2019)

Another consideration is door configuration, which will have profound effects on processes and cost. Literature states two different types of door configurations; u-flow or flow-through

(Bartholdi III and Hackman, 2019; Frazelle, 2002). The u-flow configuration means that the doors are located on the same side, which renders storage locations near them more convenient whilst at the same time creating less convenient locations away from the doors. The flow through setup means that the doors are located on opposite sides which creates more convenient locations, but not as convenient as for the u-flow setup. In this case convenience means the total distance required to travel to and from a storage location from receiving to shipping. The differences in convenience is illustrated in figure 2.3 below.

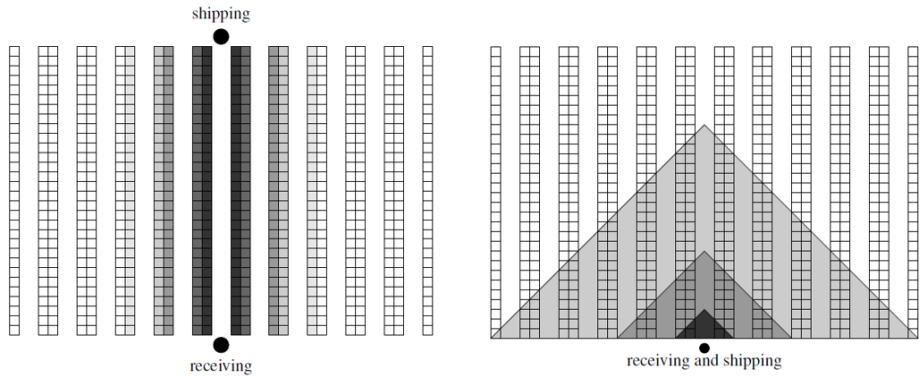

Figure 2.3 - Flow-through (left) and U-flow (right) where black is more convenient (Bartholdi III and Hackman, 2019)

From the literature a way of conceptualizing the physical layout problem emerges. This emerges by looking at the configuration elements and establishing the influencing factors that affect the decisions that are linked to each element. In table 2.2 the literature is condensed to give an overview over the physical layout problem.

Table 2.2 - Overview of considerations for physical layout (Bartholdi III and Hackman, 2019; Frazelle 2015)

	Components	**Decision element**	**Theoretical basis for decision**
Facility layout problem	Capacity needs		*Maintain utilization of 80%*
	Space allocation	Allocation for processes and departments	*According to space requirements*
	Physical location		*Placement of departments and processes according to operations and logical flow*
Internal layout problem	Aisle configuration	Number of aisles	*According to needs and physical constraints*
		Length	
		Depth	*According to formula (demand/flow)*
		Width	*According to SKU dimensions*
		Orientation	*Should be parallel to material flow*
	Door orientation	U-flow	*Suitable for strong ABC skewing*
		Flow-through	*For long and narrow buildings, and where volumes are large*

2.2.2 Equipment

Another consideration that needs to be made is the one regarding storage and handling equipment (Eriksson, 2019; Gu et al., 2007; Kembro et al., 2018). For what pallet and storage equipment is concerned literature has looked at an assortment of different types of racks. Where each type is different in both function and suitability for different setups and picking

policies. In the case of boxes and cases, shelves or gravity flow racks might be employed. Here, it is equally so that different setups will require different equipment. Pallets can be handled within the warehouse by trucks and regular pallet jacks and, cases and boxes can be moved by conveyors just to name a few examples (Bartholdi III and Hackman, 2019; Frazelle, 2002). For all intents and purposes this thesis adopts a twofold view of the material handling equipment consideration, dividing it into material handling and storage equipment. In table 2.3 an overview is given for what the literature has presented in terms of equipment and what to regard when choosing it.

Table 2.3 - Overview of consideration for material handling equipment (Bartholdi III and Hackman, 2019; Frazelle 2015)

Storage equipment	Pallets	Floor storage		*Depending on stackability of goods and formulas*
		Racks	Single rack	*According to demand, SKU characteristics and shipping policy (FIFO, LIFO etc.)*
			Double rack	
			Push-back rack	
			Drive through	
			Flow rack	
	Cases	Shelves		*Depending on flow characteristics*
		Gravity flow racks		
Handling equipment	Trucks	Pallet jacks		*According to physical layout and storage equipment*
		Counterbalance		
		Reach truck		
		Turret truck		
	Miscellaneous	Conveyors		*Mainly for cases*

A major part in storing in a warehouse is the type of storage mode or equipment used to do so. If floor storage is not an option, the choice will be some kind of racking solution. There are a few different varieties to choose from and in table 2.4 these are presented together with a description of which situation they are suitable to be used in and what to regard with each of them.

Table 2.4 - Overview of racking systems and their suitability (Bartholdi III and Hackman, 2019; Frazelle 2015)

Type	**Description**	**Suitability**
Single rack	Regular racks with levels where pallets can be stored. Each location takes one pallet	*Makes every pallet directly available from aisle, but increases the need for aisles*
Double rack	Regular racks with levels where pallets can be stored. Each location takes two pallets behind one another	*Alleviates space utilization problem of single rack, but requires a special truck*
Push-back rack	Deeper, 3-5 pallet positions, and requires the operator to push the pallet in to fit the next	*Suitable for LIFO operation and for medium to fast moving SKUs when you have around 3-10 pallets on hand. Ensures pick face availability*
Pallet flow rack	Picking and storing is done from opposite sides. Pallets flow from back on rollers to the front	*Suitable for FIFO operations and for fast moving SKUs. Good for space utilization*
Drive-through	Allows trucks to be driven within racks. Drive-through enables picking from opposite sides. Around 5-10 pallets deep	*Suitable for FIFO operations and for slow moving SKUs. Good for space utilization but reduces traveling speeds*
Drive-in	Allows trucks to be driven within racks. Drive-in enables picking from the same	*Suitable for LIFO operations and for slow moving SKUs. Good for space utilization but reduces traveling speeds*

Type	Description	Suitability
	aisle as regular floor storage. Around 5-10 pallets deep	
Mobile pallet rack	Racks are movable like moving shelfing in archives	*Suitable when space is scarce and/or expensive, also for slow moving SKUs with up to 3 pallets on hand*
Gravity flow rack (cases)	Tilted shelves with rollers that let cases flow from back to front. Enables simultaneous replenishment and picking	*Suitable for increasing pick-density, pick-speed and decreasing travel time*

2.2.3 Automation

Automation is another area of concern for warehouse design (Kembro et al., 2018). Automation can mean many things, but the main idea is to utilize machines in different applications to reduce the need for labor (Bartholdi III and Hackman, 2019). Additionally, companies also employ automation solutions to accommodate growth and improve customer service (Baker and Halim, 2007). There are different types of automation for different applications, pallet storage can be automated with automated storage and retrieval systems (AS/RS) and pallets can be transported with automated guided vehicles (AGV) (Bartholdi III and Hackman, 2019; Baker and Halim, 2007). Automation is however expensive and involves high investment costs which requires the right prerequisites such as throughput (Baker and Halim, 2007). A framework proposed by Naish and Baker (2004), figure 2.4, provides a tool for assessment of which level of automation that is appropriate. From the framework it becomes clear that to bear an automation solution, sufficient volume needs to flow through the warehouse or that the SKU mix is high and complex (Naish and Baker, 2004). Additionally, choosing the correct automation and the correct level of automation is important for the efficiency of the solution, getting it wrong can actually decrease efficiency (Baker and Halim, 2007).

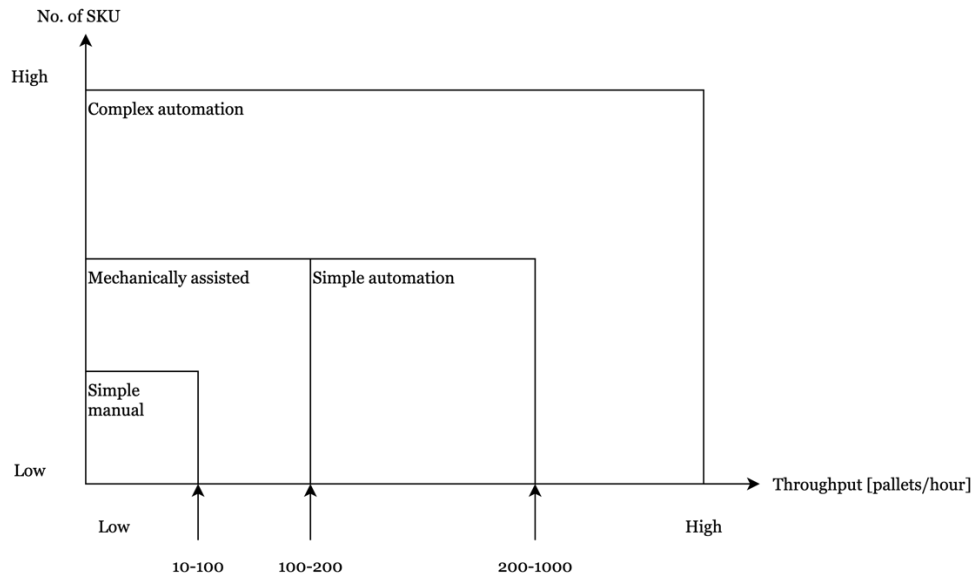

Figure 2.4 - Automation level assessment (Naish and Baker, 2004; Geuken and Jäger, 2015)

2.2.4 Information systems

Another aspect of the warehouse is the ability to manage, control and coordinate its flows, inventory and people to ensure effective and efficient operations (Connolly, 2008). Most warehouses use a specific system for warehouses, a warehouse management system (WMS) (Faber et al., 2013). A WMS typically controls inventory, manages storage locations, creates picking lists, allocates goods and manages staff. There are different types of WMS and depending on the specification, which differs between warehouses, it will have different abilities (Bartholdi III and Hackman, 2019; Faber et al., 2013). In addition to the WMS a warehouse control system (WCS) can be used to control automation in the warehouse. A third frequently used system is an enterprise resource planning (ERP) system that handles longer term planning and may manage information regarding sourcing, human resources and more. These systems can be used to share information with each other or other systems as well (Kembro and Norrman, 2019c).

2.2.5 Labor and management

The last design and resource consideration is labor and the management of it. Most of the time warehouse design goals aim to lower cost of operations and a driving force for cost is labor (Bartholdi III and Hackman, 2019; Eriksson, 2019; Hassan, 2010; Rouwenhorst et al., 2000). Even if the goal is to reduce the labor cost, labor is still a crucial resource and has to be managed accordingly (Bartholdi and Hackman III, 2019). The management's role is multifaceted holding labor costs down, planning schedules and keeping the workforce safe. The safety aspect is important for obvious reasons and this includes ergonomics, proper safety equipment, training and mental health (Frazelle, 2002; Eriksson, 2019). To improve working conditions rotations of tasks is proposed as a solution for improving health, especially for those who work in low temperature environments (Davarzani and Norrman, 2015).

2.3 Warehouse operation aspects

Warehouse operations can largely be viewed as a sequence of processes to receive a product, store it and when a customer orders it, pack it and ship it. Warehouse material flows in literature remain largely the same, with what can be viewed as standard warehousing sequence or process (de Koster et al., 2007; Bartholdi III and Hackman, 2019; Rouwenhorst et al., 2000; Kembro et al., 2018). Figure 2.5 below shows the warehouse process and the flows that are present in the warehouses.

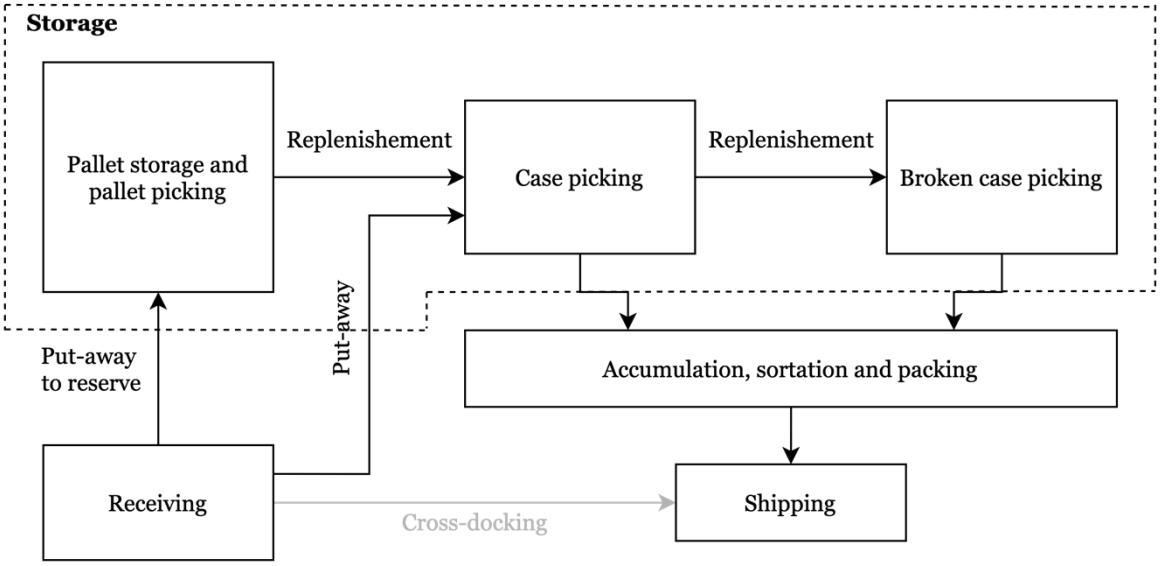

Figure 2.5 - Warehouse process and flow, adapted from (de Koster et al., 2007)

2.3.1 Receiving

The warehouse processes, as seen in Figure 2.5, begins either when goods arrive or when an advance notice is received (Bartholdi III and Hackman, 2019; Gu et al., 2007). When the actual physical goods arrive, it is unloaded and prepared for put-away (Bartholdi III and Hackman, 2019). The goods get scanned, or in another way identified, and inventory is updated, which is an important step so to not introduce discrepancies later on. Quality and quantity are also checked at this stage so to ensure that everything is according to what has been ordered. Depending on external factors, pallets or cases that are arriving might need repackaging onto pallets or into standardized containers (Frazelle, 2002, de Koster et al., 2007). Receiving operations therefore need material handling equipment and information system support for the operator when registering the goods. Moreover, receiving operations are tightly coupled with other warehouse processes and activities which makes it more difficult to manage and configure (Gu et al., 2007; Eriksson, 2019).

Receiving has not received much attention in research and few models for managing it has been proposed. However, consideration and decision to be made are throughput requirements, carrier-dock assignment policy and, equipment and resource allocation. Additionally, information system support for receiving information beforehand on such information of arrival time and quantity can help with planning the overall receiving process (Gu et al., 2007).

2.3.2 Put-away and storage

After all necessary checks and repackaging activities are complete, each received SKU is assigned a storage location somewhere in the warehouse. Each SKU is brought to the location which is scanned to update the information systems for inventory control purposes. It is important to have information on hand on storage requirements for the SKU being put-away to ensure quality and safety (Bartholdi III and Hackman, 2019, Eriksson, 2019). How and where the goods are put-away and stored depends on multiple factors, storage policy, zoning, storage requirements and so on (Gu et al., 2007). The put-away procedure affects downstream

activities such as picking (Davarzani and Norrman, 2015) but it also, in itself, is a cost driver and accounts for around 15% of operation costs (Bartholdi III and Hackman, 2019).

Warehouses mainly function as a means to store goods for later shipment but how goods are stored is decided by storage policies. The literature discusses a few different concepts with advantages and disadvantages, as well as suitability for different setup and SKU requirements.

Table 2.5 - Storage policies (Gu et al., 2007; Bartholdi III and Hackman, 2019; de Koster et al., 2007; Rouwenhorst et al., 2000; Berg and Zijm, 1999; Petersen, 1999)

Storage policy	Description	Suitability
Random	Each SKU is assigned a random storage location. No storage locations are dedicated	Main advantage is increased utilization, at the cost of traveling distance. Pickers cannot learn the location of specific SKUs and one cannot control where popular SKUs are stored
Dedicated	Every product has reserved storage locations which the incoming SKU is assigned to	Reduces travel distance and helps pickers to learn the location of specific SKUs. Additionally, popular SKUs can be stored in convenient locations. However, this reduces utilization
Class based	Classes of products are defined, mostly according to ABC/Pareto distribution, and classes are assigned a dedicated area in the warehouse. Within each area storage assignments are random	A hybrid between random and dedicated that results in reduction of travel and increases utilization. Gives the opportunity to store popular SKUs, within the class, more conveniently.
Family grouping	Products that are related to each other, in some way, can be stored together. For example, batteries and flashlights might be stored together which is why these should be stored together	Can be likened to class based. This can simplify put-away and picking processes, but also downstream processes at the customers' store for instance. This is suitable for less than pallet quantities
Forward- reserve	The stock is divided into a bulk (reserve) area with full pallets and another, forward area. From the forward area items are picked and replenished from the reserve area to the forward area	Used to decrease picking cost and to store in bulk for increased utilization. Needs to calculate which SKUs that are suitable and how much of each SKU that is to be allocated. This is suitable for less than pallet quantities

From table 2.5 it becomes evident that there are multiple ways to configure storage procedures. Random storage is expected to have better space utilization, but at the expense of travel in later stages (de Koster et al., 2007). Random storage introduces problems for workers and the warehouse processes. Products will be stored at different locations at different times, likewise, the same product might be located at different locations simultaneously. This poses issues with increased travel for put-away and it can also introduce incentives for workers to pick products from other locations than assigned to them. These issues, however, can be combated with better software support (Bartholdi III and Hackman, 2019). Dedicated instead is easier to manage but is expected to have less space utilization because temporarily out of stock products are still assigned a location. On the upside, workers will become familiar with the locations of the products which will increase efficiency for other processes (Bartholdi III and Hackman, 2019; de Koster et al., 2007). Class based storage aims to group products into classes and often with the help of popularity or according to the Pareto principle. Often a few products contribute with most of the work which means that they should be assigned more convenient locations, whilst less popular products receive less convenient locations. Class

based storage takes advantage of both random and dedicated because within a class area, locations are assigned at random (de Koster et al., 2007).

The family grouping and forward-reserve approaches are most suitable for less than pallet quantities. For instance, picking pallets with batteries near a pallet with flashlights will not provide any benefits, but picking cases of batteries and flashlights will provide benefits because they can be picked simultaneously. The forward-reserve approach also has similar benefits, reducing cost for picking as well as simplifying replenishment. Pickers will pick the product from a more convenient location while full pallets are stored in a reserve area (de Koster et al., 2007; Rouwenhorst et al., 2000). Figure 2.6 below shows how the forward-reserve approach works.

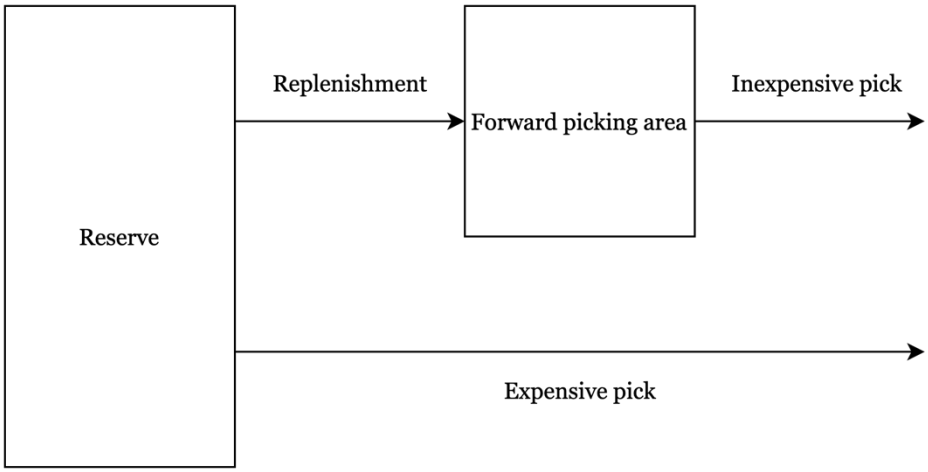

Figure 2.6 - Forward-reserve approach adapted from (Bartholdi III and Hackman, 2019)

Another factor that impacts storage assignment is the chosen retrieval policy. For instance, goods that have shorter shelf life require a first-in-first-out (FIFO) approach. Also, some products might not be suitable for storage next to each other and some products might not be suitable for some storage locations (Gu et al., 2007).

2.3.3 Picking and sorting

After storing products, customers begin to request the products hence, it needs to be picked and transported to the shipping area. The literature is seemingly in agreement that order picking is the most researched area of the warehousing processes and that it is the most cost intensive. It is estimated that 50-75% of total operation costs can be attributed to order picking. (Bartholdi III and Hackman, 2019; de Koster et al., 2007; Petersen and Aase, 2004; Davarzani and Norrman, 2015). A picking strategy can consist of several different considerations that together form the strategy and it is not uncommon to have different picking strategies in the same warehouse (de Koster et al., 2007). One can establish if orders are to be picked in parallel or in sequence. Parallel picking implies that orders are picked by several pickers at the same time. After picking is done the orders are consolidated, which requires activities between picking and shipping. Sequential picking means that an order is picked by a single picker at a time (de Koster et al., 2007; Gu et al., 2007). A second consideration is if to employ a single order picking or batch picking approach, meaning if the picker should pick one order or several orders together. There are more considerations that

create an intricate system of decisions and considerations and de Koster et al. (2007) illustrates these in figure 2.7 below.

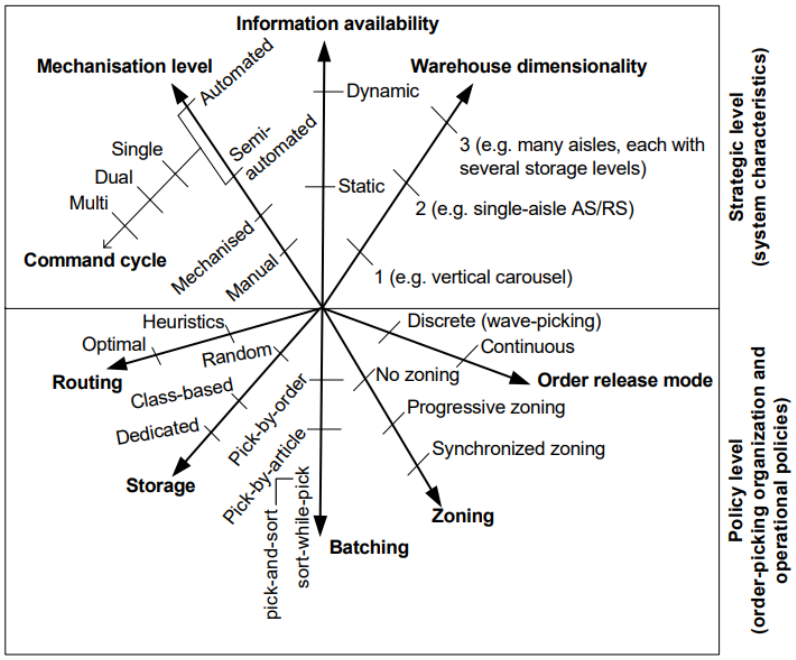

Figure 2.7 - Order-picking complexity (de Koster et al., 2007)

Reducing overall cost is important and non-value adding activities are especially important to eliminate. Travel within the warehouse is often not value adding and therefore needs to be reduced. To decrease the amount of unnecessary travel and to avoid congestion different routing heuristics can be employed (Eriksson, 2019). There are several heuristics, but literature seems to state six types: transversal (or s-shape), midpoint, return, largest gap, optimal, composite (or combined) (Petersen II, 1997; de Koster et al., 2007; Bartholdi III and Hackman, 2019). In figure 2.8 below the different routing heuristics can be seen and the reader is referred to Petersen II (1997) for more information.

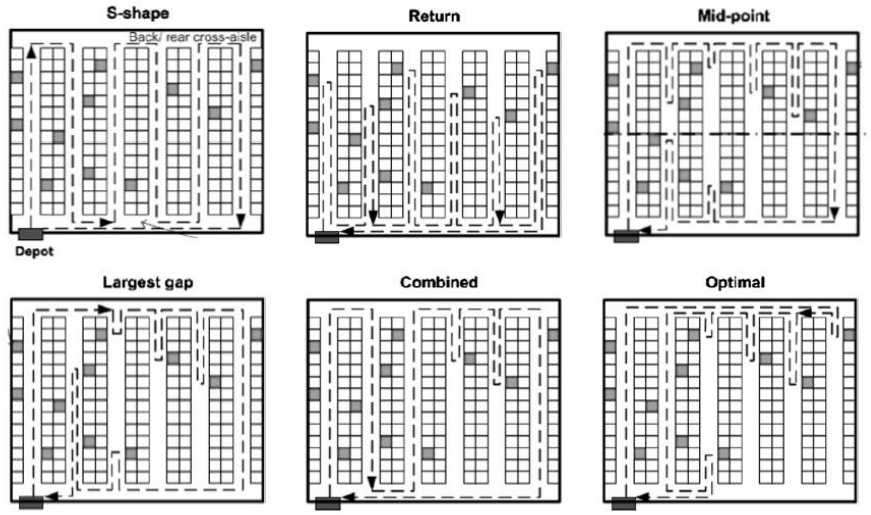

Figure 2.8 - Different routing heuristics (de Koster et al., 2007)

Important to note is that there is no single way to solve the routing problem in an optimal way. The optimal routing problem is just the traveling salesman problem which is very difficult to solve (Bartholdi III and Hackman, 2019). With different approaches one can approximate an optimal solution and this is often the best heuristic, followed by a composite solution (Petersen II, 1997). For the purposes of this thesis order-picking operations will not be as complex as for other warehouses and other concepts such as complex zoning and order release procedures will not be explored.

2.3.4 Packing and shipping

Lastly, when orders have been picked, they are consolidated, checked, packed and then loaded into the awaiting transport mode (Rouwenhorst, 2000). Literature in this area is scarce and there are few models or frameworks for this type of operation (Davarzani and Norrman, 2015; Gu et al., 2007). However, one aspect that is important for shipping is door-carrier-dispatch planning. To plan time windows for departing shipments can help with resource allocation within the warehouse. (Gu et al., 2007).

2.4 Warehouse design approach

Due to the plethora of interdependent variables and decisions, designing a warehouse is a highly complex task. It is therefore vital to follow a clear and predetermined design process when confronting this task. There are several step-by-step frameworks for this, presented in the literature. Goetschalckx and Ashayeri (1989) developed a framework consisting of nine steps divided into external strategic policy planning and internal planning and design. Furthermore, Hassan (2002) developed a linear framework consisting of 14 steps that addresses the main decision points in chronological order. Baker and Canessa (2009) developed a comprehensive systematic method of eleven steps, with tools and techniques provided for each step. The three step-by-step frameworks mentioned in this paragraph are summarized in table 2.6 below.

Table 2.6 - Step-by-step processes for warehouse design from different authors

Step	Hassan (2002)	Baker and Canessa (2009)	Goetschalckx & Ashayeri (1989)
1.	Specifying the type & purpose of the warehouse	Define system requirements	External strategic planning
2.	Forecasting & analysis of expected demand	Define and obtain data	Material characteristics classification
3.	Establishing operating policies	Analyze data	Product demand analysis
4.	Determining inventory levels	Establish unit loads to be used	Storage capacity determination
5.	Class formation	Determine operating procedures and methods	Storage policy selection
6.	General layout	Consider possible equipment types and characteristics	Mechanization level selection
7.	Storage partition	Calculate equipment capacities and quantities	Layout design evaluation
8.	Material handling, storing & sortation systems	Define services and ancillary operations	Information control system design
9.	Design of aisles	Prepare possible layouts	Batching & picking policy selection

Step	Hassan (2002)	Baker and Canessa (2009)	Goetschalckx & Ashayeri (1989)
10.	Determining space requirements	Evaluate and assess	
11.	Number & location of I/O ports	Identify the preferred design	
12.	Number & location of docks		
13.	Arrangement of storage		
14.	Zone formation		

Gu et. al. (2010) emphasizes the interconnected nature of five major decision areas in warehouse design: overall structure, sizing and dimensioning, department layout, equipment selection and operation strategy. These decisions include or are closely interconnected with the warehousing process and amongst themselves. Overall structure includes material flow patterns, specification of functional departments and their flow relationships. Sizing and dimensioning are evidently the size of the warehouse and its departments. Department layout is concerned with department configurations, e.g. aisle configuration. Equipment selection deals with e.g. material handling equipment and degree of automation. Lastly, operation strategy addresses the decisions concerning operations design, such as storage policies or picking strategies (Gu et al., 2007). Table 2.7 below summarizes the decision areas and decisions to be made for each of the areas.

Table 2.7 - Warehouse design areas and related decisions, adopted from (Gu et al., 2010)

		Decisions
Warehouse design	Overall structure	• Material flow • Department identification • Relative location of department
	Sizing and dimensioning	• Size of the warehouse • Size and dimensions of departments
	Department layout	• Pallet block-stacking pattern • Aisle orientation • Number, length and width of aisles • Door locations
	Operation strategy	• Level of automation • Material handling equipment selection • Storage strategy • Order picking method

An important distinction to be made is that the design decisions in table 2.7 are effectively impossible to decouple from one another and should not necessarily be dealt with individually (Gu, et al., 2007). This interweaving and interdependence is visualized in figure 2.9 below.

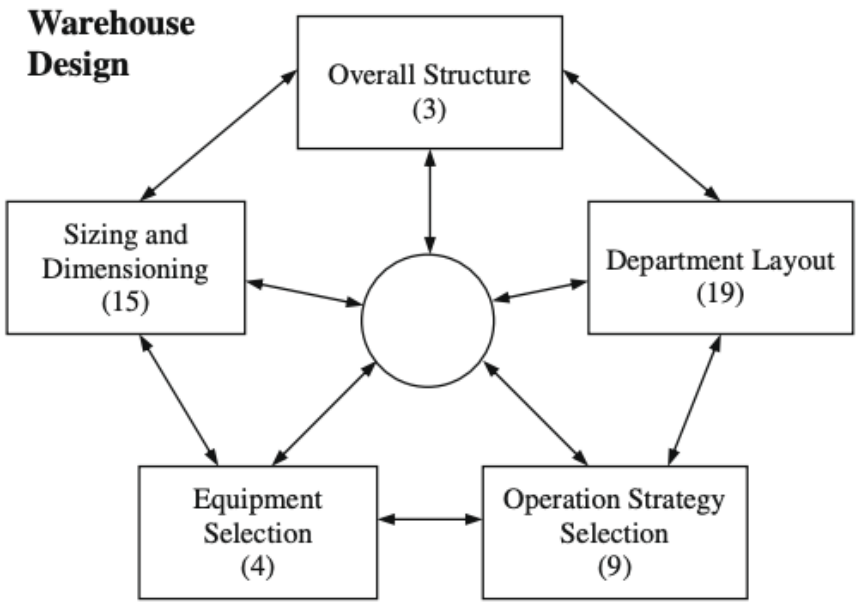

Figure 2.9 - Interdependent warehouse design model (Gu et al., 2010)

Karlsson and Sänneskog (2017) developed their own framework for warehouse design in their thesis with inspiration gathered from e.g. Hassan (2002) and Goetschalckx & Ashayeri (1989). Since there are several interdependent decisions regarding warehouse design, the framework aims to consider multiple decisions simultaneously. This is achieved by dividing the warehouse configuration into four decision modules (A-D), where each module consists of multiple decisions that are closely linked to each other. The initial step of the framework is to determine objectives and limitations of the warehouse facility. When these parameters have been determined, multiple solutions for each module (sub-problem) are to be developed. It is an iterative process, where each module is analyzed separately and then refined when processing another module. The sub-solutions for each module are gradually refined and matched with the other sub-solutions to reach a viable final solution. Following this iterative process ensures that several decisions and possible solutions are reviewed simultaneously and compared with each other before a final solution is decided upon.

A major part of this thesis is to deliver a proposal of a complete warehouse configuration to the case company. The different frameworks and approaches for warehouse configuration presented in this section are all taken into consideration for the configuration process. It is evident that a clear understanding of the context in which the warehouse operates is paramount. By identifying the contextual factors and variables, it is possible to make informed decisions regarding the different configuration elements and design aspects. Another insight gained from the discussed configuration approaches is the interrelationship between elements, stressing the importance of a holistic top-down approach to avoid sub-optimization. Furthermore, it is vital to understand that warehouse configuration involves multiple trade-offs and will require several iterations before reaching a final proposal.

2.5 Conceptual framework

The literary review is conceptualized by using the proposed framework from Eriksson (2019) and, Norrman and Kembro (2019). This framework is an attempt to create an overview of the complex subject of warehouse configuration. Each configuration element is an integral part of the warehouse that needs consideration, according to the literature. From the literature it stands to reason that a warehouse is not created in a vacuum, but instead is tightly connected with outside factors (Norrman and Kembro, 2019). These factors, or contextual factors, are both industry specific and generalizable factors true for multiple industries. The latter are represented by "general" that includes factors that affect every warehouse. However, this thesis aims to uncover the former, the industry specific contextual factors. Due to the lack of literature in the area this box has been left blank, which shows the opportunity for research. Which, consequently, leads to the first research question to answer. Namely, what are those industry specific factors that influence the warehouse configuration. Moreover, it can be seen in figure 2.10 below, that the contextual factors somehow influence the configuration elements as well as configuration goals and processes. From this emerges the second research question that seeks to understand how the context influences the elements.

This framework will be used to fulfill the aims of the research. Whilst providing an overview of the subject area, it will also be used to form the thesis structure as well as guiding the analytical process. Later it will be revisited and updated with the findings from this study, working as a part of the conclusion.

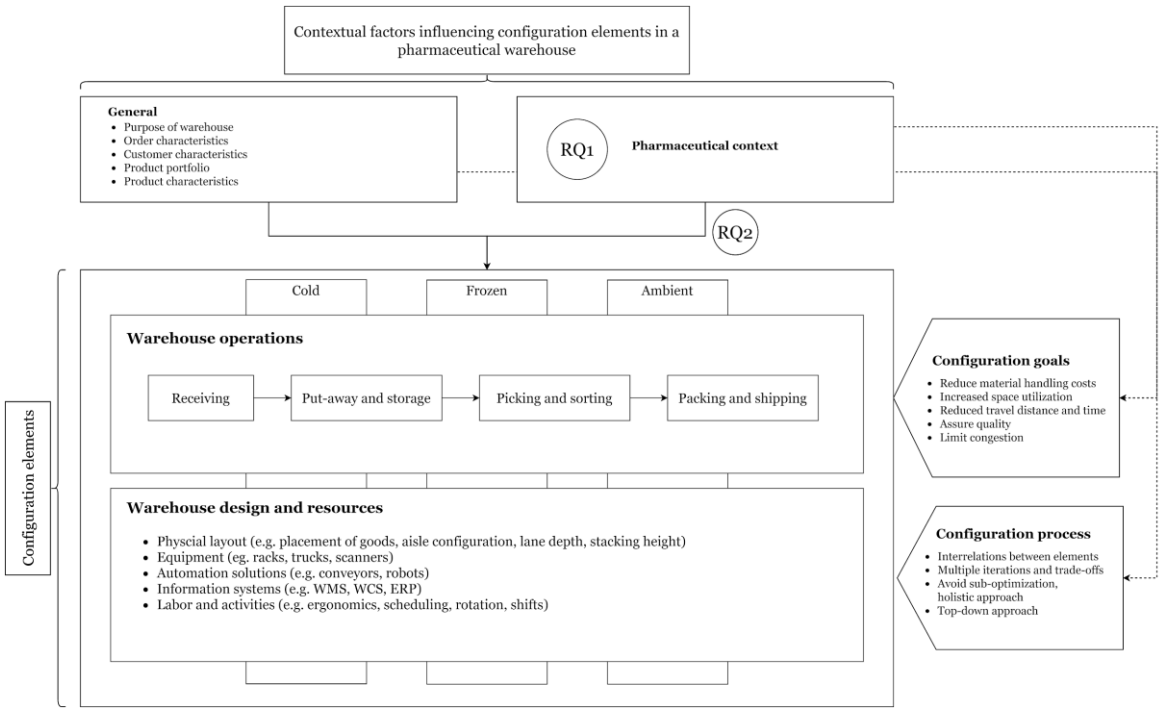

Figure 2.10 - Overview of warehouse configuration and contextual factors (Kembro and Norrman, 2019b; Eriksson, 2019)

3. Methodology

3.1 Research strategy

There are various methodologies to choose from when approaching a problem, and problems may be more or less suited for certain methodologies. In order to determine what strategy to use, a crucial initial task was therefore to understand the problem at hand. The questions asked was the starting point for what type of research that would be appropriate (Yin, 2018). For this particular purpose it seemed that case study research was the most appropriate strategy to use. Case research can be used when a phenomenon is to be studied in its particular setting, where questions such as why, what and how can be asked. Further, when the phenomenon and variables are unknown or not understood (Voss et al., 2002). As prescribed by Robert K Yin 1984, via Zainal (2007), case studies explore and investigate phenomena via contextual analysis.

In broader terms, a case study deals with a situation where there are multiple data sources that lend themselves to enable triangulation to help guide the research to achieve its goal (Yin, 2018). Furthermore, there are three types of case categories; exploratory, explanatory and descriptive (Zainal, 2007). For the purpose of this thesis, the first two categories were most suitable. Because of the nature of the research, the study set out to answer what the contextual variables are and how they affect warehouse configuration. Also, Voss et al. (2002) discusses the purpose in conjunction with the type of case and research question. Exploration and theory building seemed to be the theme for which our research should be framed. This leads onwards to the next consideration, what type of case or cases. In depth single case or a few focused multiple cases is prescribed by Voss et al. (2002). The notion of a single case being able to provide rich theory building conclusions is supported by Flyvbjerg (2006) which challenges the notion of the need to investigate several cases.

The amount of resources and availability of cases will mainly affect the decision to use single or multiple cases (Flyvbjerg, 2006). In our situation, the limited resources and availability of pharmaceutical case companies ultimately led us to conduct a single case study. Consequently, with one case as a starting point, decisions of what should be done had to be taken. A combination of several data sources seemed to be the overall recommended route, and this was interpreted as combining qualitative and quantitative data from multiple sources. The single case study should collect data from warehousing activities and also other types of data that the case company collects. This data can provide insights that might otherwise be overlooked.

3.2 Research design

When the research strategy has been determined, the following step is to develop the research design. It is the methodological plan for the research, a sequence of steps to get from the initial research idea to a set of conclusions. The research design will work as a guide for planned research activities and, as described by Yin (2018), a link between posed research questions and the data which will be collected and analyzed. The research design for this thesis is outlined in figure 3.1 below.

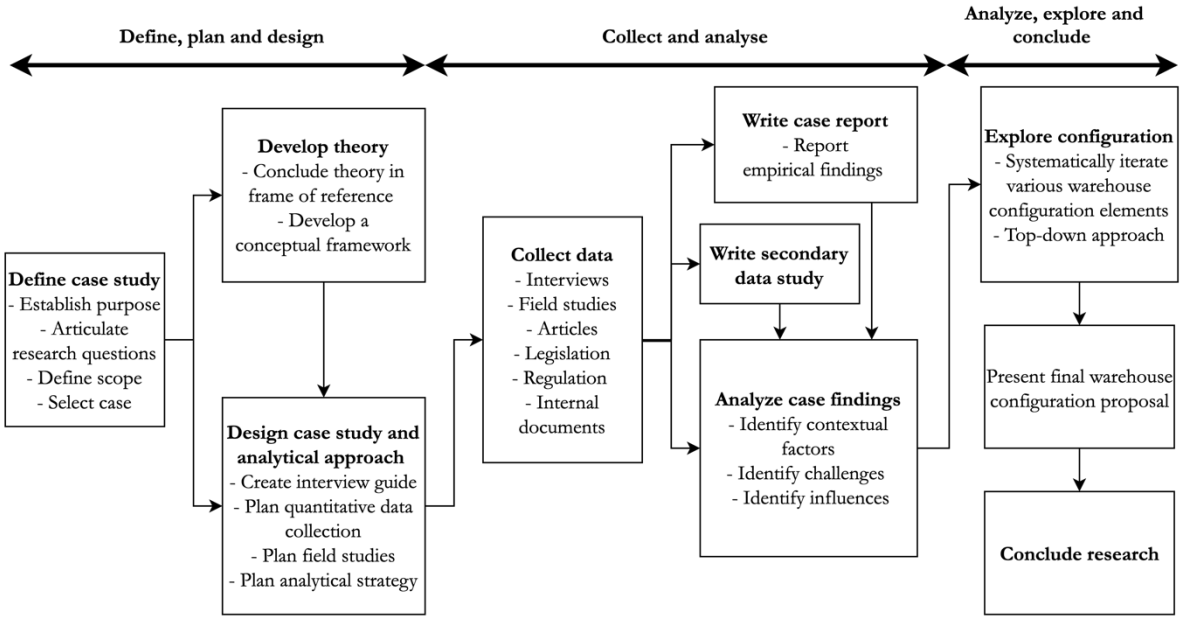

Figure 3.1 - Research design, inspired by Kembro and Norrman (2019b).

3.2.1 Unit of analysis

In order to define a case study, a unit of analysis must be established. The unit of analysis depicts the entity that frames what is being analyzed in a research study. A well-established unit of analysis will enable the researcher to address the purpose of the research and ultimately answer the posed research questions (Yin, 2018). For this thesis the purpose is to *explore the pharmaceutical context and understand how it influences warehouse configuration*. From this it stands to reason that the entity that is analyzed, the unit of analysis, is the interface between two units of analyses; the first being *warehouse configuration* and the second the *pharmaceutical context*. Therefore, the unit of analysis in this case is *warehouse configuration in a pharmaceutical setting*.

3.2.2 Unit of observation and data collection

There is some confusion regarding unit of analysis, unit of observation and the data collection. Whilst the unit of analysis is the entity that the research analyzes, the unit of observation is the entity where one would make measurements. Data collection then refers to which means that are used to make the measurements (Kumar, 2018). The unit of observation in this case is divided into two parts; the case company's warehousing operations and a secondary data study regarding pharmaceutical laws, regulations, directives and guidelines. The first part regarding the case company can be further divided to clearly specify what is being measured and observed. Within the case company interviewees are one observational unit, but there will be field studies and quantitative data as well. The means by which these units of observation will be observed are data collection methods which will be described further on.

3.3 Case company

The case company was founded in 2007 after assets from another company were acquired. With this acquisition, pharmaceutical manufacturing has been continuously ongoing at the

production site since the 1950's. In 2019, the case company had a turnover of 350 MSEK and 180 employees. The growth has been significant in recent years, illustrated in figure 3.2 below, and the growth is expected to be 20% per year in the near future.

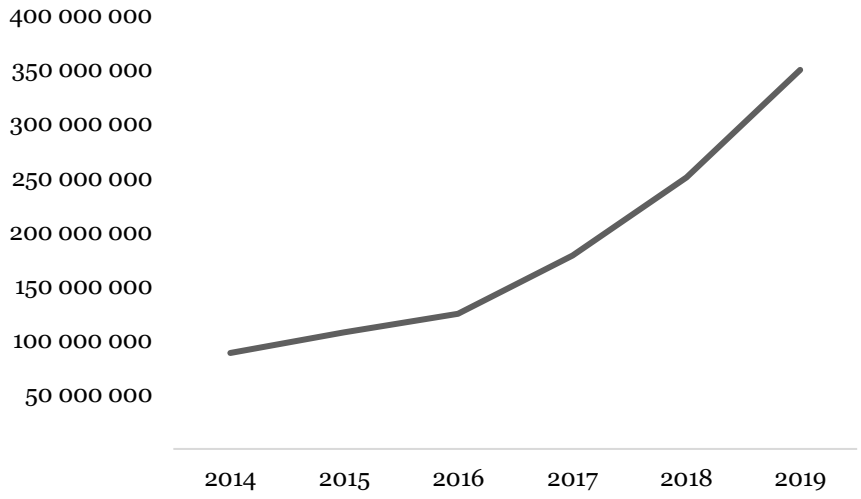

Figure 3.2 - Turnover from 2014 to 2018

Unfortunately, overall logistical processes and warehouse capacities are unable to cope with the substantial growth. The current warehouse is utilized above its maximum capacity, leading to inefficiencies in the daily warehouse operations. To manage this situation, the case company is building a new production site at a new location. Initially, this site will only operate as a warehouse but in time, all of their business will relocate to this location. The new production site will have a warehouse that is substantially larger than the current.

The case company acts as a contract manufacturer, with manufacturing of mainly aseptic injectables and sprays for oral and nasal administration. Besides contract manufacturing, they also develop and manufacture their own products. This enables the company to offer customers the entire manufacturing process: from phase 2 development through validation, manufacturing, serialization, packaging and labeling. The primary customers are pharmaceutical manufacturers who have outsourced parts, or all, of their manufacturing. Virtually all of the case company's production is made to order (MTO) and finished products are shipped to the customers' distribution centers.

The case company operates in compliance with current GMP requirements for pharmaceuticals, in Europe: Directives 2001/83/EC, 2001/20/EC, and 2003/94/EC as well as amended directives such as "The Falsified Medicines Directive" (2011/62/EU). Furthermore, they operate under Swedish national regulations in regard to handling and manufacturing of narcotic substances and products. Their quality system also fulfils US FDA regulations: "Current Good Manufacturing Practice for Finished Pharmaceuticals" (title 21 of the Code of Federal Regulations (CFR) parts 210 and 211).

An in-depth understanding of the studied phenomena requires a case company which enables the right level of detail in the analysis. The case company is a good selection for this thesis since the company spans many areas of concern for pharmaceuticals, e.g. all phases of the manufacturing process. This will reflect several aspects of the context which in turn will yield rich results and a basis for generalization. For instance, they manufacture different types of

pharmaceuticals with unique characteristics and storage requirements. Furthermore, the global market presence requires compliance with several different regulations and will also reflect demands for different markets. To conduct a quantitative analysis, data can be extracted from the Enterprise Resource Planning (ERP) system and the extensive documentation system allows for more information to be gathered. Finally, the case company is in the process of building an entirely new warehouse, a solid starting point when researching contextual considerations for warehouse configuration.

3.4 Data collection

The case study included multiple data collection methods and data was collected from multiple sources. The collection techniques used were interviews, a secondary data study, and observations, as well as collection of relevant quantitative data, documents and archival records. This smorgasbord of collected data served as the subject of data analysis which later became the foundation that conclusions were drawn from, see illustration in figure 3.3 below. The following segments in this section will describe the data collection methods used in more detail.

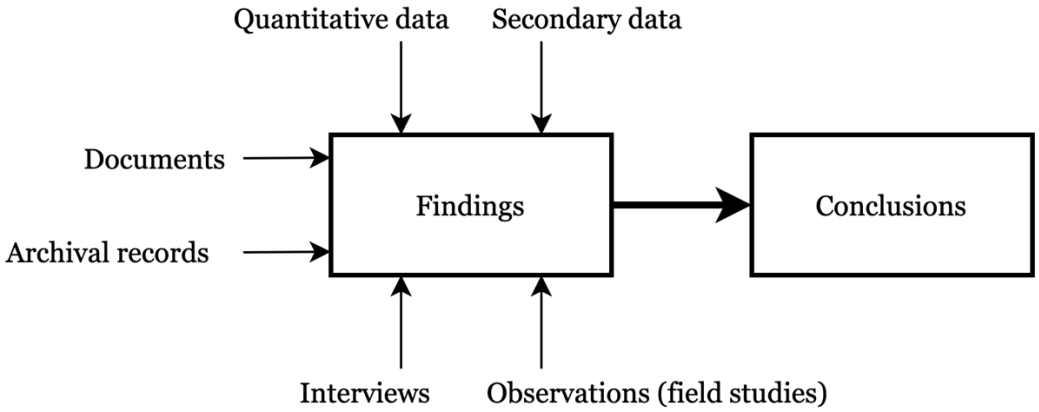

Figure 3.3 - Illustration of the different data collection methods used to reach conclusions

3.4.1 Secondary data study

Data collected by someone other than the user is referred to as secondary data. Common sources for secondary data may be information collected by government departments, internet searches, libraries, organizational records or data originally collected for another research purpose. In the case of this thesis, a secondary data study was conducted prior to the collection of primary data. As mentioned in the introduction, pharmaceutical manufacturers are required to operate in compliance with GMP and other legislation. The aim of the secondary data study was hence to form an understanding about pharmaceutical regulations and guidelines, as well as what implications they have on warehouse configuration. This knowledge was later helpful when deciding what primary data to collect and when developing interview guides. The secondary data study was also referred to during the analysis to help answer the research questions.

3.4.2 Quantitative data

Due to the nature of this thesis, a rich variety of data and inputs from multiple sources were required. When configuring a new warehouse design, a vital category of the data collection is quantitative data, also known as objective or numerical data. This kind of data enables numerical analysis, for instance through statistics, graphs and tables. For this thesis, a key objective was to map and analyze the flow of materials. The necessary quantitative data to initiate such a task is order data, both orders for procurement from suppliers and orders from customers. Additionally, internal order data to facilitate production orders were required for analysis of the internal material flow. However, this internal order data was not stored in the information system and could not be analysed. Coupled with the order data, it is important to understand the characteristics of the material being handled. A comprehensive data collection plan was developed. In essence, it aimed to gather all available information for every registered SKU. Furthermore, to decide dimensions and storage equipment for the new warehouse, analysis of historic inventory levels was required. The data needed for this task was inventory level on a daily basis (e.g. how many pallets and cartons in stock) for a set period of time. The inventory levels were coupled with "snapshots" of the warehouse for the same period of time to map the storage positions of the SKUs. Finally, essential for configuration of the layout for the new warehouse design, data regarding the new facility (e.g. blueprints) was collected.

3.4.3 Qualitative data

One of the most important means of gathering qualitative data is interviewing (Qu and Dumay, 2011). The interview can be used as a tool to explore a subject, get in-depth explanations and insights into phenomena that are otherwise difficult to obtain (McGrath et al., 2019; Rowley, 2012). Interviewing is useful in qualitative research for an array of different reasons and Jamshed (2014) highlights the ability to obtain and explore new fields of study. The interview can also be useful if the research aims to understand processes, attitudes, values or just obtaining facts amongst other things. Additionally, if there is little known about the subject of interest to construct a questionnaire, an interview can provide a means of collecting data (Rowley, 2012). The interview as a tool can take many forms depending on the researcher who is conducting it. Different perspectives, or epistemological stance, can affect how the interview is conducted and how it is theoretically viewed in terms of what it is perceived to be able to provide to the research (Qu and Dumay, 2011). Perspectives such as neo-positivism, romanticism, localism and constructionism are some of the perspectives that have been proposed by the literature (Qu and Dumay, 2011; Rowley, 2012). The neopositivist viewpoint sees the interview as an effective tool to be used to extract objective truth, while the romanticist takes a more human centered viewpoint focusing on the human to human interaction. The localistic views the interview as an empirical situation that can be studied, in contrast to the neopositivist viewing it as a tool for collecting data in isolation (Qu and Dumay, 2011). The constructionist sees an opportunity to co-create data in unstructured or semi-structured interviews. The perspective taken affects how the interview is used and how it is performed. For instance, a neopositivist might focus on asking "good questions", minimizing bias and taking a less active role trying to minimize the effect he or she has on the findings.

The type of epistemological perspective that is chosen, with regards to the type of research that is conducted, will affect the type of interview that should be used. There are three types of interviews: structured, semi-structured and unstructured (Qu and Dumay, 2011; Britten,

1995). They are all quite different from each other. In the structured interview the interviewer asks predetermined questions in a specific order. This style of interview is rigid and leaves little room for deviation from the planned course of action and this style is mostly influenced by the neopositivist perspective. As a consequence, the structured interview assumes that correctly asked questions will provide all the necessary information. Unstructured interviews stand in stark contrast to the structured interview, focusing on the conversation and the interviewee whilst adopting a romanticist perspective. The interview could be viewed as a regular conversation with a high degree of adaptability and adjusting as the interview progresses (Qu and Dumay, 2011). The last type, and the most popular, is the semi-structured interview. The structure is existent, but looser in a sense that it allows for exploring during the interview. Conducting a semi-structured interview requires sufficient planning and an interviewer that can adapt during the interview (Britten, 1995, Qu and Dumay, 2011; Rowley, 2012). The semi-structured interview is popular due to its flexibility, accessibility and ability to uncover hidden facts (Qu and Dumay, 2011).

Interviewing is not a trivial task and there is not a single, one correct way to do it. It takes preparation and careful planning and even more so if adopting the neo-positivist perspective. There are, however, traits or principals for a good interview (Qu and Dumay, 2011; McGrath et al., 2019; Rowley, 2012). Most important for the interviewer is maintaining the discussion and flow of the conversation, closely linked to this is also the control over the interview situation as to assure that the interview goes as planned (Qu and Dumay, 2011; Britten, 1995). Another important factor is sustaining a positive relationship with the interviewee by avoiding offering opinions, responses or non-verbal cues on what the interviewee is saying (McGrath et al., 2019; Qu and Dumay, 2011). To avoid the latter, one just has to talk less and listen more and avoid filling in the blanks when a silence arises (McGrath et al., 2019). It is important for the interviewer to remain unbiased which would otherwise affect the credibility of the data (Qu and Dumay, 2011). A good interview can be affected by common pitfalls and in table 3.1 below some of them are presented and suggestions on how to overcome them.

Table 3.1 - List of common pitfalls adapted from (Britten, 1995)

Pitfall	**Remedy**
Interruptions	Let interviewee finish before speaking
Distractions	Ensure that you conduct the interview in a quiet, disturbance free environment (ringing phones, near a street etc.)
Stage fright (for interviewer or interviewee)	Be calm and ease situation with small talk in beginning of interview
Asking embarrassing or awkward questions	Be prepared on what you want to ask
Jumping from one subject to another	Be prepared on a logical path for you interview, create an interview guide and maybe do a mock interview
Teaching (e.g. giving advice)	Try to stay in the role of the interviewer, refrain from stepping out of it
Counseling (e.g. summarizing responses too early)	Follow your interview plan and let interviewee finish. Clarify things if necessary. Come back later for summarizing
Presenting one's own perspective	Try to stay in the role of the interviewer, refrain from stepping out of it
Superficial interviews	Be prepared for what you want to ask and create an interview guide
Translator (e.g. accuracy)	Difficult to overcome, use a translator you trust

Before conducting an interview there are several things that are needed to be in place. First, the type of interview needs to be decided, then an interview guide with clear links to the research questions needs to be formulated. Additional decisions to be made are the number of interviews being conducted and how long they should be. When deciding and forming the interview guide it should follow the principles of a good interview, or at least help the interviewer achieve a good interview. Articulating questions will be of great importance and one must be vigilant to not use the wrong kinds of questions that could affect the outcome. Questions or things to avoid are jargon, leading questions, implicit assumptions, multiple questions in one, yes or no questions, vague or general questions and invasive questions (Rowley, 2012). Additionally, there are different types of questions that can be asked, and these are presented in table 3.2 below (Qu and Dumas, 2011).

Table 3.2 - Different types of questions that can be used during an interview (Qu and Dumay, 2011)

Type	**Purpose**	**Example**
Introductory	To start the interview	"Can you tell me about…"
Follow-up	To direct questioning to what was just said	"Mm…"
Probing	Draw out more information	"Can you elaborate…"
Specifying	To develop more precise descriptions from general statements	"What did you think then?" or "How did you react then?"
Direct	To get direct responses	"Have you worked in this industry?"
Structuring	Used for controlling the interview	"I would like to introduce this subject now"
Silence	For a smaller brake or for the interviewee to start speaking	"…"
Interpreting	Similar to probing, getting clarification	"You then mean that…"
Throw-away	To relax the subject if a sensitive area has been breached	"Oh, I forgot to ask you…"

The structure of the interview is determined by the type chosen, but the interview most likely will start with an introduction of the researcher, the research, purpose, length of the interview and confidentiality issues that might present themselves. Thereafter, the interview should progress as planned and without distractions and interruptions. During the interview it can be necessary to engage the interviewee which can be done by silence, repeating the questions or using "what, why, how and who" questions (Rowley, 2012). An additional interesting concept that could be employed is a card-game approach. Cards with descriptors, pictures or anything, can be used to get the interview subject to explore propositions for instance. There are indicators that this approach can be used to: validate components in a model, describe processes, issues with components or explore relationships. This approach can also help to structure the interview, promote reflection, generate insight, reduce involvement and bias and later on help with the analysis. (Rowley et al., 2012).
This thesis has adopted a less strict neo-positivist view which means that the interview functioned as a means of extracting information that was used for further analysis. Furthermore, the interviews were semi-structured at varying degrees of structure depending on the interviewee and the information that was needed in that particular case. Some interviews were more or less fully structured while others were more exploratory and unstructured. However, adopting a neo-positivist viewpoint required careful consideration

and planning of the interview guides. For these reasons a sequential approach was employed to ensure the quality of the interview guides and questions. The importance of the regulatory environment that surrounds pharmaceuticals affected the questions that were asked and how the interview approach was outlined. In figure 3.4 below the sequence for the interview approach is provided.

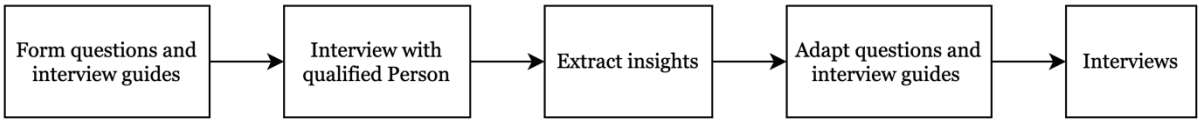

Figure 3.4 - Interview approach

With the conceptual framework in mind, questions that needed to be answered were conceived by brainstorming following the different areas that are outlined in the conceptual framework. To ensure that the regulatory context was well understood a few topics were also conceived to guide a more unstructured, semi-structured, interview with the qualified person. The initial conclusions from that interview helped and guided needed adaptations of the questions and interview guides. The adapted interview guides were used for the subsequent interviews and the complete interview guide can be found in Appendix A. To further underpin the regulatory understanding the conclusions drawn from data where discussed with the qualified person with the aim to add a validation step. During the interviews a card-game approach (cf. Rowley et al., 2012) was used to support the interview and to help facilitate analysis and information retrieval. This approach was based on the conceptual framework and included cards with the warehousing process steps. The cards purpose was to provide an artefact that could help the interviewee keep focus and to help the interviewer to structure the interview.

The interviewees were selected together with the company supervisor to ensure coverage of sufficient breadth of the company's operations. Interviewees were selected from all levels of the organization from workers at the warehouses to top management. The interviews were held in two days with back-to-back interviews, all of which were transcribed. Table 3.3, below, shows what functions that were interviewed and for the sake of anonymity, their names are not disclosed. Also, the perspectives that each respondent provided are included.

Table 3.3 - Interviewees for the qualitative study

Interviewee	Position	Perspectives
R1	Head of Quality Assurance and QP	Regulatory context aspects
R2	Senior Advisor	Overall business strategy
R3	CEO	Long-term future perspective
R4	Systems and logistics administrator	Information system aspects
R5	Supervisor Dispatch & Storage (warehouse employee)	Detailed understanding of warehouse processes
R6	Manager Packaging Production	Interface between production and warehouse
R7	Logistics manager	Warehouse operation on tactical level
R8	Warehouse employee, external warehouse	Detailed understanding of warehouse processes

Except for interviews, other means of collecting data were necessary to provide broader and more in-depth insights. Field studies, or on-site visits, were conducted to take pictures, investigate current procedures and to gain a better overall understanding of the material handling situation. Additionally, documents and standard operating procedures (SOP) were

collected to help with the analysis and gain further insights in the procedures and their links to the applicable regulation.

3.5 Data analysis

This thesis employs an analytical approach that is twofold, first analyzing empirical data to identify contextual variables and their influence on warehouse configuration. Then, exploring ways to configure a new warehouse according to the findings. The latter was a great opportunity to examine how the findings could be used in a practical setting. Nevertheless, the analytical approach could be viewed as being sequential with a seemingly unorthodox progression. In figure 3.5 this progression can be seen, where the research answers research question two before question one.

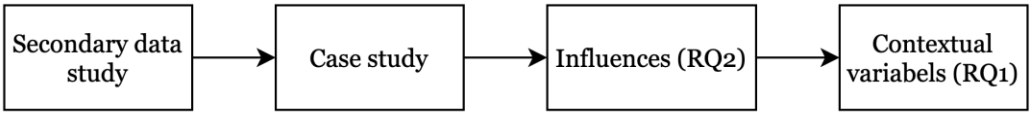

Figure 3.5 - Analytical approach progression

The approach began with conducting a secondary data study that would encompass the applicable regulation. This data study was largely used to explain the pharmaceutical context, but also as a basis for conducting the case study. When the actual case study had been conducted the analysis could begin. First, interviews were transcribed essentially in verbatim to provide transcripts for further analysis (Basit, 2003) and to increase the quality and to ensure that nothing was overlooked. Additionally, this provided a means for the researchers to check that the information was perceived correctly. For the further analysis the transcribed interviews were sorted into matrices to facilitate the analysis (Voss et al., 2002), letting theory influence a structure (Basit, 2003; Weston et al., 2001). Warehouse configuration is the research area of this study therefore the conceptual framework was used for this structure. Four matrices were drawn up according to a sequence found in figure 3.6 below.

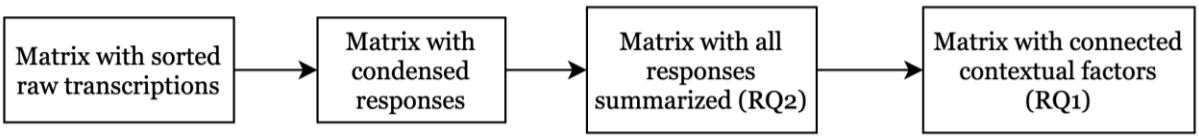

Figure 3.6 - Matrices used in analytical approach to fulfill purpose of the study

The first two matrices had a horizontal axis for respondents and a vertical axis for configuration elements (warehouse operations and, warehouse design and resources). The blanks in the first matrix were filled with raw unedited transcription data. This data contained responses from each interviewee that mentioned something that would have implications for any of the configuration elements. Each response was sorted into the appropriate blank space that corresponds to the configuration element that the respondent was referring to. For example, if the respondent said that you need to dock trucks directly into a cold storage room, then this would be sorted into receiving, shipping and physical layout. This was carried out for every respondent where each column represented one respondent. For the second matrix each column with raw data where condensed to bullet points that captured what the respondent said, but in more concise form. Taking the second matrix and combining all the responses into one column conveniently transformed the matrix into a third matrix that actually answered

research question two. Given that respondents answered questions regarding different components of a warehouse, this is not that unexpected. By identifying the influences first, the identification of the actual underlying contextual factors was helped. Burnard (1991) talks about an approach of identifying themes that can be used to group data. In this case the data are the influences that were grouped, and the themes are the contextual factors that were identified.

To identify the contextual factors each influence in each of the configuration elements in the matrix were given one or multiple descriptors that would then later become the contextual factors. These descriptors were conceived by using the secondary data study that encompassed the pharmaceutical context. An example can illustrate this; if one of the influences were that the case company received chilled goods this would be given the descriptor "product characteristics". This was also done for each influence and by iterating and adapting the descriptors, also in line with Baset (2003), the contextual factors were identified. Thus, answering research question one.

The second part of the analysis entailed exploration of different warehouse configurations. These were closely linked to the findings of the study, but also connected to classical warehouse theory, section 2. The warehouse configuration phase followed a top-down approach with first deciding capacity needs and bigger issues. Then later more detailed issues were addressed. Many options were explored combined with an iterative approach that ensured that as many options as possible were considered as well as continuously improving the proposed solutions. The case company was highly involved in this iterative process through workshops and meetings to ensure that nothing was overlooked as well as keeping an alignment with overall company goals. This part of the analysis was a great way to see if the findings were reasonable in a practical sense as well.

3.6 Research quality

Quality and trustworthiness are important matters when conducting a research study. To ensure this, triangulation of multiple data sources and inputs was done when gathering and analyzing the data. The major strength of triangulation is that conclusions are made after establishing that evidence from multiple sources converge (Yin, 2018; Eisenhardt 1989). Although data triangulation is a time-consuming activity (Yin, 2018), it has been carried out to the largest extent possible throughout the study. The quantitative data withdrawn from the information systems was triangulated against the secondary data study, interviews, document, and observations from field studies. The findings from these triangulations were then analyzed together to reach well-founded conclusions. This process of evidence convergence leading to conclusions was discussed in section 3.4 and conceptualized in figure 3.3.

The quality and credibility of a research study can be judged through aspects of reliability and validity (Voss et al., 2002; Yin, 2018). Reliability is concerned with whether or not the study would arrive at the same findings and conclusions if it is repeated by another researcher. Validity is concerned with whether or not the study actually describes what it aims to describe. Both validity and reliability have multiple dimensions but there are four tests commonly used to establish the quality of empirical research (Kidder and Judd, 1986). Yin (2018, p.42) summarizes the four tests as:

- **Construct validity:** identifying correct operational measures for the concepts being studied
- **Internal validity** (for explanatory or causal studies only and not for descriptive or exploratory studies): seeking to establish a causal relationship, whereby certain conditions are believed to lead to other conditions, as distinguished from spurious relationships
- **External validity:** showing whether and how a case study's findings can be generalized
- **Reliability:** demonstrating that the operations of a study – such as its data collection procedures – can be repeated, with the same results

Throughout this study, several efforts have been adopted to increase trustworthiness. Table 3.4 below is a summary of the efforts made to increase reliability and different dimensions of validity for each phase of the research.

Table 3.4 - Efforts made to increase trustworthiness throughout the research, inspired by (Kembro and Norrman, 2019b; Yin, 2018)

	Define, plan and design	**Collect and analyze**	**Analyze, explore and conclude**
Construct validity	- Feedback on interview protocol from research supervisor. -Multiple informants from different internal functions interviewed.	-Terminology explained to informants to avoid misunderstanding. -Multiple sources and perspectives of data collected.	-Preliminary results presented and discussed with supervisor and case company to compare and contrast views.
Internal validity		-Identical responses on the same phenomenon from multiple informants. -Collected data displayed in tabular form to enable pattern matching.	-Interrelations between configuration elements explained. -Different bodies of literature (warehousing, GMP, contingency theory, pharma) used.
External validity	-Identified appropriate theory and theoretical propositions.	-Provided detailed case description to allow for comparison with other pharmaceutical companies.	-Results presented and discussed with a knowledgeable researcher (supervisor) to check validity.
Reliability	-Standardized interview guides for informants within similar functions.	-Used case study protocol. -Developed case study database. -Maintained a chain of evidence.	-Case study database revised to ensure full documentation of analysis procedure.

4. Empirical data

The first part of the empirical data is the secondary data study, an exploration of the pharmaceutical context. This is based on regulatory records from different regulatory bodies. Following is the case company study, where the information presented has been gathered via interviews and field studies. The interview approach was thoroughly described in section 3.4.3.

4.1 Secondary data study – The pharmaceutical context

As mentioned in the introduction, pharmaceutical manufacturers are required to operate in compliance with the international rules and guidelines of GMP. This is, in essence, systematic work to prevent mix-ups, cross contamination and false labeling; it allows for complete traceability of raw materials, packaging materials and finished products (European Commission, 2011). To ensure that pharmaceutical manufacturers operate in compliance with GMP, many countries have adopted and legislated their own GMP guidelines. In the EU, the major legislation framework is volume 4 of "The rules governing medicinal products in the European Union", also known as EudraLex. The regulatory body in the US is FDA, who enforces "Current Good Manufacturing Practice" which stems from regulation documents published in the Code of Federal Regulations (CFR) (FDA, 2018). To ensure that manufacturers operate in compliance with GMP regulations, regular inspections from national and international regulatory bodies are conducted. The Swedish Medical Products Agency (LV) mainly inspects Swedish manufacturers, whereas FDA conducts inspections worldwide.

GMP is mainly providing guidelines for quality assurance, documentation procedures and hygienic manufacturing. However, it also contains guidelines for storage, handling, labeling and distribution of pharmaceuticals. Since this thesis is focusing on warehouse configuration, these are the GMP topics that will be discussed further. The following two paragraphs regarding storage areas and materials are the main principles of GMP that affects warehouse configuration, adopted from WHO (2014) and the European Commission (2011).

In accordance with GMP regulations, the capacity of storage areas should be sufficient to allow proper storage of the various products and materials with orderly segregation and separation. For instance, storage of recalled, rejected, or returned goods should be provided a segregated and secure (locked) storage area. All sorts of dangerous pharmaceuticals and substances (e.g. highly active materials and narcotics) presenting risks of abuse, explosion or fire should be safely stored in secure areas. Storage should allow for batch segregation and stock rotation by a first-expire-first-out rule. The design and adaptations of storage areas should ensure good storage conditions; they should, particularly, be dry, clean, sufficiently lit and kept within appropriate temperature limits. It should be easy to clean the premises and sufficient actions for pest control are required. When distinct storage conditions are necessary (e.g. humidity, temperature), these should be provided, monitored, controlled and recorded. Additionally, bays for receiving and dispatch should protect goods from the weather and be separated from each other. If necessary, the receiving areas should also be equipped to handle the cleaning of incoming hygienic containers. Furthermore, if quarantine status – products or materials awaiting decision of release for use or distribution – is physically ensured by storage in separate areas, these quarantine areas must be clearly marked and restricted to authorized

personnel. Systems replacing this physical quarantine (e.g. information systems) should provide equivalent security. Moreover, printed packaging materials are critical to the conformity of a pharmaceutical product, and special attention should be paid to the safe and secure storage of these materials. Finally, if sampling of starting materials is performed in the storage area, it should be done in a separate area and in such a way as to prevent cross-contamination or contamination.

Finished products and incoming materials are to be quarantined directly after processing or receipt, until they are released for use or distribution. All incoming goods should be controlled to ensure that the consignment corresponds to the order and containers should be checked for at least integrity of package and seal. In addition, containers should be cleaned if necessary and labelled, if required, with prescribed information. If additional labels are added to the container, the original information should not be lost. If damage or other problems with containers are detected it should be reported to the quality control (QC) department for further investigation. Furthermore, starting materials in the storage area are required to be labelled appropriately. Labels should at least include the following information: Table 4.1 below is a summary of GMP implications on storage areas and handling pharmaceutical materials.

- The designated product name and internal reference code
- The supplier's batch number and, after receipt, the manufacturer's batch or control number, if any, documented to ensure traceability
- The contents' status (e.g. on test, released, in quarantine, recalled, rejected, returned)
- When appropriate, expiry date or date beyond which requires retesting
- If the manufacturer uses fully validated computerized storage systems, not all of the information above has to be in a legible form on the physical label

Table 4.1 below is a summary of regulatory implications on storage areas and handling of pharmaceutical materials.

Table 4.1 - Regulatory implications on storage areas and handling of pharmaceutical materials (WHO, 2014)

Aspect	**Regulatory implication**
Separation	- Capacity should allow for orderly separation - Segregation of recalled, rejected, or returned goods - Storage should allow for batch segregation and stock rotation (FEFO) - Bays for receiving and dispatch separated from each other - Sampling in separate area
Secure areas	- Storage of recalled, rejected, or returned goods in locked area - Safe storage of dangerous pharmaceuticals and substances - Safe storage of printed packaging materials
Storage conditions	- Storage areas should be dry, clean, sufficiently lit, and kept within correct temperature limits - It should be easy to clean premises - Sufficient actions for pest control - Distinct storage conditions monitored, controlled and recorded
Quarantine	- Information system with equal security as physical quarantine - Products quarantined directly after processing or receipt
Labeling	- Materials must be labelled with extensive information; if fully validated information systems are used, not all information must be on the physical label - If additional labels are added, the original information should not be lost

There are requirements for extensive documentation of materials' origins, one of the main reasons is the matter of 'traceability'. It is the process of taking necessary actions to enable visibility of the history of transfers and locations of a pharmaceutical product. For every finished product, it should be possible to trace the origin of all components that make up the product. If primary packaging material or printed packaging material becomes outdated or obsolete, it should be destroyed, and the disposal recorded. Finally, waste materials awaiting disposal should be properly and safely stored. As required by national legislation, flammable materials and toxic substances should be stored in separate, enclosed cupboards of suitable design.

Pharmaceutical products have unique characteristics and many of them require specific storage conditions. Proper storage is important to ensure that the quality is not compromised, in the wrong conditions pharmaceuticals may deteriorate and lose potency which influences the efficacy and safety (Shafaat et al., 2013). The most important factors involved in drug degradation are high and low temperature, and relative humidity (Kommanaboyina and Rhodes, 1999) but conditions of sanitation, light, ventilation and segregation can all have a significant impact on the final quality (Shafaat et al., 2013). Due to these unique storage requirements, it is vital for the manufacturer to know and understand the characteristics of each SKU as well as designing the storage areas in accordance with the different storage requirements. Additionally, the storage requirements have implications on the distribution network and supply chain management, namely cold chain logistics. The objective is to, through a sequence of storage efforts, ensure that the product is stored within temperature limits throughout the entire supply chain. While on the subject of supply chain, the matter of distribution as a 'known sender' is worth discussing. In the EU, pharmaceutical products, and especially narcotics, are subject to security checks in customs when exported via air freight. It is possible to bypass this security check if the sending supplier has a special permission, so called "Known Consignor Approval" granted by the authorities (Transportstyrelsen, 2020). It ensures that the supplier manufactures and stores cargo in facilities with restricted access.

It is common for pharmaceutical manufacturers to handle drugs classified as narcotics. The handling of narcotic classified substances is regulated by national legislation to ensure proper handling and prevent unauthorized access and use of the substances (Läkemedelsverket, 2011A). For a substance to be classified as a narcotic, it must be considered to be addictive and hazardous to health or euphoric. In Sweden, there are five subgroups in the official classification (Läkemedelsverket, 2011B).

- **Class I:** Drugs considered to have no medical value, e.g. heroin and some hallucinogens. It is prohibited to manufacture, import or sell these substances.
- **Class II-IV:** Drugs with value for medicinal use, e.g. morphine, amphetamine and benzodiazepines. With permission from national authorities, it is permitted to manufacture, import and export these drugs.
- **Class V:** Drugs not covered by international conventions, e.g. weaker opioids and anesthetics. These substances do not require import or export permits.

In conclusion, pharmaceutical manufacturers handle drugs with narcotic classification II-IV and are required to apply for permits to purchase, handle, import and export these drugs. Besides the need for permits, legislations induce implications for the manufacturer's operational procedures. Since the focus of this thesis is warehouse configuration, the following

paragraph summarizes how the legislations affect this area. Adopted from the Swedish Medical Products Agency's (LV) regulations (2011A).

Pharmaceutical manufacturers are required to have routines and systems in place to prevent theft and diversion of narcotics. For instance, narcotics must be stored in a secured area with restricted access. In the fundamental permit for handling narcotics, the manufacturer must state one person to be responsible for all narcotics matters. This person then provides access to the secure storage area and authorizes a few selected employees to handle, store and release narcotics. For each procurement of narcotic substances, an import permit application is sent to LV, the substance cannot be ordered before the application is approved. The process is similar for export of narcotics, but the application must include an import permit from the appropriate authority in the recipient country. Upon arrival of incoming goods, before receipt, it is mandatory to confirm that the delivered quantity corresponds with the permitted quantity by LV. The imported quantity is reported to LV and is also included in the quarterly and yearly reports. The control of goods is conducted by personnel authorized to handle narcotics and is then stored in the secured storage area. Documentation is a vital part of the narcotics handling aspect. The documentation must contain information of every singular event which results in a change of narcotics inventory. Events such as purchase, receipt, production, sale or other transfer, import, export, withdrawal for use within their own operations, disposal or destruction. To ensure that the documented inventory is correct, the inventory must be inspected regularly. If the inventory does not match the documented quantity, the reason for the deviation must be investigated and documented. Table 4.2 below summarizes the unique characteristics of pharmaceutical products and their implications.

Table 4.2 –Summary of pharmaceutical product characteristics and their implications

Product characteristics	**Implications**
Temperature sensitive	- Products may deteriorate and lose potency when stored in areas with wrong temperature levels - Monitor and control temperature in accordance with products' storage requirements - If products require cold storage, ensure cold chain is kept during distribution
Humidity sensitive	- Products may deteriorate and lose potency when stored in areas with wrong humidity levels - Monitor and control humidity in accordance with products' storage requirements
Narcotic substance	- Routines and systems to prevent theft and diversion - Store in locked, restricted areas - Multiple permits required for handling, importing, and exporting narcotic substances - Thorough receipt process and report sent to regulatory body upon receipt - Extensive documentation when changes in inventory occurs

4.2 Warehouse operations in a pharmaceutical setting

To understand the operational aspects of a pharmaceutical company, the processes that are in place at the case company will be explored in detail. From the section regarding scope it is stated that what will be investigated is the current setup of the case company. In this case this

entails both the external site and the production site which will be described from a material and information flow perspective. To facilitate understanding in the processes a general outline of the material flow is given in figure 4.1 below. This shows how the material flows from the external warehouse to the production site and lastly to the customer.

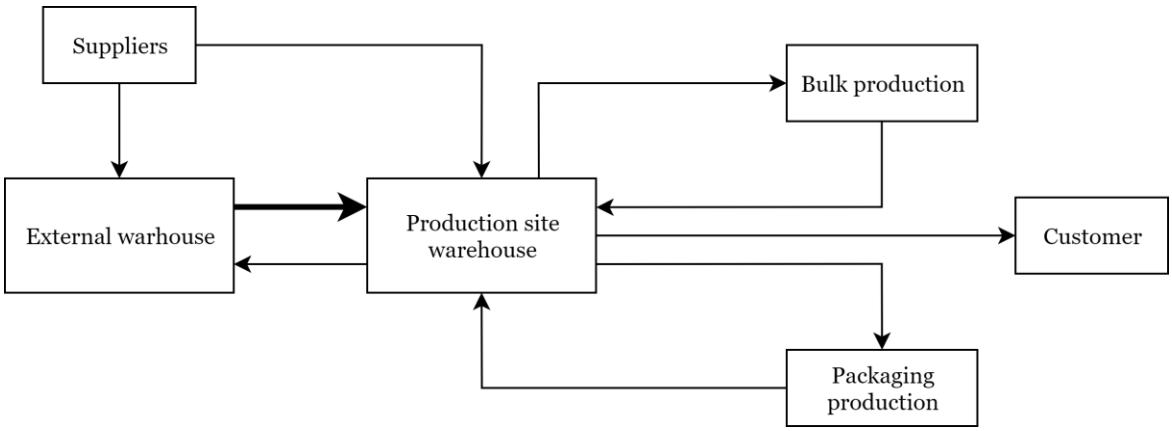

Figure 4.1 - General material flow for the company's setup from supplier to customer

The external warehouse only handles returns from the production site and incoming goods from suppliers. As stated earlier a more comprehensive description of the flows will be provided in the following sections below, but figure 4.2 shows a simplified version of the flow for this particular warehouse.

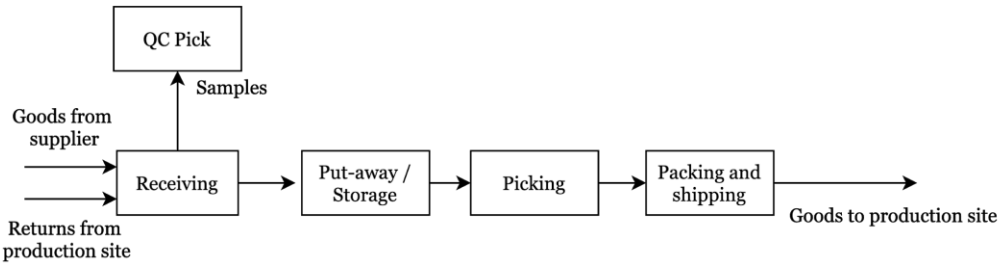

Figure 4.2 - Process map for the external warehouse, from receiving to shipping

The most complex looking figure, figure 4.3 below, shows the intricate flows and processes involved to take goods from receiving all the way to shipping, and to the customer. This figure is only a conceptualization that contains a few simplifications for the sake of understandability. The process includes many steps and many iterative steps in production, where goods in the form of work in process (WIP) can take up to three rounds before being finished. These processes will also be described in greater detail in the following sections.

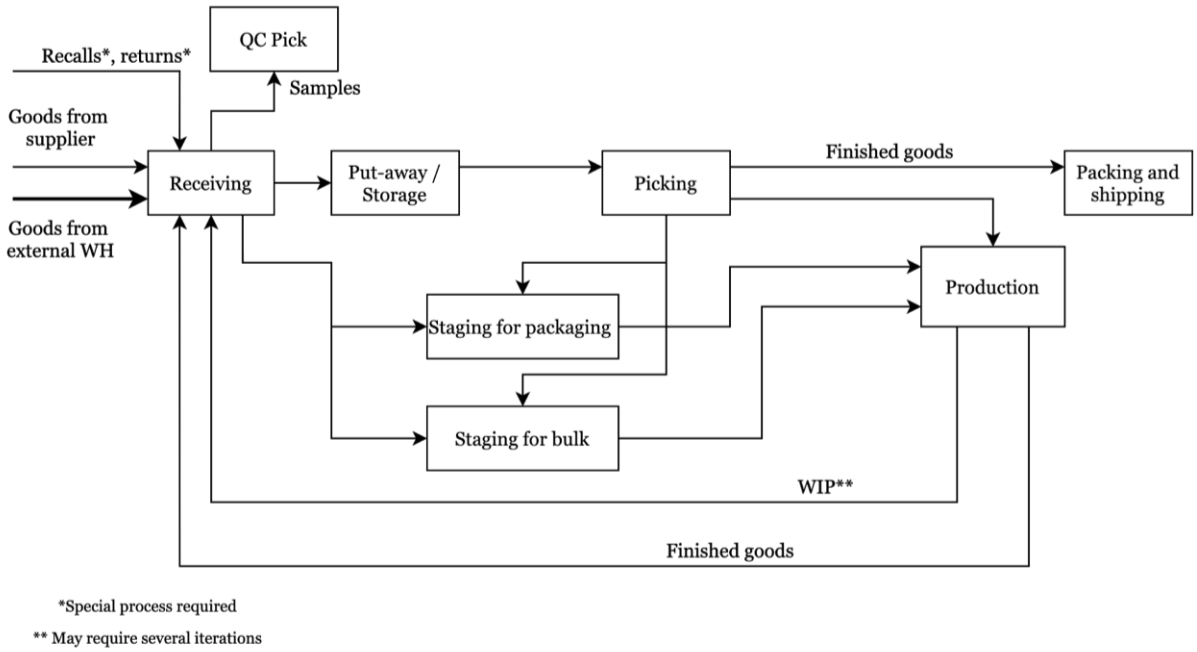

Figure 4.3 - Detailed process map for the production site, including iterative steps in production

4.2.1 Receiving

The warehouse located in the production building receives goods from suppliers, the external warehouse, and internal production departments. Shipments from suppliers are usually small in quantity and the receiving process is the same as for the external warehouse. The first step is to assess the storage conditions for the incoming goods and directly transfer it to a properly temperate location. If the goods carry temperature logs, the second step is to print these and check that the goods have been stored in correct conditions during the transportation. If the logs are satisfactory, the next step is to initiate the receipt process, which in the pharmaceutical context may be an extensive process. To ensure a rigorous and compliant receipt process, each article has unique documents (PI-documents) with information about receipt of the specific article. The documents contain information about, for instance, the product's origins, a checklist of what to verify before receipt and how to proceed if something is incorrect. When everything on the document has been verified, the document is sent to the production department. The receipt may now be registered in the information system and the goods may be put-away. The whole receiving process for goods from suppliers can be seen in the illustration below, figure 4.4. Before put-away however, the goods must be labeled with internal reference code and batch number. If the pallet contains multiple cartons, every single carton must be labeled. Some articles are sub-lot-controlled, which means that each piece of the received article must undergo the receipt process individually and be labeled with a unique batch number.

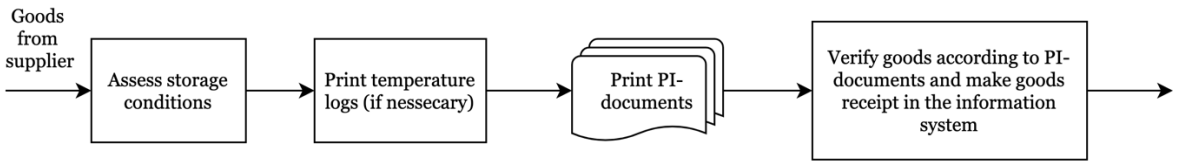

Figure 4.4 - Receiving process for goods from suppliers

All of the handled material has storage requirements regarding temperature and a considerable amount requires cold storage. Neither the external warehouse nor the on-site warehouse has a port connection from the loading bay to cold storage. Consequently, the cold chain is inevitably broken when receiving goods with cold storage requirements. The cold chain is not broken beyond regulated time limits, but it is undesirable and puts a strain on the receiving process. An exception is when the goods are transported in passive temperature-controlled containers. This container is then transferred to the cold storage before unloading the goods. These containers are not to be kept and must be loaded onto the truck after unloading, which requires the process to run efficiently. Moreover, the company handles narcotic substances with unique storage requirements enforced by regulations. Narcotics must be stored in locked premises with limited authorized access at all times. Given exceptions are during the receiving and dispatch processes or when used in production. Evidently, from the answers of the interviewees, the receipt process for narcotics is time-consuming and requires several more documents to be filled out. Even if the receipt process is time-consuming for narcotics, it must be conducted directly when the goods arrive.

The on-site warehouse receives the majority of goods from the external warehouse. These goods require no extensive receipt process, since it has already been done and registered at the external warehouse, it is merely movement of inventory. The goods received from the external warehouse are usually connected to a production order and will not stay in the on-site warehouse for an extended period of time. Furthermore, the material flow within the production site involves the on-site warehouse in every step and the WIP-goods are stored between each step. This means that a pallet is received from the production or packaging departments multiple times (usually three or four) before it is finally received and stored as finished goods.

4.2.2 Put-away and storage

As mentioned in the previous section, the put-away process begins with assessing the article's storage requirements and is followed by finding a suitable storage location. The information system (eWMS) does not, as of today, suggest a storage location. Both the external warehouse and the on-site warehouse use random storage for allocation of the materials. It is random both in terms of status (e.g. in quarantine or released) and type of material. There are different temperate zones and locked zones (one for narcotics and one for rejected materials), but within each zone the storage is random.

The secondary data study as well as the interviews determine that segregation and separation of materials is an important matter. To facilitate this, there are routines in place to only store one batch of an article per storage location, but due to physical capacity constraints this is difficult to accommodate. Warehouse personnel are often forced to store pallets on the floor because there were no vacant storage locations.

Printed packaging materials (labels) are to be handled with special care, which is evident both from the secondary data study and interviews. The printed packaging materials are critical to the conformity of pharmaceutical products. Furthermore, the European Union adopted a new directive in 2011 with new safety, tracking, and security requirements which is the Falsified Medicine Directive (FMD). In order to be compliant with this directive, the company has chosen to not store the labels in the warehouse. After receiving the labels, warehouse

personnel immediately transfer them to responsible personnel in the packaging department who then store them in locked premises.

Some of the different aspects of the put-away and storage processes from this section are highlighted in the table 4.3 below.

Table 4.3 - Highlighted aspects of put-away and storage

Entity of configuration	Current configuration	Reason
Storage allocation	Manual	No information system support
Storage policy	Random	Due to capacity issues and
Zoning	Yes (Ambient, Cold, Frozen and Deep freeze -80°C)	Product characteristics
	Separate locations with restricted access	Regulation

4.2.3 Picking, packing and shipping

The on-site warehouse is responsible for all shipments to customers while the external warehouse only ships to the production site. All orders are made to order (MTO) and once they are finished the customer is notified, the customers then order transportation and notify the case company when the truck will arrive to pick up the order. This information is transferred from the logistics department to the on-site warehouse through a picklist. The warehouse personnel then pick on order at a time and prepares it for dispatch. There are clear instructions for how the products should be packed on pallets, the instructions differ depending on where it is to be shipped. It is usually full pallets consisting of one article from one batch that are shipped out to customers, and no attention has been given to picking strategies. When the pallets have been picked for dispatch, they are staged and prepared on the floor in aisles. The preparation for dispatch includes wrapping the pallet (often done directly when received from the packaging department), adding temperature recordings if required, marking the pallet correctly, and preparing documents. Once the goods have been picked and prepared by one worker, it is controlled and documented that everything was correctly done by another worker. When the truck arrives to pick up the goods, it is ideal to have everything in order. If the goods require cold storage, it is common to print out a temperature log of the temperature in the truck and fill out a document that everything is up to par before initiating the loading. When shipping narcotics there are additional documents to prepare with information regarding the goods as well as the license plate of the truck and the personal identity number of the driver. Importing and exporting narcotic substances also require certain licenses but this does not affect the warehouse personnel, they just receive the necessary documents and add them to the shipment.

The whole process from order picking to order dispatch and shipping is illustrated with figure 4.5 below. This process omits narcotics and temperature-controlled goods that require some further steps that are explained in the text above. However, the process that is presented is valid for all types of products.

When the interviewees were asked about challenges in the shipping process it was evident that the lack of multiple ports and space are the most pressing issues. The consequence of capacity constraints is that picked goods for dispatch must be staged and prepared on the floor in aisles, blocking the entrance to pallet racks. Warehouse personnel often experience that they do not

have the required space to pack the goods in a safe manner. Having only one port means no physical separation of the inbound and outbound materials and prohibits good material flow in the warehouse. It also means that it is not possible to load and unload a truck at the same time. Furthermore, as mentioned in the previous segment about the receiving process, having no port connected to the cold storage is the main problem. Since the majority of shipped goods require cold storage, the lack of said port amounts to additional planning and prolongs the process significantly.

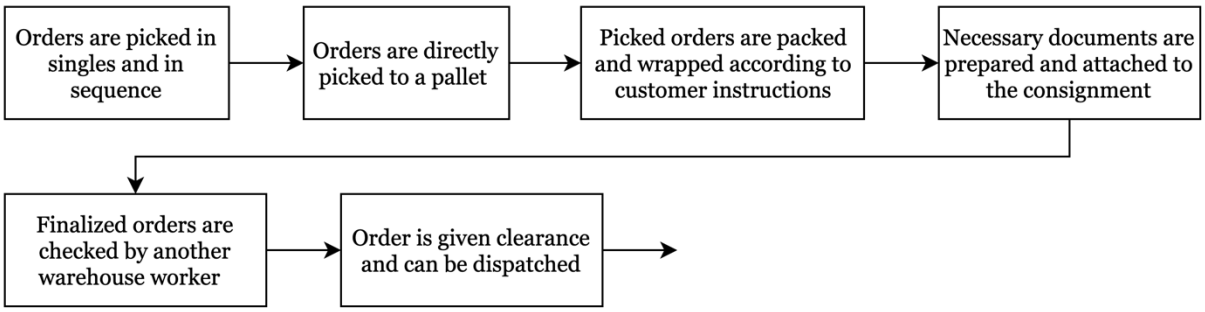

Figure 4.5 - Process overview from order picking to shipping to customer

4.2.4 Ancillary processes

In the previous segments about the warehousing process, there were a few mentions of ancillary processes (additional processes outside of the classic warehousing process). For instance, pallet wrapping before shipment since it is not allowed to ship unwrapped pallets. In this context, many of the ancillary processes involve sanitation and quality control. It is primarily the external warehouse that is affected by these, since the majority of shipments from suppliers arrive there. After the goods have been received, the warehouse personnel often withdraw a few samples and transfer them to the "QC-shelf". Goods arrive with quarantine status and the samples, along with documentation, are used in the process of releasing the material for use or distribution (performed by the QA department). This QC-picking process that is done before put-away is necessary and will affect the overall warehouse process and figure 4.6 shows this effect.

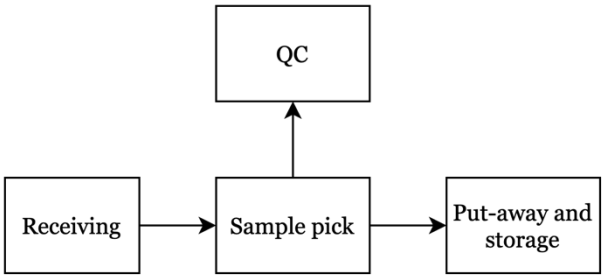

Figure 4.6 - An illustration on how sample picking affects the overall warehouse process

Moreover, goods shipped from the external warehouse to the bulk production must be transferred from the standard EU pallet on which it arrived on, to a hygiene pallet on top of a transport pallet which can be removed before entering production. A pallet turner and a pallet changer are used to facilitate this process. In some cases, the goods are too bulky to fit in the pallet turner which requires the warehouse personnel to manually break the pallet and transfer the goods to another. Once the hygiene pallets are shipped back to the external warehouse

from the production site, it is mandatory to wash them to ensure sanitation. Another sanitary operation performed at the external warehouse involves plastic bins used for WIP-materials by the production department. Once the bins have been used, they are shipped to the external warehouse for cleaning followed by stock keeping. An industry washer is used to clean and sanitize the bins.

4.3 Warehouse design and resources in a pharmaceutical setting

4.3.1 Physical layout

External warehouse - current setup

There is consensus amongst the interviewees that the external warehouse is a production warehouse. It is used primarily for handling and storing palletized goods from suppliers, as well as picking and dispatching raw material for production. Additionally, some goods are stored in cartons, such as archive samples and test samples. These are stored on shelves throughout the warehouse. The site is roughly 1500 square meters, with a long and narrow footprint with one port at one short end. The aisles are placed both parallel and orthogonal to the flow of material and enable pallets to be stored up to 5 to 6 pallets high. This setup has evolved through time and the current setup is mainly due to ad hoc changes and adaptations to increased storage capacity needs. There is a logical division of the main storage area into zones with specific numbering and letters for each zone, rack and level. However, the aisles are not entirely logical which creates intricate movement paths to some storage locations.

For the warehousing processes there are assigned zones that serve different purposes. In the front of the site, near the port, retrieving and shipping operations are performed. This area facilitates repacking of pallets, labeling, turning and changing of pallets, and wrapping of pallets. The main body of the site contains storage for dry and ambient goods. Almost in the back, furthest away from the port, two cold storage rooms with room for around 100 pallets are located. To one of the sides, behind some of the aisle, is a special area for destruction located. This area can be, and should be, locked. These special storage locations are used for goods that are destined for destruction which are material that are rejected or scrapped. Another area in the warehouse that is locked and controlled is the area for narcotics. This area is a regular storage area with racks for pallets, but it is locked when not in use. Also, the aseptic production uses blue bins which, after use, are returned to the external warehouse. To ensure that no cross-contamination takes place these bins are cleaned, which requires a dedicated area within the warehouse.

Storing material for medical production requires special control for storage conditions. This warehouse stores material with two storage temperature requirements, cold and ambient. Every temperature is a controlled temperature, this also includes ambient temperature. The ambient temperature is +15°C to +25°C and the cold temperature is +2°C to +8°C. These temperatures are monitored by a control system connected to both the production site and to an around the clock control service. The cold rooms are fully temperature mapped. Also, all the different temperatures are summarized in table 4.4 below.

Table 4.4 - Temperature ranges for different temperature requirements at external warehouse

Temperature description	**Temperature range**	
	Lower bound	*Upper bound*
Ambient	+15 °C	+25°C
Cold	+2°C	+8°C

Additionally, every entry way into the warehouse is locked. This ensures that no unauthorized access can take place. One reason for this is the nature of the goods that are stored. Some are very valuable, and some are narcotics which have requirements prescribed by law. The risk of tampering and falsification of medicine is a concern and to ensure patient safety, one measure is to control access strictly.

The table below, table 4.5, provides an overview of some of the different configuration decisions that the case company has made. This highlights the key takeaways from the physical layout.

Table 4.5 - Overview of some highlights of the physical layout of the external warehouse

Entity of configuration	**Current configuration**	**Reason**
Warehouse type	Raw material	Capacity constraints in production site
Footprint	Long and narrow	N/A
Ports	One in the front	Due to site constraints
Site access	Partly restricted	Due to the storage of narcotics
Aisle configuration logic	No logic regarding aisle layout	Due to ad hoc changes over time
Material flow and aisles	Aisle are both parallel and orthogonal with material flow	Due to ad hoc changes over time
Zones	Ambient, Cold and restricted access	Product characteristics

Production site - current setup

At the production site warehouse, the goods are more diverse in quantity and in quality. Mainly, goods are handled on pallets, but cartons and plastic bins are stored as well. The site functions as a hub for goods destined for production, storage for WIP and for the storage and dispatch of finished goods. The site is considerably smaller than the external site and can stack pallets up to 4 pallets high, in pallet racks. The layout is nondescript and comprises several rooms that contain both shelves for cartons and storage racks for pallets. Due to the constraints of the existing building there is no logical flow or zone division. This results in longer travel for some articles, especially cold articles that are furthest away from the only port that is located on one of the sides. Also, this affects aisle placement which is configured so they just fit as to maximize the amount of storage locations. This in turn affects the rationality and logic behind numbering of the storage location identifiers. As per a comment from a respondent who clearly stated that there is no logical system, which makes it difficult to understand what part of the warehouse that is referred to.

This warehouse handles many different types of flows simultaneously which requires enough space to be carried out. Due to the aforementioned space constraint the many processes are not given sufficient space to function properly with effectiveness and efficiency. Aspects such as compliance and safety are also affected, which also is pointed out by the Swedish Medical Product Agency's latest audit report. The warehouse lacks possibilities to receive and stage chilled goods for shipping, which is currently done in the over utilized cold room. Likewise,

there is not enough room to receive and stage ambient goods for shipping. This is however done near the port, but the space that is free is also needed for staging of goods destined for production. Another major issue for this site is storage locations, in all temperature intervals. More often than not, the goods are stored directly on the floor in front of existing pallet racks, thus incurring unnecessary handling of the same pallet. This also increases the difficulty of picking the correct material as well as increases the risk of injury. This warehouse also stores narcotics, which also means that they have lockable storage locations to accommodate these.

Special storage requirements are important for this warehouse as well. This warehouse however has all levels of temperature; ambient at +15°C to +25°C, chilled that is between +2°C to +8°C, frozen that is -15°C to -25°C and lastly below -80°C which of course is stored in a designated storage vessel. These are controlled and monitored like in the case for the external warehouse. To ensure that optimal storage conditions are upheld, the port is provided an airlock type of setup. Additionally, all the different temperatures are summarized in table 4.6 below.

Table 4.6 - Temperature ranges for different temperature requirements at external warehouse

Temperature description	**Temperature range**	
	Lower bound	*Upper bound*
Ambient	+15 °C	+25°C
Cold	+2°C	+8°C
Frozen	-15°C	-25°C
Deep freeze	N/A	-80°C

Similarly, for the external warehouse, every entry way is locked. The same reasons apply, but there is another aspect that is important to note. The company is what is called a known sender for air freight which is a customs pre-clearance concept. This concept lets the company waive the usual security checks that are otherwise prescribed by law. These security checks could affect both integrity and efficacy of the goods, therefore it is necessary to have this clearance. A company is granted a known sender by the Swedish transport agency. Which demands, amongst other things, that all access to premises are restricted for only authorized activities and personnel.

The table below, table 4.7, provides an overview of some of the different configuration decisions that the case company has made for the production site warehouse. This highlights the key takeaways from the physical layout.

Table 4.7 - Overview of some highlights of the physical layout of the production site warehouse

Entity of configuration	**Current configuration**	**Reason**
Warehouse type	Some raw material, WIP and FG	N/A
Footprint	Non-descript, several rooms that make up the warehouse	Due to site constraints and changes over time
Ports	One of to one side	Due to site constraints
Site access	Restricted	Known sender clearance
Aisle configuration logic	No logic regarding aisle layout	Due to ad hoc changes over time
Material flow and aisles	Aisle are orthogonal with material flow	Due to site constraints
Zones	Ambient, cold, frozen, deep freeze and restricted access	Product characteristics

4.3.2 Equipment

The handled and stored goods are mostly stored in cartons on pallets, whilst work-in-progress (WIP) material is stored in special blue hygienic plastic bins. The palletized goods are not stackable and are therefore stored in a single rack system with every pallet being accessible from the aisle. This setup is valid for both the production location and the external warehouse. Single cartons are stored at both sites which has required another type of storage equipment. Today, regular shelving is employed as a means of storing cartons. Blue bins that contain WIP can be both stored on pallets within the racking solution or on shelves. These bins, when filled, are often stored at the production site and empty bins are stored in bulk on pallets in the external warehouse. They are then stored both on the floor and in pallet racks. In some cases, the external warehouse also stores filled blue bins, usually slow-moving materials used for development projects. In the external warehouse plastic hygienic pallets are stored, these are used for aseptic production at the production location.

All materials are handled on pallets, or at least are picked to pallets. The setup for both warehouses is a bit different from each other mainly due to physical requirements. At the external warehouse reach trucks and manual pallet jacks are used and at the production site stacker trucks, a counterbalance truck and manual pallet jacks are used. The counterbalance truck is used to unload incoming shipments and is also equipped with long forks for retrieving two pallets at once. Other material handling equipment is used on both sites. Due to hygienic requirements in aseptic production wooden pallets are not allowed, therefore the pallet needs to be changed to a plastic pallet. This is facilitated by a pallet turner for some goods, but a few types of goods cannot fit in the current machine and for this pallet change is used. This machine changes the pallet by sliding another pallet under the goods whilst pushing the old one away. These two pieces of equipment are only used at the external warehouse. To secure goods for storage and for shipping the pallets need to be wrapped which is done with pallet wrapping machines which are located at both sites.

The equipment used at both sites of the case company is presented in table 4.8 below. This shows what equipment that is used and the reasons why.

Table 4.8 - Equipment used by the case company

Equipment		**Reason for having it**
Single racks		Stackability of pallets
Shelves		For cartons
Plastic hygienic bins		To hygienically store WIP
Hygienic pallets		For aseptic production where wooden pallets are not allowed
Trucks	*Counterbalance truck*	For unloading and loading
	Pallet jack	To move pallets
	Reach truck	To pick pallets
	Stacker truck	To pick pallets
Pallet turner		For aseptic production where wooden pallets are not allowed
Pallet changer		For aseptic production where wooden pallets are not allowed
Pallet wrapper		To secure goods for transport

4.3.3 Automation

Currently, no type of automation is used at either site with regards to warehousing activities. In other words, everything from retrieving to shipping is done manually. However, the company is not inexperienced in dealing with automated solutions. In their production several types of semi or fully automated machines are employed. They are in the midst of installing and validating a new fully automated machine for quality control of produced goods, which previously was a manual process. From that background, the study finds that the company sees potential in automated solutions in general, but it is stressed that automation within warehousing has not shown enough of a business case. Different types of warehousing automation solutions were not discussed further.

4.3.4 Information system

Last year, 2019 that is, a new ERP system, Jeeves, was chosen for the whole company. With this, the old WMS was also changed to a Jeeves WMS extension, EasyWMS. This WMS extension is used at both sites today, however, with varying results. The system handles everything from inventory management to the tracking of movement of pallets to different locations within the warehouse. It can be noted that movements from the external warehouse to the production site is only a stock movement and not a completely new receiving process within the system. The system is also equipped with handling orders, a function which is used in some cases, mostly for shipments to and from the external warehouse. Additionally, the WMS creates picklists and print scannable labels. Hand scanners for the warehouse staff are connected to the system, which enables the retrieval of picking assignments and scanning of goods for instance.

System support can be a good thing and it can help automate and facilitate good workflows. However, there are problems with the current setup. At this time, the order functionality is not fully used in all processes. The digital process is only used in the flow from the external site, whereas orders in paper form are used at the production site. Another issue is the handheld scanners which sometimes do not scan correctly which can cause serious goods tracking problems. Many respondents share a concern for this new system and points to a lesser trust in it due to the problems that it has caused. Some respondents share stories about orders not being correctly shown or, as stated previously, scanning being faulty. Largely, this is attributed to a hastily implementation and one respondent eluded to the specification for the system not being fully developed or understood. This spills over into problems in the information storing side of it all. The information that can be tracked, is not. This results in difficulties of facilitating analysis and creating reports that might be useful for an array of different tasks. Additionally, a large portion of the daily work is not covered by the ERP and therefore not by the WMS either. This also creates an information gap that can cause problems down the line.

However, the system has a lot of functionality that today is not used, and the respondents emphasized the untapped potential of this new system. More information can enable more analyzes and reports. Also, with extensions one can optimize storage with automatic storage allocation and automatic picklists.

Other systems that facilitate warehousing processes are not currently used. Additionally, no connection such as electronic data interchange connections are made to systems outside the organization.

4.3.5 Labor and management

The sites operate during weekdays with normal workdays. There are five employees in total and these are divided in a two, two and one configuration. Where there are two employees at each site and one driver that ships goods between the sites.

Neither of the sites uses key performance indicators (KPI). However, many respondents alluded to KPIs having importance but could not really explain what to measure. They highlight the difficulty to measure in general and specifically deciding what to measure. Nonetheless, some examples came up, such as checking age of goods and order fulfilment.

Something that is important for every employer is safety. From the literature it is clear that too high utilization will increase the risk for injuries. It was observed that some employees had to climb over pallets to reach certain things and during the study one employee had a minor injury which resulted in sick leave.

4.4 Conclusion of empirical data

The empirical data presented in this section has provided an understanding of the pharmaceutical context as well as the case company. It is evident that the pharmaceutical industry is heavily controlled through laws and guidelines, as well as inspections from regulatory bodies. In addition, the empirical data gave insights about pharmaceutical product characteristics, both through the secondary data study and the case study. The case study also provided rich information about possible ways to adhere to different regulations and other industry requirements. With all the information presented here, the next step is to analyze the data and uncover contextual factors, fulfilling the research purpose of this thesis. Furthermore, this section has provided a thorough understanding of the case company's current setup and processes, which will be of use further on in section 6 where a proposal for the new setup will be provided. During the interviews, the interviewees were asked to speak their mind about the challenges in the current setup. The major challenges are summarized in table 4.9 below and will be addressed later in section 6.

Table 4.9 - Challenges experienced by case company employees in the current setup

Challenge	**Implication**
Single port	- No separation of inbound and outbound materials - Prohibits good material flow - Not possible to load and unload truck at the same time - Not possible to load and unload into cold storage, amounts to additional planning and prolongs the process
Capacity	- Limits possibilities to physically separate goods - Goods must be staged on floor in aisles, blocking entrance to pallet racks - Not enough space to pack goods in a safe manner
IS functionality	- Not all orders are handled digitally - Not all warehouse workers use the handheld scanners - Low trust for the information systems - Not all material equipped with scannable barcodes, prohibits consistent use of scanners - Information gap between daily work and information systems

5. Analysis and discussion

5.1 Contextual factors in a pharmaceutical setting

Based on the case study, together with the secondary data study, we identified several contextual factors that influence warehouse configuration in a pharmaceutical setting. This was achieved through the methodology described in section 3.5. In summary, the interview responses were matched with configuration elements and condensed into bullet points; each bullet point was then given one or multiple descriptors, who were later identified as contextual factors. As an initial overview, these factors are presented in table 5.1 below. As can be seen in the table, there are two major factors – compliance and external environment – with underlying sub-factors. Following in this section, the contextual factors – together with their sub-factors – will be identified and explained, thereby answering the first research question.

Table 5.1 - Identified contextual factors in a pharmaceutical setting

Compliance			**External environment**	
Control	Regulation	Separation	Product	Customer

5.1.1 Compliance

The first major contextual factor is compliance. From both the case study and the secondary data study, it is evident that the pharmaceutical industry is laden with laws, directives and guidelines. It is vital to operate in compliance with these, otherwise authorities may take action and withdraw necessary operating licenses, or customers may lose trust and terminate their business collaborations. For the sake of readability and production of something actionable, the compliance factor has been broken down into three sub-factors: control, regulation and separation. Compliance is a broad theme; the sub-factors are not mutually exclusive but may be collectively exhaustive because of the significant influence of compliance. Forthcoming are our definitions of the aforementioned sub-factors.

Control

The aspect of control constitutes another broad theme within compliance. It is not a well-known factor mentioned in literature or found in the secondary data study; it is rather our own development for the sake of capturing an important element of the pharmaceutical context. By our definition, control entails – for instance – overall control of operations, control of inventory levels, control of picked goods, control of requirements, and control of distribution (e.g. truck temperature). In most industries, companies strive for control and high service levels, but the pharmaceutical context brings an additional dimension. In this context, control is important for the companies' own sake, but it is also paramount to be able to demonstrate control towards suppliers, customers and authorities.

Regulation

The regulatory aspect of the pharmaceutical context is the central, and the most significant factor. The industry has a direct effect on the health of the global population; hence several international regulatory bodies monitor matters like drug quality, safety, patents and pricing. Examples of such organizations are WHO and EU. Apart from international organizations,

each country has its own regulatory body, such as FDA in the US, MHRA in the UK, and LV in Sweden. If a pharmaceutical manufacturer engages in trade with a foreign country, they are subjected to that country's specific regulations. For instance, the Swedish case company of this thesis exports drugs to the US and are hence regularly inspected by the FDA and required to operate in compliance with their specific regulations. The country specific regulatory bodies have unique demands for different regulated areas; therefore, the case company routinely chooses to operate in compliance with the strictest demand. This ensures the company to always be up to par with regulations, regardless of what country or organization inspects them. Figure 5.1 below is an illustration of the multiple regulatory bodies with influence on pharmaceutical warehouse configuration.

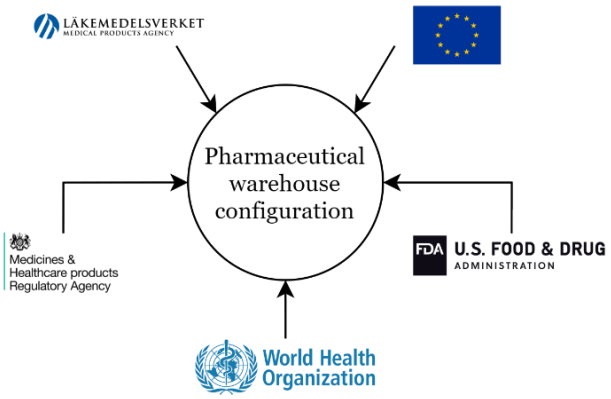

Figure 5.1 - Illustration of multiple regulatory bodies with influence on pharmaceutical warehouse configuration

The secondary data study, as well as the case study, shows that pharmaceutical regulations directly influence warehouse configuration. To prevent mix-ups and contamination, there are clear and specific regulations for configuration of storage areas and how materials within the warehouse are to be handled. It is important to adhere to applicable laws and regulations on many different areas depending on what type of products are handled. For instance, there are specific regulations for narcotic substances as well as for rejected materials destined for destruction. The 'Falsified Medicine Directive' directly influences how to store and handle printed packaging material. Another important area is traceability of the pharmaceutical products, taking necessary actions to enable visibility of the history of transfers and locations of a product.

Separation

The last identified compliance related factor is separation, which is closely related to control and regulation. In this case, the term separation entails separation of goods, flows and processes. It may seem like a minor part of the regulation aspect, but we determined that it deserves to be a standalone factor. The reasoning for this was partly due to the significance it showed in the secondary data study, but mostly because of the case study. When the interviewees' condensed responses were given descriptors, a multitude of the responses received separation as a descriptor. From the case study it was also evident that separation of goods, flows and processes is an important matter during inspections by regulatory bodies.

The matter of separation is crucial for prevention of mix-ups and contaminations. All material stored in the warehouse is destined for a product of a specific batch, and that specific batch is composed of specific batches of different materials. Because of this, the same materials – but

from different batches – cannot be stored at the same location, they must be separated. This is further accommodated by separating flows within the warehouse to prevent materials from crossing paths. As mentioned in the secondary data study, materials of different status (e.g. in quarantine or released) must be separated. Nowadays, this form of separation is possible to achieve through information systems, as is done by the case company. Materials destined for destruction must be segregated from all other materials, an important reason for this is the 'Falsified Medicine Directive' previously mentioned.

5.1.2 External environment

The second major contextual factor is the external environment. This is shared with other industries and is captured in the conceptual framework, figure 2.10, under general contextual factors. However, there are certain unique characteristics for certain aspects in the pharmaceutical industry that deserve special attention.

Product characteristics

The characteristics of pharmaceutical products have a significant influence on warehouse configuration. An area that has received wide attention is the products' various temperature and humidity requirements. This has a direct influence on warehouse configuration, for instance warehouse premise design, interior layout and internal flows which ensures unbroken cold chains. Moreover, pharmaceutical products are typically fragile and very expensive, one pallet may carry a value of several 100 MSEK. The material handling within the warehouse must hence be conducted with care to not compromise product integrity and quality. Another product characteristic with major influence is that some pharmaceutical products are classified as narcotics. This matter was discussed in the previous section regarding regulations, all these contextual factors are on some level intertwined with one another. Table 5.2 below shows an overview of pharmaceutical product characteristics for different aspects.

Table 5.2 - Overview of pharmaceutical product characteristics for different aspects

Aspect	Characteristics
Storage requirements	Humidity and temperature, strictly controlled
Value	High, especially for orphan drugs
Fragility	High, non-stackable
Societal importance	High, public health and safety
Narcotics	Handling, exporting, and importing strictly regulated

Customer characteristics

The customer characteristics in the pharmaceutical industry are identified as the last contextual factor. From the case study it was evident that reputation and trust from customers is paramount. Contrary to many other industries, mix-ups are unacceptable. In the fashion industry it may be acceptable to deliver the wrong shirt, but delivering the wrong quantity of a pharmaceutical product, or the wrong product, is devastating. This means that quality and safety is of the essence, and not speed. Moreover, since the case company is a third-party manufacturer and starting materials are expensive, customers usually own the stock. Because of this, customers regularly conduct inspections to ensure that their material is handled in a safe and responsible manner. This ties back to the previously discussed factor 'control', the

importance of demonstrating control and compliance with regulations. The customers have their own brand and reputation to protect, and it is important for them to ensure that everything upwards in the supply chain is conducted correctly.

5.2 How contextual factors influence warehouse configuration

It has been alluded to throughout the report that warehouse configuration is complex and that it is synonymous with interdependent decisions. This is true in this case as well and the pharmaceutical context exacerbates that notion. It becomes clear from a first influence analysis of the matter that there is considerable complexity added by the pharmaceutical context. To illustrate both complexity and interdependence a figure, figure 5.1, was conceived to help with understanding and appreciating this issue. Consequently, this figure is not meant to provide factual results or lend itself for any practical use.

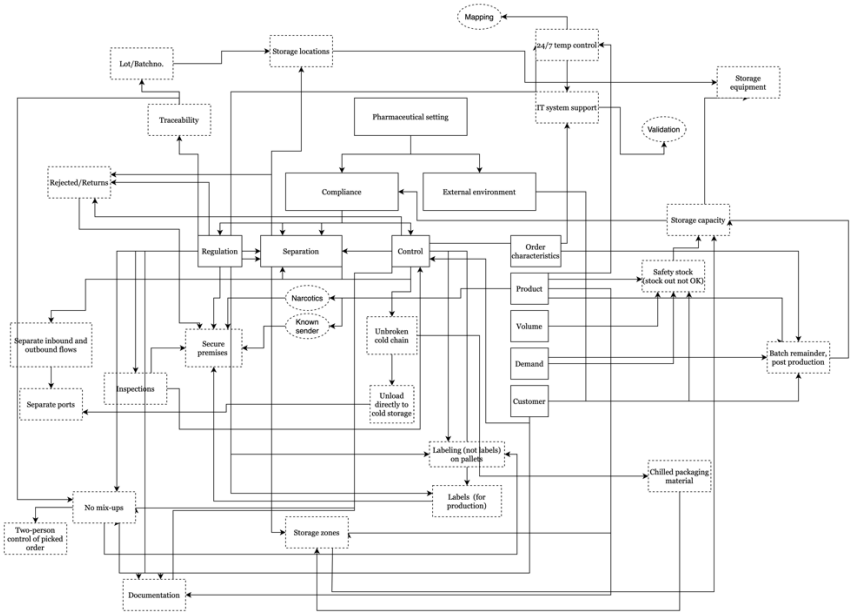

Figure 5.2 - Illustration of complexity and interdependence

Due to this complexity and interdependence, an attempt to structure the factors' influence on configuration elements was made. The factors by themselves are not mutually exclusive which required us to build the analysis around each configuration element seen in the conceptual framework, figure 2.10, earlier in the thesis. Table 5.3 below illustrates which configuration element that is influenced by a particular contextual factor.

Table 5.3 - Illustration of contextual factors' influence on configuration elements

	Compliance			External environment	
	Control	Separation	Regulation	Product	Customer
Receiving	-				-
Pre-put away	-	-		-	-
Put-away and storage	-				-
Picking	-				-
Post-picking		-		-	
Packing and shipping			-		
Physical layout					-
Equipment	-	-			-
Information systems				-	
Automation	Was not captured by the study				
Labor and management		-		-	

The following sections will explore how the identified contextual factors influence different configuration elements.

5.2.1 Receiving

Receiving operations are affected by both the compliance part of the context, as well as the external environment. More specifically, it is influenced by the regulation, the separation and the product context. First, the compliance factor, regulation, is viewed in different subunits that all have an effect on how this particular activity is performed. Beginning with regulation regarding narcotics which has a stricter application, rather than being hortative. Dealing with medical products classified as narcotics will affect how this particular receiving process should be set up. The receipt of narcotics cannot, under any circumstance, be delayed or postponed. It needs to be performed in conjunction with the arrival and receipt of the substance. The legislation requires direct reports to the overseeing authorities on what has been received and in what quantities on weight-by-gram basis. It is also important to ensure that the received amount does not exceed the ordered amount, for which approval has been given. To control what amount that you have received is prescribed by law, but this also is an extension of the broader subject of inventory control. The inventory control dimension also requires that everything that is received needs to be registered correctly and in the correct amount. As mentioned above, spot-checks are performed and for that reason the inventory control in the receiving process needs to be correct. Therefore, there is a need for sufficient resources in terms of time and space for the receiving process to function properly. Onward, but in the theme of inventory control, are labels. These labels are the labels intended for use on the pharmaceutical product which are used by patients or medical staff. This area is highly regulated for several reasons and results in a special process to ensure outermost control. How this is managed can differ from company to company, but you need to ensure that each label is accounted for, on piece level, and that labels cannot be exposed to any form of shrinkage in the warehouse. Additionally, another dimension of the regulatory factor is the need for traceability. Every actor in a pharmaceutical supply chain is bound to facilitate traceability which also puts requirements on the receiving process. All goods that flow through the supply chain can be identified by the particular batch number but in some cases, this is not enough. There are examples of products that need an extra level for the batch number, or lot number, to adhere to certain provisions. The goods requiring this are called sub-lot controlled and the goods will receive this identification upon arrival to the warehouse. This means that a pallet

containing e.g. 25 jerry cans, or flasks, must be received in 25 instances instead of one. Which of course increases the need for resources in the receiving process.

Separation is the other part of the compliance factor that affects receiving. It can also be viewed in the light of regulation as well, but this distinction is done solely to increase readability and understandability. Separation in this case affects the way goods can flow, in what directions and in which point in time. There is a need to separate incoming flows from other flows, and there is a need to not cross flows. This might mean that you would not want to handle incoming goods that just arrived whilst also handling finished goods for example.

As for the external environment, the product factor is influencing the process. Here, narcotics and temperature play a role in how receiving is performed. Narcotics both belong to product and regulation but will have the same effect, so the previous discussion is valid here as well. Temperature, however, will play a vital role in the process. A major part is temperature control for all temperature levels, but especially for lower temperature. Controlling temperature throughout the chain is important for quality assurance and in some cases to maintain a cold chain. This means that receiving should, in some cases, be able to be done directly to and within a temperature stable and controlled environment. As a summarize for all the above stated influences a table, table 5.4 below, shows the contextual factors and their influences on the receiving process.

Table 5.4 - How receiving is influenced by the context

	Contextual factor	Influence
Compliance	Control	-
	Separation	- Separate inbound flows from other flows, crossing flows are forbidden
	Regulation	- Receipt of narcotics cannot be delayed - All received goods must be registered with correct quantity and additional information - Product labels must be strictly controlled, shrinkage absolutely forbidden - Some products are sub-lot controlled and requires extensive receipt processes, originates from the need of traceability
External environment	Product	- Receipt of narcotics cannot be delayed - When applicable, unloading should be done directly into correct temperature zone
	Customer	-

5.2.2 Pre put-away

After the receiving process has been performed, put-away is next according to the general warehouse process. In the pharmaceutical warehouse the put-away process cannot take place right after the receipt has been done. There is a step before the actual put-away and storage phase which has to be done in order to proceed. This process, that we call pre put-away, is a result of the regulatory factor and is mandated, somewhat, by law. The most time-consuming part of this activity is labeling of pallets and cartons. Because of information requirements labeling must be done for every single carton and, in some cases, pallet and pieces. The labels are printed on site with certain information such as batch number and reference number to

ensure traceability and are then placed on the cartons, or pallets and pieces. This can be exceedingly time consuming, and it can be illustrated with an example. Let say that an order arrives with ten pallets with 32 cartons on each pallet, 320 cartons that is. Then, you would have to touch each carton at least once resulting in a lengthy and time-consuming process. Sometimes you would have to de-palletize the products before labeling which results in a need for re-palletizing after the labeling process is completed. The labeling process is done for narcotics as well, but the process itself does not change in execution, only in time and speed. Narcotics cannot be left unattended, the pre put-away labeling must be performed without delay directly after the receipt has been performed.

In this pre put-away process sampling is included. Sampling is also mandated by law, to ensure quality of all material that is used. The actual quality control is performed by the quality control department, but they will need samples from every batch to perform this control. Therefore, the warehouse staff must pick samples from each batch of material that arrives at the warehouse. These sample picks, or QC-pick, are made according to a predetermined plan and involve picking pieces from specific parts of the batch. Table 5.5 below summarizes how the identified contextual factors influence the pre put-away process.

Table 5.5 - How pre put-away is influenced by the context

	Contextual factor	Influence
Compliance	Control	-
	Separation	-
	Regulation	- Required to label each carton - Sample picking for QC
External environment	Product	-
	Customer	-

5.2.3 Put-away and Storage

Of these two processes, mainly storage is affected by the studied context. Regulation, separation and product are the factors that influence these particular processes. From the regulations stems provisions regarding labels on primary packaging and narcotics. Labels that are used for the identification of the drug, that are placed on the pharmaceutical product, are strictly regulated. Labels are important for patient safety and they function as a last line of defense against errors. Labels contain information regarding substance and concentration that must be correct, even if the outer packaging is incorrect. Together with falsified product concerns, this creates certain requirements for storage of these types of articles. Therefore, labels must be stored separately, and it should be stored in a locked environment to ensure that absolutely no shrinkage can take place. Narcotics have the same requirements as labels, requiring separate storage with restricted access. Additionally, narcotics cannot be left unattended for any period of time, which then requires the put-away to be conducted immediately after the receipt has been done. The second factor that affects storage and put-away is separation. Besides narcotics and labels, rejected and obsolete material must also be stored separately and locked away from the rest of the inventory. The reasons are mainly falsified product concerns, where you do not want rejected packaging or similar to end up elsewhere. It would have serious consequences if rejected material where to be used in production or sent to a customer.

Lastly, the product factor will influence both how the put-away is conducted as well as the actual storage. Temperature is one product characteristic that influences storage, and not so much the actual put-away. What can be noted is that every temperature requires control, meaning that even ambient is a controlled temperature. It is therefore important that each article is stored at the correct temperature. Besides temperature, some labels also require humidity control, which then also requires that the product can be placed in an environment suitable for its requirements. Another characteristic is the perishability of pharmaceutical products, they all have best before dates which are closely monitored. From a storage and put-away perspective this means that you should put-away and store the goods so to facilitate easy access to avoid double or multiple handling. One other interesting characteristic, especially in the pharmaceutical industry, is the enormous values that can be stored on a single pallet. Also, that the product can be fragile and must be handled with care, results in a need to proceed with caution when putting it away and storing it. Some respondents also point to maybe not storing expensive and fragile pallets high up or in areas with frequent traffic. Table 5.6 below summarizes how the identified contextual factors influence put-away and storage.

Table 5.6 - How put-away and storage is influenced by the context

	Contextual factor	Influence
Compliance	Control	-
	Separation	- Rejected and obsolete material must be securely stored, segregated from other material
	Regulation	- Product labels must be strictly controlled, shrinkage absolutely forbidden. Case company facilitates this with storage in locked areas. - Narcotics must be stored in areas with restricted access
External environment	Product	- Goods must be stored in correct and controlled conditions - Store to facilitate FEFO - Handle with care, do not store expensive and fragile goods high up or in areas with frequent traffic
	Customer	-

5.2.4 Picking

In the pharmaceutical warehouse picking is an essential part, as for many other warehouses as well. Picking is largely performed the same as in other warehouses but there are certain factors that influence the picking process. Regulatory influences can be seen in the need for traceability which translates into how you would pick a certain article. In this context one would pick, not only an article, but also a specific batch. This means that the most convenient pick might not be the pick that can be performed. If the order is for one pallet of article A and batch X, you cannot pick batch Y, even if you are right next to it and batch X is placed on the other side of the warehouse. Therefore, this could result in longer travel distances within the warehouse. With this discussion one can also revisit the different storage policies, particularly the forward-reserve policy. This storage policy will probably not be suitable for a pharmaceutical production warehouse. Given the requirement to pick specific batches, it would be very difficult to maintain a forward-reserve policy.

Continuing the travel discussion, the separation of goods can also introduce longer traveling distances. Pallets might be needed to be placed in less convenient just because of their storage

requirements which then would introduce longer travel distances. Moreover, the last factor that influences the picking process is product characteristics. Pharmaceutical products are perishable which will directly and clearly influence the picking strategy. Perishable goods favor first-expiry-first-out (FEFO) which will not directly affect the warehouse staff, but it will affect the production orders. That will be sent to the warehouse. Thus, indirectly affecting how and where the pick will be performed. Another part of the product characteristics is value and fragility of the goods. When picking pharmaceutical products, one would need to proceed with caution when picking to ensure quality and safety.

In theory section picking is investigated and many picking strategies are explored. There is no indication in this study or at the case company that would indicate something that would favour a certain picking strategy. The case company picks their orders in singles and in sequence. This is mostly due to company and order specific parameters rather than context related. The study cannot claim to know exactly what order picking method that is the correct one. However, it seems that the picking method is largely determined by order characteristics and the size of the flow. One could further bolster this notion by highlighting that the next step in the process will facilitate several different methods. Even if you would choose a batch pick method, the order would still be controlled in the next step. Table 5.7 below summarizes how the identified contextual factors influence the picking process.

Table 5.7 - How picking is influenced by the context

	Contextual factor	Influence
Compliance	Control	-
	Separation	- Longer travel distance
	Regulation	- Longer travel distance
External environment	Product	- Pick products with care
	Customer	-

5.2.5 Post-picking

After order picking has been performed the next step would be packing and shipping. This is not true in this context. What has been very clear from the interviews and also the secondary data study is that order control is extremely important. It is not enough to just be extra cautious when picking orders, so this step becomes necessary either way. This process, post-picking, is a result and is influenced by control, regulation and the customer factors. From a regulation perspective it is not mandated to do this, but according to the EU you need to take "sufficient" action (EudraLex vol 4, n.d.) to avoid any mix ups. Adding to that, the company itself wants to have extra control over this particular step because it's the point where things can go wrong. If things were to be wrong, this would defeat every precaution that has been taken up to that point. Thus, the two-person control is one way of alleviating this concern. Also, even if it would be technically possible to manage this with an IT solution the respondents say that they would be highly skeptical to implement such a system.

Another dimension that in itself influences this process, but also strengthens the internal control need, is the customer factor. From a customer perspective mix ups are unequivocally unacceptable. It would be a serious matter if a company were to send the wrong product. Not only would this create problems with shipping, but it has long term effects on trust and reputation. If you would send products incorrectly, this would erase the trust the company has built amongst its customers and its reputation might be hurt. This is true for many

pharmaceutical companies, but especially so for third party manufacturers. Clearly, this illustrates why there is a skepticism for other solutions than the two-person system. Table 5.8 below summarizes how the identified contextual factors influence the post-picking process.

Table 5.8 - How post-picking is influenced by the context

	Contextual factor	Influence
Compliance	Control	- Two-person control of picked goods, to ensure correctly picked order
	Separation	-
	Regulation	- Ensure correctly picked order and avoid mix-ups
External environment	Product	-
	Customer	- Incorrectly picked order or mix-ups are unacceptable

5.2.6 Packing and shipping

The packing and shipping processes are influenced by the contextual factors; control, separation, customer characteristics and product characteristics. The influence of control and product characteristics is mainly derived from temperature control and narcotics handling. To facilitate this in practice, the case company routinely chill packaging material before packing and store the packed finished goods in the correct temperature at least 24 hours before departure. But the responsibility does not end there, it is also important to control that the truck temperature is correct before loading the goods. Moreover, the control factor is also evident when shipping narcotics. To ensure that it is the right forwarding agent, an ID and truck registration number verification, along with proper documentation, is necessary in this case. The other influencing compliance factor is separation. As mentioned, multiple times before, it is important to separate the outbound flows from inbound flows. It is also an issue of compliance during inspections. The ideal way to facilitate this is to have separate ports for inbound and outbound. If this is not possible, there must be clear separation of the received goods and the goods destined for dispatch inside the warehouse. Finally, customers influence the packing process with detailed instructions for how the goods should be packed. This may not be true for all pharmaceutical manufacturers, but this is the situation for the investigated case company. Table 5.9 below summarizes how the identified contextual factors influence the packing and shipping process.

Table 5.9 - How packing and shipping is influenced by the context

	Contextual factor	Influence
Compliance	Control	- Packaging material chilled before use - Finished packaged goods stored in correct temperature at least 24h before departure - Ensure correct truck temperature before loading - For narcotics, check truck registration number and ID of driver, proper documentation
	Separation	- Separate outbound flows from other flows, crossing flows are forbidden
	Regulation	-
External environment	Product	- Same as for control
	Customer	- Detailed packaging instructions

5.2.7 Physical layout

All parts of the compliance factor influence the way the physical layout is conceived. One of the major points, both in the case study but also the data study, was that enough space or capacity is needed to achieve a certain level of operational effectiveness. Enough space will, in theory at least, facilitate rational, effective and efficient flows. The takeaway from this is that you need to fully understand the required space needed for storage and activities performed. Enough space and capacity falls under the compliance dimension regulation. From a regulator's point of view, it is important to not mix and intertwine material flows. The layout should facilitate this, and it should also facilitate facility keep up and cleanliness. How this should be done is left unstated in the regulation, and it will be by the discretion of the practitioner to figure this out. Continuing with regulation factors, there are some things that require specific solutions to comply with regulations and provisions. A practitioner needs to have locked storage areas or locations for the storage of narcotics, rejected or obsolete material, returns and labels. This means that a portion of the warehouse will be dedicated to these types of materials in order to comply with provisions. Another part of the compliance factor is separation. For the physical layout this means several things. First, it has been indicated before that inspections have resulted in cautions to the case company regarding separation of ports for inbound and outbound flows. This, together with overwhelming support from the study's respondents, shows that a pharmaceutical warehouse needs separate port for the different flows. Aside from this, everything is handled in separate batches which must be separated. This increases the demand for more, in numbers, storage locations for each batch to be stored. Another regulation aspect that is, in part, due to product characteristics as well, is the need to comply to know sender regulation. This results in a clearly stated, in regulation, that premises need to be locked and enough measures must be taken to ensure that unauthorized access is not possible. This means that you need to have locked perimeters and limited access to all facilities.

Another, equally important, aspect is product characteristics. There are two major characteristics that affect the physical layout namely requirements on storage condition and value. Storage conditions encompass mostly temperature, but also humidity. First, one important thing to understand regarding temperature is that everything is a controlled temperature even if it is called ambient. Thus, there is a requirement for different temperature zones within the warehouse. To add more complexity into the mix there are regulatory requirements for temperature mapping to ensure storage conditions. Temperature fluctuations can occur by outside temperature changes or the opening of ports for example, and these will affect this temperature mapping. To combat this each port or opening must be equipped with a temperature barrier solution such as airlocks for example. The other part, humidity, influences this particular area but to a far less extent than temperature. Only some labels are required to be stored in humidity-controlled environments. The value component of the product characteristics can be viewed in at least two perspectives; quantifiable monetary value or the qualitative value of health and safety of patients. Pharmaceutical products, especially orphan drugs, have high value. An illustration of this is one small pallet of a specific orphan drug API. It has a total value of almost 100 million Swedish crowns and the case company stores a certain number of these pallets that result in an inventory valued at upwards of two billion Swedish crowns. Additionally, on piece-level the finished product value increases by 250-300 percent. This clearly shows that, from a monetary perspective, the product has a very high value. It can be noted that all products are not equally expensive such as regular over the counter paracetamol. The other perspective of patient wellbeing and health also affects

how the physical layout is conceived. Drugs in general and orphan drugs in particular, are important for patients to be and to maintain health. Steady supply of product to the market is both a monetary matter but also a matter of public health and safety. The industry in general handles this with caution to ensure this supply. This results in keeping safety stock at nearly all nodes of the supply chain, in terms of raw material, API and finished goods. Additionally, contingency measures are also in place to ensure product availability. This can involve keeping material, API especially, in separate facilities or coolers in the case of failure. Revisiting the monetary discussion also adds to the product availability issue, because stock out can result in considerable amount of lost revenue. For the physical layout this translates into an extra need for more capacity to handle the extra safety stock. Table 5.10 below summarizes how the identified contextual factors influence the physical layout configuration.

Table 5.10 - How the physical layout is influenced by the context

	Contextual factor	Influence
Compliance	Control	-
	Separation	- Separate ports for inbound and outbound flows - More storage locations needed per SKU
	Regulation	- Facilitate separate flows and cleanliness - Areas with restricted access - Ensure no unauthorized access - Monitor and control different temperature zones
External environment	Product	- Zones with different storage conditions - Increased safety stock - Contingency measures, store goods in different premises
	Customer	-

5.2.8 Equipment

A pharmaceutical warehouse requires, mostly, the same equipment as a regular warehouse. However, there are some things that are needed specifically in a pharmaceutical warehouse. From before it is clear that regulation demands that batches are stored separately which increases the need for storage locations. Additionally, from a manufacturing and traceability perspective, not only are products ordered by article type, but specific batches of that particular article are ordered. This means that you must not only pick the correct article, you need to pick the correct batch of that article. Consequently, you will need to facilitate easy and convenient access to each article and batch to avoid multiple handling and to reduce the risk of errors. As a direct consequence, solutions including deep storage bins or lanes are not suitable. However, lane or bin depth is also dependent on how batch and lot sizes are configured in terms of size. So, there is a dimension of customization on a case-by-case basis to consider. A more concrete effect of the context, and the regulatory factor, is the need to achieve full information and inventory control. One of the resulting activities is the re-labeling of each carton on an incoming pallet. This is described earlier and how to handle re-labeling is at the practitioner's discretion. In this case re-labeling is done without any particular equipment, but there are certainly other ways of solving this problem, especially from an ergonomic perspective. One way could be to use a depalletizer to breakdown the pallet to facilitate easier labeling. Then one could use a palletizer for the cartons or just do it manually. Another way could be to use height adjustable tables to ensure optimal working conditions.

Another factor that will influence which equipment that is used is product characteristics. From a product characteristic perspective, you could see four parts influencing specifically storage equipment. These are; picking strategy first-expiry-first-out (FEFO), fragility, value, and type of drug. The picking strategy demands that goods with the shortest best-before date is picked, resulting in a need to be able to easily access that particular batch and article. The products are often fragile and non-stackable as well as expensive, where a pallet of an active pharmaceutical ingredient (API) can be worth up to 100 million SEK and above. All of this of course rules out any floor storage solution which then results in a need for some kind of racking solution instead. The type of drug will also affect equipment aspects. The case company deals with orphan drugs which are often more expensive which add to the value discussion. Additionally, orphan drugs will also often have smaller batch sizes which require smaller and more storage locations. Smaller batches also favor single deep storage solutions due to requirements to not store different batches at the same storage location. This whole discussion on product characteristics and regulation results in a need for the goods to be stored in racks mostly single deep, but this is also dependent on batch and lot sizes.

Trucks and other equipment used to move goods are influenced indirectly by the contextual factors. The need for racks creates a need for trucks that can handle pallets that are stored in racks and higher up. Depending on aisle width this results in a need for a certain suitable truck for the racking solution chosen. Other equipment is, however, used in the pharmaceutical warehouse. If the production is producing aseptic products, such as the case company, cleanliness is an important factor. Wooden pallets may not be received into the aseptic production which then requires equipment in the warehouse to change pallets. This is done by a pallet changer or a pallet turner. This changes the wooden pallet to a hygienic plastic pallet. Table 5.11 below summarizes how the identified contextual factors influence the equipment selection.

Table 5.11 - How equipment is influenced by the context

	Contextual factor	Influence
Compliance	Control	-
	Separation	-
	Regulation	- Must facilitate easy access to each article and batch - May need de-palletizer, palletizer and labeling machine
External environment	Product	- Goods not suitable for floor storage - Single-deep racks most appropriate, in most cases - May need pallet changer or pallet turner
	Customer	-

5.2.9 Information systems

Information systems can be used in a plethora of different applications, industries and processes. The previous theoretical section names a few systems that the case company also have. In general, the requirements for whatever system you want to employ are largely the same. The systems need to be working properly and must support the business processes, which it also needs to do in a pharmaceutical setting. However, there are still some factors that influence what systems you would use, and need, as well as how those systems would be implemented. First, there is a control factor that comes into play regarding systems. Largely,

this is due to a general need for information control. This is hardly surprising, but it is important for a pharmaceutical company to have control over the information they keep. By the same token, the level of standardization is also affected favoring more standardized solutions. Adding to this, each system used, or planned to be used, needs validation. This means that a new system or an update of an old one needs to be validated to ensure that everything is running correctly. This of course introduces more complexity when introducing new systems. Regulation will also affect systems in a similar way, both directly via statues and indirectly via different requirements, with a resulting need of validation. The regulation requires the practitioner to track the quarantine status of all the goods in the warehouse. Also, authorities conduct spot-checks where they check both quarantine status in particular, but also inventory control in general. The overseeing agency, both Läkemedelsverket and FDA in this case, will check to see that the goods placement corresponds to the placement in the system. Thus, results in a need for validation, but also adds to the control factor as well, demanding that the processes in which the system is used, are correct. Lastly, the regulation also has specific system requirements with regards to temperature. As an effect, temperature control systems are needed. These systems are required to monitor every temperature level, including ambient, in real time all the time to ensure quality and efficacy of the products.

The quarantine status that was a part of regulation also belongs to the separation factor. The purpose of the quarantine status is to ensure that only approved goods are used in production or are shipped. This can be done in different ways, and one of those is with an IT-solution. The separation part becomes evident when looking at why this status exists and how it came to be. Quarantine before meant that you, literally, separated goods in their particular status e.g. storing goods approved for production in a specific part of the warehouse. Now this separation is achieved, as stated above, by including it in a WMS.

Apart from the compliance factors, the external environment influences how information is handled in a pharmaceutical setting. The customer, in this instance, may own the goods themselves and often this is the API itself which can be exceedingly expensive. In our case, the company needs to have correct inventory levels registered for reporting purposes. Manly because of business related reasons such as trust and professionally. Table 5.12 below summarizes how the identified contextual factors influence the configuration of information systems.

Table 5.12 - How information systems are influenced by the context

	Contextual factor	Influence
Compliance	Control	- Strive to use standardized systems - Every system must be validated
	Separation	- Separation of different articles and batches of different statuses in the information system
	Regulation	- Every system must be validated - Track status for each article and batch (e.g. in quarantine or released for use or distribution) - Inventory control, spot checks may be conducted from authorities - Temperature control system
External environment	Product	-
	Customer	- Control of inventory information

5.2.10 Automation

Automation solutions can provide benefits for many warehouses that seek to be more productive and efficient in their processes (Custodio and Machado, 2019). A pharmaceutical warehouse is probably not an exception to this. However, this study was not able to capture this particular area of warehouse configuration. The case company did not use any automated solutions, in the warehouse at least, and their operations would not support an automated solution. Some respondents did however express that automation can be one piece in the complex warehousing puzzle. Regardless, they stress that they would need to validate the solution and they would be cautious trusting it fully, especially in the order picking process.

5.2.11 Labor and management

There are labor and managerial implications due to the pharmaceutical context. Control is one of those that affect how the staff works and how they are managed. KPI is one of those tools that can be used to manage staff. In this context, or in this case at least, it has been proven quite difficult to articulate KPIs that are suitable for this context. The case company does not use KPIs to measure their staff, nor do they measure other things pertaining to warehouse operations. The difficulty lies in the fact that there is so much control and varying degrees of control for different products which hinders regular KPIs such as pallets per hour to be effective. One day one might get a sub-lot-controlled order whilst another day there are only small orders, which of course will affect the metric considerably. Besides KPIs, the control factor also results in a strict two-person control system to ensure outgoing orders. Which will result in a greater staff need as well as always demanding two staff members at all times when orders are being dispatched. Lastly, ensuring that warehouse staff understands cleanliness is imperative. Pharmaceutical products must be handled in a way that does not affect the product. Therefore, you must ensure that the staff understand cleanliness in general, and that you have routines in place to facilitate understanding and cleanliness. This ties together with the product factors as well, with the same implications. Just bolstering the notion of understanding cleanliness.

The regulation factor affects this particular area in very specific ways. First, cleanliness and the understanding of it, is also a part of regulation. The regulation requires routines for cleanliness which also goes together with the control factor as well. Secondly, regulation will affect companies that are handling narcotics. For those who do, special training is required to be able to handle protected substances. Third, and the biggest part, is traceability. In this context there is a strict requirement to be able to trace every batch in every pharmaceutical product. The staff must understand the importance of this and how it affects their work. To illustrate with an example, all goods are booked on batch level and this means that you must pick that specific booked batch. Sometimes the same article, but a different batch, might be more convenient to pick. It would probably be tempting to pick it, but it would not be compliant. Consequently, the staff needs to fully understand why specific batches are picked in the way they are.

Additionally, in this context as a third-party manufacturer, the customer has a slight influence. The customer will visit, in person, to inspect different things. One of which is the handling of their goods. As a direct consequence, warehouse staff must be made aware of how they handle goods, in particular customer's goods. Lastly, the product factor is identified as an influencing factor in this regard. Besides cleanliness, value plays an important role in how the company

approaches handling of the goods. There is an intrinsic value to pharmaceutical products, both economical and, from a public health and safety perspective. This instills a moral or social responsibility to ensure patient safety. This has a profound effect on how you work with risk and quality. Instead of focusing on just targets and goals, one would mostly focus on handling the goods with care to achieve the highest level of quality and to minimize risk. This is true, even at the expense of cost or efficiency. Table 5.13 below summarizes how the identified contextual factors influence labor and management.

Table 5.13 - How labor and management is influenced by the context

	Contextual factor	Influence
Compliance	Control	- Difficult to develop KPIs - Warehouse staff must understand the need of hygienic and clean premises
	Separation	-
	Regulation	- Utilities to maintain cleanliness - Routines to handle controlled substances - Warehouse staff must understand the importance of traceability
External environment	Product	- Rather focus on handling risk and quality than only focusing on targets and goals
	Customer	- Handle goods with care

5.3 Bridge to concluding chapters

The previous sections of the analysis of the case study data as well as the secondary study results in the uncovering of contextual factors and their influences. For the chapters to come the result from this analysis will be used to achieve the ultimate goals of this thesis. The many tables in section 5.2, regarding contextual influences, will be used to answer research question two. These will also work as steppingstones going into the configuration of the case company's new warehouse. The five contextual factors will be used to answer research question one, which will describe the pharmaceutical context. Below, figure 5.3, an illustration on how the analysis ties to the succeeding chapters can be seen.

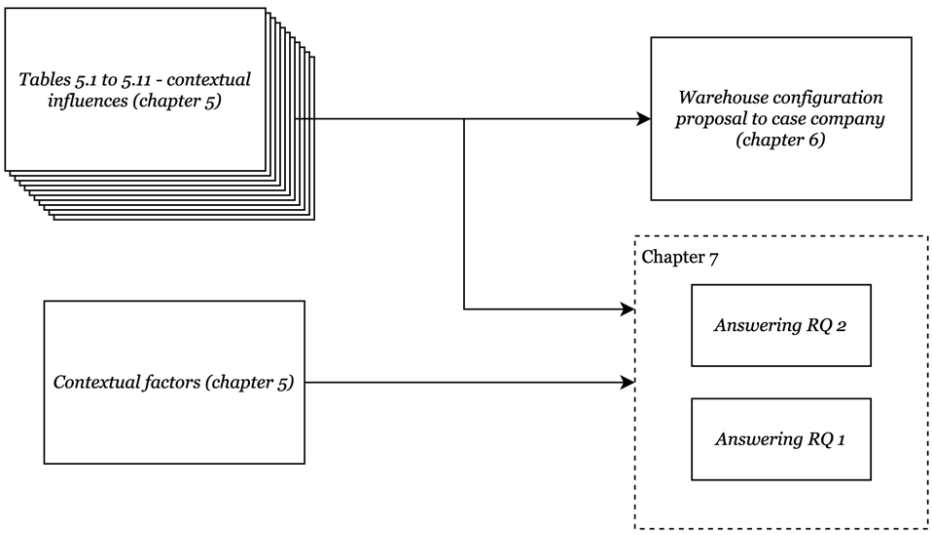

Figure 5.3 - Illustration of how the analysis and discussion results in both chapter 6 and chapter

Going into chapter 6 to configure the case company's warehouse we will draw from the many conclusions in the chapter 5. Concrete examples from above will form a basis on which the configuration is conceived. Moving past the warehouse configuration, the conclusions will tie everything together and provide a high-level summary of chapter 5 and overall findings.

6. Practical implications for the case company

This section aims to capture the findings of the study and unite them with general warehouse theory to deliver a warehouse configuration proposal to the case company. The main request from the company was a thorough layout proposal, which can be found further down in section 6.2. In addition to the layout proposal, this section also discusses our observations and general proposals of how to configure warehouse processes and administer resources. In this section, data which may be interpreted as empirical data will be presented, such as quantitative order characteristics for the case company. The reason for this not being included in the empirical data (section 4) is because it does not add any value or insights for the research purpose, it is only applicable for the proposals discussed in this section.

To confront the complex task of configuring a warehouse, we adopted an iterative top-down approach (elaboration in section 2.4). The initial step, similar to what Hassan (2002) proposes, was to identify the warehouse type, purpose and goals. Drawing from table 2.1 we determined that the warehouse is a production warehouse that holds inventories for all stages of the production cycle (i.e. RAW, WIP and FG). Evident from the case study, the overall goal of the warehouse is to be cost efficient and have enough storage capacity to ensure orderly separation of goods, similar to theory. An additional goal, since the case company is a contract manufacturer, a strategic business area identified is flexibility within the warehouse. Being able to swiftly respond to customers' needs in terms of material handling and changes in production flows is believed to be a major strategic capability.

With the knowledge of the overall goals of the warehouse, the following parts of this section will dive into the theoretical framework and investigate each configuration element. Some of the insights originate from meetings and discussions with the case company, while other insights were derived from our study and analysis.

6.1 Warehouse processes

One of the two major building blocks in warehouse configuration is the warehouse processes. Therefore, as a part of the proposal given to the case company, we will provide our views on their warehousing processes. The many insights and observations that have been made will be shared in this section.

First, however, the case company will successively move their operations to a new site. This will change their logistical setup and consequently their material flows. Instead of receiving most raw material at an external site and then ship production kits to the production unit the new site will receive all material. The new site will have production in the form of packaging production but aseptic production, or bulk production, will remain in the old site for some time. This new setup can be viewed in figure 6.1 below.

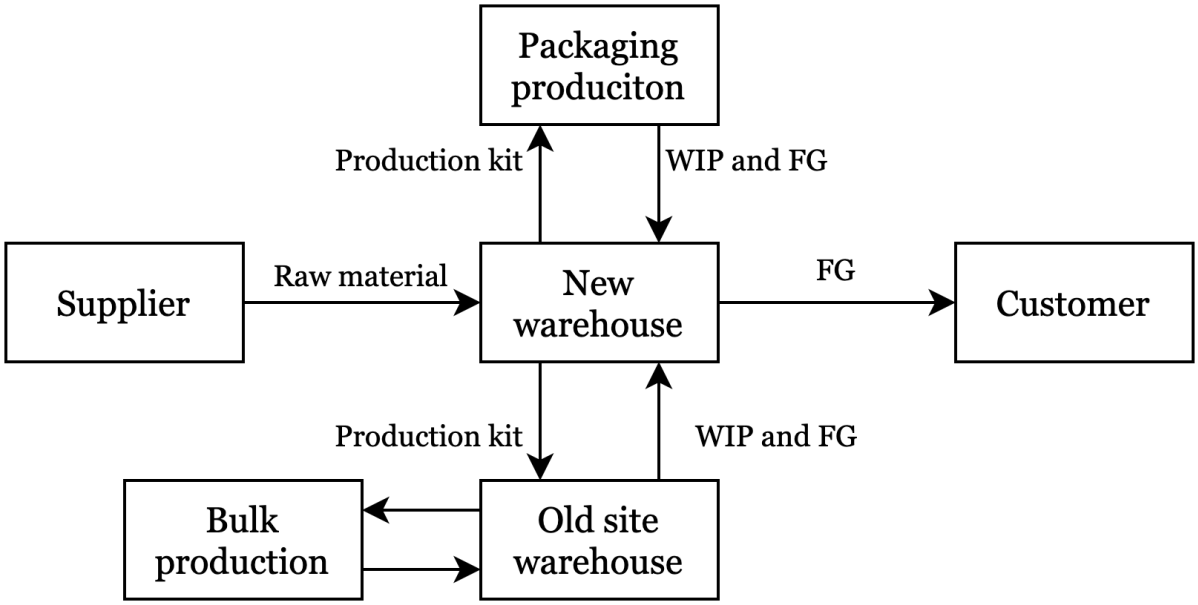

Figure 6.1 -New setup with new material flows

With this new flow the old site will be used as an external production unit and in the long term this site will be moved to the new site as well. Now, the new site will handle all flows; raw material, WIP and FG. This means that there will be new processes in the company's warehouse operations. The succeeding sections will describe how these new processes can be conceived and configured.

Receiving, will be largely the same in terms of work process but now the new warehouse will receive all three flows. For this new site the receiving processes will mainly remain the same as today. However, the flows regarding WIP and FG could benefit from further investigation on how to increase visibility in terms of information. Currently, these flows are handled as material movements within the IT-system and not as internal orders that are recorded. In the long-term this should be handled differently. Instead of just handling the internal flows as only material moves, internal flows should be handled as internal orders. These internal orders should be recorded digitally and not on paper. As a consequence, this would increase the opportunities for inventory control and insights in the material flows at large.

Another opportunity for further investigation is advance notices. From the interviews it was discovered that inbound trucks just showed up without prior notice. It could be investigated if it were to be possible to receive pre notice of arrival from shipping companies. This would increase the possibilities of planning resources according to the needs.

To support the new receiving process the flow needs to be characterized for later use in the layout design process. The case company's current raw material flows in receiving can be seen in table 6.1 below. The WIP and FG inbound flows are not currently recorded and will not be included in the table below. As for the long-term growth it is difficult to make any prediction on how the flows will change. It might be reasonable to assume that as the business grows and the number of products and customers increases, the bigger and more frequent the flows will be. This needs to be considered when allocating resources to this particular process.

Table 6.1 - Characterization of purchase order flows for the period May to Dec 2019

Orders per day	Max: 33 Min: 1 Avg: 4.5
Pallets per day	Min: 1 Max: 45 Avg: 8
Order size	Max: 24 Min: 1 Avg: 4
Order lines per order	Max: 23 Min: 1 Avg: 2
Share of operating days without orders	15% (25 days)
Temperature requirements per order	1

A few notes should be added to table 6.1. There were considerable difficulties in estimating how many pallets that were received because the system only tracked order amounts in pieces. The number of pallets could however be estimated by physically counting pieces in the most common articles and extrapolating that information. This information is uncertain, but it should give some insight. Onwards, order size can be commented with that most of the orders, 80%, are one to five pallets. These 80% averages at two pallets per order. Also, the number of order lines per order is mostly one, 80% of orders are one order line. To secure resources and to plan for the future the receiving resources should be scaled accordingly. It is evident that the resources should not be configured according to the extreme cases, which certainly would result in unused capacity which is wasteful. We propose that one should be able to cover 80% of the cases. This means that you should be able to stage and receive at least five orders, or 8 orders which would cover 90% of the cases and calculate with an order size of five pallets. This would cover many of the current cases, however, this new site should be able to handle future cases as well. Consequently, the number of staging places for receiving could be increased further to facilitate growth.

The next process, following the new warehouse process, is pre put-away. For the case company this is done manually; picking out samples and labeling cartons. As of now it is unclear exactly how much work and resources these two processes require. The sampling process is deemed not to benefit from any further analysis, but the labeling process deserves some attention. In the short term we estimate that it will not be necessary to make changes in this process, but in the medium to long term we see opportunities for improvements. When the case company starts tracking cartons and pallets it will be easier to estimate the work required to label all the goods. This information can be used to estimate the cost of having an employee doing it manually. With this cost analysis it can be determined if it is great enough to have a net positive effect on an eventual investment in some kind of automation.

Next, the put-away process and storage will be reimagined quite drastically. The put-away, in the short term will probably remain the same, but we propose that the WMS should give more support in allocating incoming goods to an appropriate storage location. This of course requires system support that will be discussed in later sections. Otherwise the process will remain the same with focus on handling the goods with care. Furthermore, the storage strategy we propose will be quite different from today. Instead of just storing everything at random we propose a more structured approach. First, we propose clear separation of raw material, WIP and FG, which is in line with our findings. Within these areas of separation, we look to table 2.5 (section 2.3.2) for a number of different storage policies. There are two policies that would work for raw material, class based or family grouping. However, given that

picking is one of the most resource demanding processes, focus should be on decreasing picking costs. In this case the company picks production kits for each product production run that are less than pallet amounts, for packaging at least. Consequently, we propose that raw material should be stored according to product type which should decrease the picking travel distance, the time and the complexity. For WIP we propose a random storage policy because of the varying nature of that particular flow, but we propose that certain areas should be dedicated for the storage of WIP. For FG we propose that it should be stored near the shipping areas to decrease the time and distance needed to travel to pick them. FG are mainly stored on pallets; this leads to the conclusion that they can be stored somewhat at random within the FG zone. This is because you do not receive any benefits of placing two pallets of the same order next to each other. However, you might want to place orders with a shorter departure date more conveniently to not occupy those locations for too long. Table 6.2 below summarizes our insights and proposals for the warehouse processes discussed so far.

Table 6.2 - Insights and proposals for the receiving, pre put-away, and put-away processes

Configuration element	Entity of configuration	Proposal	Reason
Receiving	Work process	Same as current but will receive all flows (RAW, WIP, FG)	N/A
	Information visibility for WIP and FG flows	Handle as internal orders and record digitally	Increase inventory control and material flow insights
	Advance notices	Investigate opportunities to receive prior notice of inbound material	Increase opportunities of planning resources according to needs
Pre put-away	Sampling	Same as current	Deemed not to benefit from further analysis
	Labeling	Eventual investment in the medium to long term	No employee bound to the activity, may be cost beneficial
Put-away	WMS	Should allocate incoming goods to appropriate locations	Follows storage policy consistently and is more efficient
	Storage policy	Clear separation of RAW, WIP, and FG	In line with research findings
	Raw material zone	Storage according to product type	Decrease picking travel distance, time, and complexity
	WIP material zone	Random storage	Varying nature of flow
	FG material zone	Random storage near shipping ports	Decrease time and distance for order pick

From the study there are no particular findings for the next process step, picking. However, we still have got some proposals. First, the actual picking process, for production at least, should remain the same for now. Single order picking, or sort-while-pick, is probably the best method now. The case company handles relatively small volumes and the information on these internal flows is too limited to say anything with outermost certainty. Second, we strongly urge the case company to move from paper to just handling everything digitally, to ensure both picking efficiency and effectiveness. Connected to picking is travel distance and the minimizing of it. The routing problem can be considered but it can also be discussed to show that some cases do not need consideration. For aseptic production, or bulk, and FG pick you mostly pick pallets which then removes the need for route optimization. For raw material and

the production kits this is solved with choosing a rational storage policy. So, even if there are routing policies these can be discarded in this case. Adding to this, the warehouse is not that large either which probably would render routing optimizations less impactful.

For the extra process of post-picking that concerns FGs is difficult to change. There is no literature on the matter and doing it with an IT-solution is seemingly difficult. As of now it seems best to do the two-person control that is currently performed. It is a quite cheap insurance against the problems that can arise from making a picking error and mix-up. However, if volumes increase too much this decision should be reevaluated to avoid surge in the workload.

Lastly, packing and shipping is done both for goods bound for the production site and FG bound for the customer. In the case of customer goods, the packaging and shipping should remain the same. The customers decide how their goods are to be packed so there is little to change in this process. Also, there are goals of being flexible and easy to work with which also points to keeping this process as it is. As for the goods bound for production it will also remain the same. However, there will be a need to secure the goods for transport from the old site back to the new site. Table 6.3 below summarizes our insights and proposals for the picking, post-picking, and packing and shipping processes.

Table 6.3 - Insights and proposals for the picking, post-picking, and packing and shipping processes

Configuration element	Entity of configuration	Proposal	Reason
Picking	Picking strategy (for production)	Single order picking, or sort-while-pick	Small volumes
	Routing	Can be discarded in most cases	Pallet picking, production kit picking solved with rational storage policy
Post-picking	Two-person control	Difficult to change	Doing it with IT solution is seemingly difficult, current system is a cheap insurance
Packing and shipping	FG bound for customer	Should remain the same	Customers decide packing, in line with flexibility
	Goods bound for aseptic production	Will remain the same but goods will need to be secured for transport back to new site	Packaging and distribution to customers at new site

To support the new consolidated shipping process, the flow needs to be characterized for later use in the layout design process. Table 6.4 below shows the order characteristics of customer orders. Like in the case for receiving there is no data on internal flows. Also, the future growth will be difficult to estimate, but it would be reasonable to assume that the frequency and size of these orders would increase.

Table 6.4 - Customer order characteristics for the period May to Dec 2019

	Ambient	***Cold***
Orders per day	Max: 10 Min: 1 Avg: 2.3	Max: 17 Min: 1 Avg: 4.7
Storage locations shipped per day	Max: 21 Min: 1 Avg: 6.2	Max: 31 Min: 1 Avg: 8.6
Order size	Max: 16 Min: 1 Avg: 4.4	Max: 26 Min: 1 Avg: 1.9
Order lines per order	Max: 8 Min: 1 Avg: 3.3	Max: 9 Min: 1 Avg: 1.1
Share of operating days without orders (from customers)	33% (52 days)	
	Storage locations	Orders
- Ambient	28%	15%
- Cold	70%	83%
- Frozen	2%	2%
Storage requirement of orders	Only one temperature requirement per order	

There are some comments needed for table 6.2. To estimate the number of pallets we have assumed that a storage location equals a pallet. This is not entirely true but given that the case company's FG storage facilities are full it can be deemed a sufficient enough estimate to use. This has also been checked at the case company in some respect to verify validity.

When looking at flows you have to divide them with respect to temperatures. First, ambient is the smaller customer flow at around 15% of orders or 28% of storage locations. The cold customer flows are much larger at around 83% of orders or 70% of storage locations. Hence, the need for chilled FG is larger than for ambient. The resource needs for these flows are difficult to estimate for the future because they can both increase in frequency and volume. As of today, however, we can clarify the needs. As with the receiving process we propose that you should cover 80% of the cases. In the table below, table 6.5, the resulting needs from this are presented.

Table 6.5 - Order characteristics, in 80% of the cases

As-is	**Ambient**	**Cold**
Orders per day	3	8
Storage locations shipped per day	8	15
Order size	7	2

In addition to the table above, it can be noted that ambient orders of up to five orders per day cover 98% of the cases and in the case of cold orders this covers 95% of the cases. The as is ambient staging needs to cover three orders per day with an order size of 7 which results in a need of 21 staging locations at least. For cold the same number is 8 orders, but only an order size of 2 which results in a need of at least 16. For the future however this will change. Given what is known and the annual growth one can only estimate this, but it needs to be more than what is proposed here.

6.2 Warehouse design and resources

The main part of the warehouse is the physical layout and for the case company this was the main configuration they wanted help with. The layout is conceived by applying the relevant theory and the findings from the study, and then discussing proposals with the case company. The last step ensured that the layout was up to code and that we had understood their needs correctly. The following parts will, as pedagogical as possible, present our proposals. It will start with equipment and then cover automation. Thereafter, the physical layout will be presented and argued for. Information systems will be briefly discussed and lastly, labor and managerial consideration will be presented.

Because of the findings we begin with equipment, so to utilize the results from the analysis. We follow the discussion from that section and swiftly get to the conclusion that the chosen storage equipment should be single-deep racks for pallets and shelves for cartons. The stackability of the case company's SKUs, along with the need to clearly separate goods, eliminates floor storage as an option. The decision to use single-deep racks originates from the need of many different storage locations and direct access to all of them, since articles are stored by specific batches and not specific articles. Tying back to the theory on storage equipment, single-deep racks are the most suitable for facilitating these needs, see table 6.6 below. Regarding storage of cartons, the option of gravity flow racks is not suitable for the case company. Replenishment of the same article from the same batch is non-existent, indicating no efficiency gains from simultaneous replenishment and picking. We have therefore determined that ordinary shelf storage is the most appropriate, which is also highlighted in table 6.6 below. In Appendix B, you can find the specific racks and shelves that are used in the layout proposal.

Table 6.6 - Overview of racking systems and their suitability, highlighting the choice of single-deep racks (Bartholdi III and Hackman, 2019; Frazelle 2015)

Type	Description	Suitability
Single rack	Regular racks with levels where pallets can be stored. Each location takes one pallet	*Makes every pallet directly available from aisle, but increases the need for aisles*
Double rack	Regular racks with levels where pallets can be stored. Each location takes two pallets behind one another	*Alleviates space utilization problem of single rack, but requires a special truck*
Push-back rack	Deeper, 3-5 pallet positions, and requires the operator to push the pallet in to fit the next	*Suitable for LIFO operation and for medium to fast moving SKUs when you have around 3-10 pallets on hand. Ensures pick face availability*
…	…	…

The evident need of single-deep racks leads to a need for trucks that can handle pallets stored in the racks. As of today, the case company already owns several trucks that handle pallets in racks, but the setup in the new warehouse will be quite different. Since the ceiling in the new warehouse will be considerably higher than in the current two warehouses, consequently the racks will be higher. It is important to evaluate if the currently owned trucks have the required capabilities for the new warehouse, otherwise investments in new trucks will be necessary. However, these investments may be postponed since the storage capacity in the new warehouse significantly exceeds the current inventory. Hence, in the initial phase, it is possible to only store pallets in the lower sections of the racks and leave investments in new trucks for

the future. In Appendix B, the specifications for the truck we have used when evaluating the rack setup is enclosed.

Besides storage equipment and material handling equipment, the case company conducts several ancillary operations which require additional equipment. Such activities are pallet wrapping, cleaning of hygienic bins and transfer of goods from one pallet to another. The pallet wrapping operation will be conducted in three places in the new warehouse, in the receiving area and in both shipping areas. Hence, there is a need for three wrapping stations. The case company already owns two functional pallet wrappers, but it might be worth looking into different solutions of varying automation levels. In Appendix B, there are specifications for a robot that can be stowed away in a corner. When it is needed it drives up to a pallet, wraps it and drives back to the corner. For transfer of goods to from one pallet to another, the case company uses both a pallet turner and a pallet changer. The pallet turner is too small for some of the handled pallets; hence it might be worth investing in a larger one. The cleaning of hygienic bins is done with the help of an industrial dishwasher today. It requires manual changing for the cleaning of each bin. There are options such as an automated solution with conveyor belts. Although, this demands more space and the flows are probably small to justify such an investment. However, if flows were to increase this might be an alternative.

Another area, related to equipment, is automation. This was briefly discussed in section 5.2 that shows that this study was not able to capture the automation aspect of warehouse configuration. However, automation solutions may provide many benefits in terms of productivity and efficiency of processes, but it is vital to adopt an automation level that reflects the needs. Baker and Halim (2007) argue that adoption of the wrong automation level may actually decrease efficiency. To assess an appropriate automation level of the case company, we have used the framework proposed by Naish and Baker (2004) (see figure 2.4 in section 2.2.3). The case company's estimated throughput and relative low number of SKUs in inventory positioned them in the lower left corner (simple manual). Following this framework an adoption of an automated solution is non-advisable. Also, the warehouse's goal of being flexible adds to this conclusion, automated processes are complex to reconfigure and will decrease the level of flexibility. There are, however, a few solutions for mechanical assistance that we believe are appropriate to investigate. These solutions are meant to alleviate the staff with time consuming tasks as well as provide a more ergonomic work environment. The process that we believe would benefit most from mechanical assistance is the pre put-away process, more specifically the labeling process. It is both time-consuming and not ideal from an ergonomic point of view. To remove the task of manually stripping pallets from plastic, handle each carton to label it, and then restack the cartons on the pallet, would reduce the strain on the warehouse staff. There are certainly fully automated systems that could handle the entire labeling process, but it would require a considerable investment. The complexity of such an automated system is exacerbated by the fact that the handled cartons are all of different sizes. However, more mechanical assistance with a de-palletizer and a palletizer, or at the very least height adjustable tables for ergonomic purposes are worth looking into.

To get a fully configured warehouse, the equipment must be laid out and other physical considerations must be made. There has been a discussion about single racks and shelves, but how they are to be configured must be decided. In our proposal the aisle configuration is designed to be parallel with the material flows. This decision is aligned with what the company wants, as well as theoretical findings. Several aisle configurations were investigated, such as

angles aisles (see figure 2.3), but were dismissed due to complexity and a bad fit for the building. Another consideration was port placement. Since the building is long and narrow, it is suitable to configure a flow-through warehouse according to theory (see table 2.2). The configuration with ports at both ends of the warehouse is not only a strong decision from a theoretical standpoint, it is also beneficial in terms of the building's value. If necessary, the warehouse could be split into two separate warehouses with their own ports. Also, a flow through setup is viewed as providing a higher property value.

From the above three configuration elements can be summarized. For the new warehouse physical layout, equipment and automation has, until this point, been discussed and decided. These three elements are thus presented in table 6.7 below.

Table 6.7 - Summary of configuration of the new warehouse, for some of the configuration elements

Configuration element	Entity of configuration	New configuration	Reason
Physical layout	Footprint	Long and narrow	Due to site constraints
	Ports	Ports on opposite sides (flow-through)	Theoretically sound and value adding
	Site access	Restricted	Known sender clearance
	Aisle configuration	Logically placed to minimize travel	To reduce cost
	Material flow and aisles	Aisles parallel with material flow	Theoretically sound
	Zones	Ambient, cold, frozen, deep freeze and restricted access	Product characteristics
Equipment	Storage	Single deep racks	Due to batch sizes and stackability
		Shelves	For the storage of cartons
	Trucks	Reach truck	For the handling of pallets and to facilitate higher reach
	Other	Pallet wrapper	To secure goods for transport
Automation	Mechanically assisted	Hight adjustable tables	Due to ergonomics
	Automated solutions	Palletizers and de-palletizers	Can be employed *if* volumes increase
		Pallet wrapping robot	Can reduce space needs of pallet wrappers

The next thing to understand is what the storage needs are and will be. Therefore, the current storage situation was investigated with quantitative data. In the data it was possible to differentiate between the external warehouse and the production site, but it was not possible to identify pallets or cartons in the production site. For the production site we have calculated full capacity utilization as the as-is situation. This was confirmed with the case company that the site was fully used most of the time. Table 6.8 below shows the capacity used currently with some assumptions regarding pallets and cartons mainly. The validity of the assumptions has been checked with the case company or by conducting field studies.

Table 6.8 - As-is, average storage situation based on a provided representable subset of recorded data

Storage	External warehouse	Production site
Number of stored ambient pallets	1000±100	• 100 pallet places

Storage	External warehouse	Production site
Number of stored cartons	450±100	(estimated) • 420 storage places in cold total (including pallets)
Number of chilled pallets	130±30	
Number of unique SKUs stored	775±75	
Time in stock	Oldest: 470 days	
	Average: 112 days	

The current situation is not optimal for the case company, with over utilization that is well above the recommended 80% from theory (see figure 2.1). The case company forecasts an annual growth of 20% and over a five-year period this results in a 250% increase. To simplify calculations, it was assumed that this growth translates directly to growth of the material flow. Consequently, the current capacity will, under these circumstances, increase more than twice. Table 6.9 below shows this increase which is an estimate of the capacity needs in the end of 2024. There are however large uncertainties in these estimates, working both ways. Hence, this layout's most important task will be to take into account the probability of an even higher growth.

Table 6.9 - The capacity needs in the end of 2024 with 20% annual growth

Number of stored ambient pallets	3000±250
Number of stored cartons	1125±250
Number of chilled pallets	550±100

Now there is enough information to develop a layout that will support the company's growth and future business. The layout is the result of an iterative process with several steps. Many suggestions were developed, discussed and rejected, all of which are enclosed in Appendix C. The resulting layout is presented below and can be seen in figure 6.2.

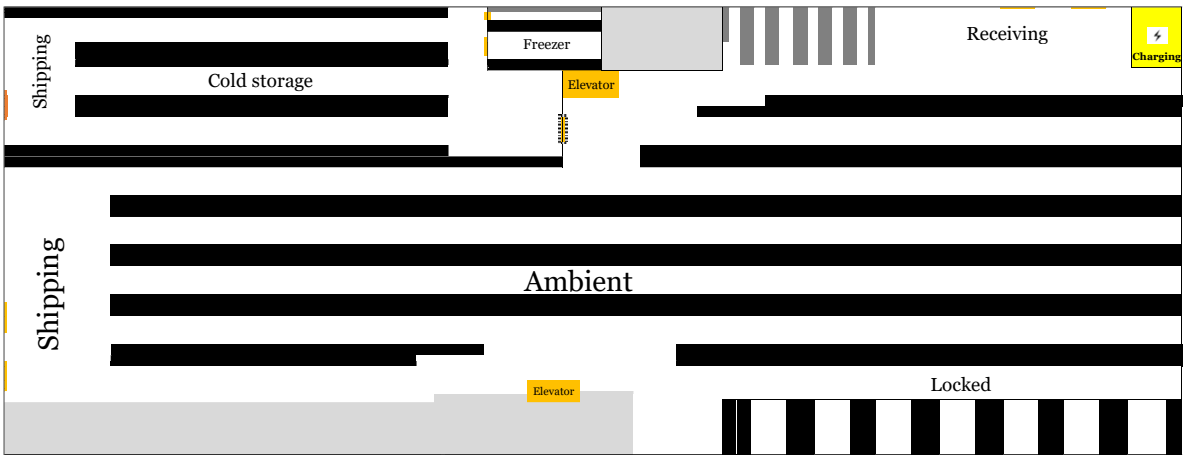

Figure 6.2 - Proposed layout for the new warehouse

The main goal of this layout and the warehouse at large is to accommodate future growth, be compliant, follow the study's findings and support the company's business. We adopted a

maximization approach to fully utilize the building's footprint and to gain as many storage locations as possible. This was to cover growth, but also to cover the need for safety stock and to protect against over utilization. The resulting capacity in this particular layout is presented in table 6.10 below.

Table 6.10 - Capacity of the new warehouse with the proposed layout

	Ambient	**Cold**	**Frozen**
Pallet storage (locked storage)	5100 (420)	1075	40
Cartons storage, shelves (locked storage)	928	0	112

The footprint of the new site is substantially larger than that of the current two warehouses. This of course affects the proposed layout and its capacity. It is clear that the proposed capacity should be able to manage an annual increase of 20% and still be able to accomplish a utilization of 80% until the end 2025. We have however chosen a five-year perspective due the uncertainty of the forecasts as time progress. At the end of this five-year period, at the end of 2024, overall utilization will be around 63%. If, however, the growth continues it will reach maximum capacity in 7-9 years depending on if it is ambient or cold. Ambient will reach 100% utilization after 8.5 years, and cold will reach it after 9 years. There is one important thing to clarify with these calculations. These are based on the current racking setup, which is calculated using the maximum pallet height, which will render much volume unusable. Consequently, the utilization calculations are based on the lowest number of pallets that can be stored in the warehouse. Thus, we are certain that this can be increased by changing the slot sizes. Below, table 6.11, the future aspects are presented for easier understanding. The years that are provided in the table represent the end of that particular year.

Table 6.11 – Capacity utilization in the future with 20% annual growth

Pallets	**End of 2024**	**80% utilization**	**100% utilization**
Ambient	64%	2026	Middle of 2028
Cold	60%	2027	2028
Overall	63%	2026	Middle of 2028

It can be noted from table 6.11 above that carton shelving utilization is not included. This is because of inadequate level of granularity in the data. Additionally, we have opted to provide the cold storage with more pallet rack capacity than necessary, and this can be used as carton storage as well. Moreover, additional shelving will be placed on mezzanines in both the cold storage area as well as the ambient storage area. This is not calculated within the scope of this thesis. Thus, no utilization calculations are necessary nor possible.

Onwards, from the proposed layout it can be seen that a flow-through setup has been chosen. Both due to the site itself and also due to wishes from the case company. However, in a traditional sense it would have ports on opposite sides but due to site constraints this was not possible to do. This setup is more like a L-flow which becomes an approximation of the flow-through setup. Also, there are several areas marked, in a light color, around goods shipping and receiving points including elevators. These areas will function as staging areas for the mentioned processes and their needs. These areas are dimensioned to be as generous as

possible without affecting storage capacity too much. The spaces will accommodate growth to ensure smooth operations in the future as well as today.

Concluding the layout proposal are a few other alternatives that were investigated but did not end up in the proposal. We tried orthogonal aisles, as opposed to the ones now, but that did not give any good results and actually decreased the number of pallet storage locations. On top of that, the amount of turns that would have been needed to access the goods would have slowed day-to-day operations. There was a discussion regarding ports for receiving and shipping on the same side. This option rendered the most pallet locations but did not support the notion of separated flows very well. In addition, following the earlier discussion about the value of the building, the L-flow setup was favored. Lastly, the perceptive reader has noticed that chilled goods are received into an ambient environment. This might seem counterintuitive and we did investigate using one large fridge or two smaller once. But after discussion with the quality department they assured that the case company's products do not have as strict cold chains as others might have. Therefore, the receiving is in an ambient environment.

Less tangible, but equally important for the warehouse configuration are information systems and, labor and managerial considerations. Kembro and Norrman (2019c) discuss trends of more functionality when using information systems. Now, they discuss it from an omni-channel retailing perspective, however, the use of optimized decision making, and visibility is not of any evil. On the contrary, for the case company there are lots of opportunities to use IT-solutions to a greater extent than today. They have systems in place already, but they are not fully utilized. This is partly illustrated by the case company having hand-scanners but still administering orders on paper. Also, material in inventory is missing barcodes, making it impossible to use the hand-scanners. The implementation of the new information system is believed to have been conducted too hastily. Our recommendation for this aspect is to employ an information system consultant to identify and implement what was missed in the original implementation. In addition to this, employees must be disciplined to use the information system and to do this the system must be trusted. All internal orders should be registered in the system, every storage location should have a barcode, and the hand-scanners should be used for every movement of material. The blue hygienic bins used for WIP materials should be equipped with unique barcodes, instead of using papers like today. It brings more visibility of information if it is stored digitally and it cannot get lost.

The final remark regarding the information system is concerned with master data. Today, the only unit stored in the information system is on piece level. It is not possible to identify pallets or cartons; the master data must be extended to facilitate this. This information must be available, otherwise it is impossible to control inventory and understand capacity needs now or in the future. Having control of the inventory and transparency of information is beneficial from many points of view. It can increase customer trust, present business opportunities in terms of being able to provide storage services and also for their own sake in terms of control and planning.

Ending the whole discussion about the case company's configuration is labor and managerial considerations. It has been discussed throughout the report and also at the case company, the need for more control and more tools for management. It is, however, difficult to create usable and actionable KPIs that clearly have desirable outcomes. Also, it is clear that to first even begin to track and measure you need to fully control the data that is collected. It is a

prerequisite that the data that is collected is correct. When this is achieved KPIs can start to be tracked. In this case we do not want to propose examples on what *should* be implemented, rather what *could* be implemented. If it is technically possible one could track the number of tries of picking errors. This means that you track each time a scanner registers a scan that is wrong according to the picked order. On a higher inventory management level, days in inventory can be tracked to make sure that goods in the warehouse are not stored for too long, especially odd cartons and customer orders. This can actually be implemented without any difficulties as of today. Also, tracking customer behavior can provide business opportunities when negotiating deals. If customers seem to be slow to retrieve their goods, this could maybe signal that they would be interested in storing their product at the site. Which then could result in more business from that customer which of course would increase profitability.

Table 6.7 above summarized three of the five configuration elements of design and resources. Now, the last two can be summarized in the same manner. These two elements are presented in table 6.12 below.

Table 6.12 - Summary of configuration of the new warehouse, for information systems and, labor and management

Configuration element	Entity of configuration	New configuration	Reason
Information systems	WMS	Everything needs to be tracked within the system	For resources and inventory control
		No papers, only digital transactions	To simplify processes and, ensure operational quality and efficiency
		Ensure that data is recorded correctly	Vital for the system to work, for tracking and control
		New and more detailed master data	To simplify analysis, strategic work and planning
		Hand scanners	To simplify processes and, ensure operational quality and efficiency
		Barcodes on hygienic bins	To track WIP and resource needs
Labor and management	KPI program	Should investigate use of KPIs	For follow up and as a management tool

Lastly, most focusing on the future and business opportunities we have seen throughout our time at the case company. First opportunity we see is the possibility to use the over capacity of storage locations immediately. Instead of accepting lower utilization during the first years of operations the case company could investigate the possibilities of providing 3PL-similar services to get a higher utilization which also would increase the return on investment (ROI). Building upon this we see a clear opportunity of increasing the offer to the customer by taking over some of their supply chain activities. Using the selling point of being able to reduce the customers' supply chain complexity could also increase the ROI. Lastly, extending the business with 3PL-similar services to smaller pharmaceutical companies could help the company tie new up-and-coming customers closer to them in an earlier stage. This all goes in line with what the theory discusses, and what the study also captures, that the warehouse can be used as a strategic advantage to increase business success.

7. Conclusions

7.1 Answering research question 1

The study set out to investigate the pharmaceutical context and how it would influence warehouse configuration. One part of fulfilling this goal was to explain the pharmaceutical context. This was done by answering the first research question '*What are the contextual factors that influence warehouse configuration?*' The question was answered by mainly using the secondary data study to explain the context. From this, together with the empirical data the study uncovered several contextual factors. These factors were divided into two main groups; *compliance* and *external environment*. The compliance factor comprises three sub-factors; *regulation, control* and *separation*. The external environment comprises two sub-factors; *customer* and *product*. Together these five sub-factors try to describe the pharmaceutical context. It is important to note that the factors are not mutually exclusive, but they are, however, collectively exhaustive. Anyway, these five sub-factors are explained in the points below.

- **Regulation:** The central and most significant factor is the regulatory aspect. Since the industry has a direct influence on the health of the global population, several regulatory bodies monitor the operations of pharmaceutical manufacturers. There are clear and specific regulations for configuration of storage areas and how materials within the warehouse are to be handled. There are also specific laws and regulations on, for instance, how to handle narcotic substances as well as for rejected materials destined for destruction. Additionally, the FMD directly influences how to store printed packaging material and traceability aspects influences documentation processes.

- **Control:** By our definition, control entails, for instance, overall control of operations, control of inventory levels, control of picked goods, control of requirements, and control of distribution (e.g. truck temperature). In this context, control is important for the companies' own sake, but it is also paramount to be able to demonstrate control towards suppliers, customers and authorities.

- **Separation:** Closely related to regulation and control, separation entails separation of goods, flows and processes. The matter of separation is crucial for prevention of mix-ups and contamination. The same materials, but from different batches, cannot be stored at the same location, they must be separated. This is further accommodated by separating flows within the warehouse, preventing materials from crossing paths.

- **Customer:** From the study it was evident that reputation and trust from customers is of great importance. Delivering the wrong quantity of a pharmaceutical product, or the wrong product, is devastating. This means that quality and safety is of the essence, and not speed. This ties back to the previously discussed factor 'control', the importance of demonstrating control and compliance with regulations. The customers have their own brand and reputation to protect, and it is important for them to ensure that everything upwards in the supply chain is conducted correctly.

- **Product:** The characteristics of pharmaceutical products have a significant influence on warehouse configuration due to, for instance, various temperature and humidity requirements. This has a direct influence on warehouse premise design, interior layout and internal flows. Moreover, pharmaceutical products are typically fragile and very expensive, the material handling within the warehouse must hence be conducted with care to not compromise product integrity and quality. Another product characteristic with major influence is that some pharmaceutical products are classified as narcotics, which has regulatory implications.

Through the findings in this study we can also update the conceptual framework to match the pharmaceutical setting. Research question one can be seen at the top of figure 7.1 below. It can be noted that the 'general' factor included both customer and product characteristics. Now, this is also a part of the pharmaceutical context to reflect its special properties in terms of warehouse configuration. Additionally, there are two new steps added to the warehouse process that reflect some of the activities that are performed in a pharmaceutical warehouse.

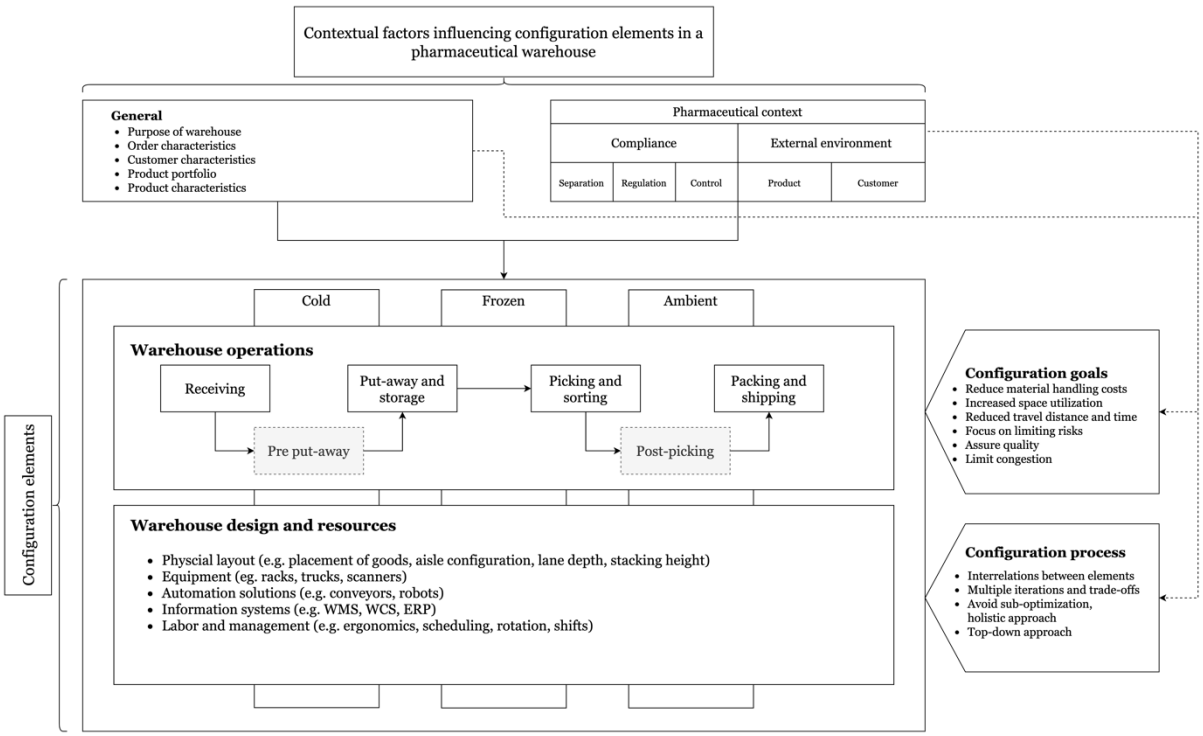

Figure 7.1 - Revised and updated conceptual framework adapted from Kembro and Norrman (2019b) and Eriksson (2019)

7.2 Answering research question 2

The second research question was, '*How do the contextual factors influence warehouse configuration?*' Throughout the second part of the analysis, the influences that each contextual factor impose on the configuration elements were explained. Each factor does not influence every configuration element, but every configuration element is affected by one or more of the contextual factors. The influences have practical implications on how to actually configure a warehouse and its components. It was attempted to summarize the answer to this research question, the conclusions from section 5.2, in tabular form. Unfortunately, it was not feasible due to the sheer amount of information. Instead, the following paragraphs in this section will

answer the research question on a high level. For more detailed discussion regarding how each configuration element is influenced by the identified factors, the reader is directed to section 5.2.

Regulation

The regulation factor affects both design and resources, as well as the warehouse processes. This factor demands a lot from the warehouse configuration, especially the warehouse processes. A great deal of detail is needed for the warehouse to be compliant with the regulations and provisions that are present. This results in more expensive processes overall with more complex flows. For instance, the receiving of narcotics cannot be delayed which makes operations more difficult to plan. Beyond the process, the regulation demands that there are areas with restricted access. This can also increase complexity and cost of the processes. By the same token, together with the aforementioned, you may miss some opportunities to optimize certain flows and activities.

Control

Control does not affect the configuration in such a far-reaching way as the previous factor. However, there are certain influences that are quite clear. First, the two-person control that emerges as a separate warehouse process is a result of the control that is needed when handling outgoing orders. Secondly, KPIs and the use of them are influenced by this factor. It is exceedingly difficult to create suitable KPIs that are appropriate to this setting. Getting KPIs wrong can be detrimental to overall compliance and it can have unexpected effects on results. Third, information systems are also affected in quite a concrete way. Information systems should be as standardized as possible and all systems must be validated. All in all, the control factor functions almost as an extra layer of caution. Which is added to the whole configuration, because you do not want to do anything wrong.

Separation

Separation affects overall warehouse operations, specifically in terms of material flow. An important aspect in pharmaceutical warehouses is the need to separate different types of flows from each other. This means that no flows should cross or get mixed within the warehouse. This in turn affects how things actually are stored and how ports are physically placed. It is evident that the separation factor means that you need to think twice, or more, about the configuration to not introduce too much complexity in how the flows should work. It needs to be understood that separation will affect travel distances and other process related activities, as well as physical components in the warehouse.

Product

The product provides some interesting considerations for the configuration. Temperature is the major product characteristic that evidently requires storage facilities that can accomodate this. Also, every product in the pharmaceutical industry, in terms of drugs, requires a controlled temperature. In addition to temperature, the product has an intrinsic value from both a monetary perspective and from a public health perspective. This increases the need for storage capacity to accommodate larger stored volumes in terms of safety stock at different levels of refinement. From that value perspective also emerges a view on risk and quality.

Instead of focusing solely on cost efficiency, the ability to handle risk and quality will take precedence.

Customer

The customer will not influence the configuration elements to such an extent as other factors might. However, there is an important aspect that is crucial in this context, that stems from the customer demands. This is the demand for no faults or mix-ups. It is clear that the customer will not take it lightly if there is a mix-up and getting things wrong can affect trust and overall reputation in the business. Therefore, it is important to understand this when configuring processes, especially outbound processes.

7.3 Contribution

7.3.1 Contribution to theory

To the best of our knowledge, this thesis is the first study in this particular area of research, and hence fills a gap in the literature. The primary theoretical contribution is the result of this thesis; a thorough understanding of how the identified factors in the pharmaceutical context influence warehouse configuration. The thesis also identified specific pharmaceutical warehouse processes not mentioned in general warehouse theory, arguing for the fact that the thesis is theory building. Furthermore, the unit of analysis for this thesis is defined into parts namely; *the pharmaceutical context* and *warehouse configuration*. As Durach et al. (2017) discuss the need to ensure the same unit of analysis across multiple primary studies, this definition will guide future primary studies in this research area. Finally, the adopted theoretical framework used to guide the data collection and analysis throughout the thesis has been proven effective. This confirms that the framework is adaptable to multiple industries and contexts.

7.3.2 Contribution to practice and case company

The study has several contributions for practitioners and the case company. First, and most important, the study includes the factors that influence how a warehouse is configured. These factors might not be the most interesting for practitioners, but their implications are. This study provides an understanding of these implications and how those affect different configuration elements. The practitioner in the particular context would appreciate the discussion, but mostly they would have more use of the concrete examples throughout the text. The study also identifies two new warehousing processes that can help practitioners to get a clearer view of their warehouse process setup. By providing a separate process step for these processes within the general warehousing process we seek to highlight these areas, in particular, as areas for improvements.

Lastly, and more concretely, the case company has received a comprehensive layout design as well as a higher-level configuration of their new warehouse. This is found in section 6 which is completely dedicated to the case company and tries, as much as possible, to span all the configuration elements according to the theory and the findings.

7.3.3 Contribution to method

Besides contributions to theory and practitioners, this thesis humbly provides two methodological contributions as well. First, the study has mainly been focused on collecting data via interviews. To achieve better results from the interviews a more far reaching interview literature overview was developed. This provided much help when forming the interview guide and formulating interview questions. To the best of our knowledge, papers and master theses are lacking in the reporting regarding this particular data collection method. Therefore, we think that this could be used as a point of reference for coming theses.

Secondly, many case studies involve data collection via interviews, and the literature describes approaches for the analysis of this data. However, these descriptions are often so generalized that they are not directly actionable. We sought to create a methodological approach for the analytics of the collected interview data which is described in section 3.5. This analytical approach did prove quite useful and quite concrete, as opposed to more general descriptions such as pattern matching and theme identification. The approach takes these concepts and turns them into something more graspable, or tangible in a way. We think that this analytical approach could be used in different applications, especially in applications similar to this thesis. Additionally, for further research in the form of multiple studies this could be a relatively easy efficient way of analyzing larger samples.

7.4 Limitations and future research

This study has captured several interesting insights regarding both warehouse configuration and the pharmaceutical context. It was clear that the area of research for this study was unexplored. The literature on pharmaceutical warehousing was limited, almost non-existent. However, this thesis has tried to give an initial overview of pharmaceutical warehousing, but everything could not, and should not, be included in this particular thesis. Given this, it is safe to say that there is still much to be explored in this area of research. This section will discuss the limitations of the thesis and connect them to future research opportunities.

The first and most significant limitation is that the thesis is built on a single case study. The investigated company has its own unique characteristics in terms of business strategy, structure, organization, customers, and way of doing things. To a certain degree, this limits the opportunities for generalization and conceptualization towards other pharmaceutical companies, other industries and other contexts. Consequently, the most evident opportunity is building upon this research with a multiple case study across different companies within the pharmaceutical industry. As Eriksson et al., (2019) shows in their research on contextual warehouse adaptation, comparative analysis across multiple cases can provide a source of more profound insights. Comparing findings from different cases would strengthen the conclusions and lend increased opportunities for generalization of the findings.

Further, continuing the discussion regarding a multiple case study, there is another area that would be interesting to give attention to. Instead of limiting the research to just only pharmaceuticals, different industries could be researched. This could uncover and highlight differences and similarities between them which could provide interesting insights. As an example, the tobacco industry, which is also heavily regulated, can provide an interface at which one could explore how similar demands can be translated into practical implications.

Additionally, it would be interesting to evaluate which factors that are the most influencing, in comparison between themselves. This also brings us to another limitation, how table 5.1 was conceived. A blank space that aligns one of the identified contextual factors with a configuration element was marked if there was any influence whatsoever. The table would have been improved and become a more actionable tool if there was some kind of measurement system involved. For instance, with different colors indicating the significance of the influence or more strict and predetermined requirements on what constitutes a mark.

From this study emerges two new warehousing processes that are not common in the general warehousing theory. Both post-picking and pre put-away are processes that are exceedingly time consuming, but at the same time critical for compliance. These processes in themselves would provide great subjects for further inquiry. How you could minimize the labeling time in pre-put away or how you could reimagine the post-picking process to be less staff intensive are both valid areas of research. Labeling each and every incoming carton can become overly exhaustive in terms of resource use, even the case of a smaller practitioner. There are probably gains to be received by looking at dyadic relationships between supplier and the practitioner or by looking at means of automating some of the standardized steps in the process. For the post-picking there are uncertainties, in this case at least, how you would reimagine this process and still remain compliant. It is uncertain if this process can be automated or handled with IT but it may be interesting to investigate. From Kembro and Norrman's (2019c) exploration of information system trends in the realm of omni-channel we can see a trend towards the use of more complex functionalities and more system support. This will probably not directly translate to this particular context, but it shows that information system research probably is of necessity. Which bolster the notion of investigating this area in this context.

Continuing the discussion about automation, and generalizing a bit more, there are also further opportunities to investigate how automation can and should be used in a pharmaceutical warehouse. This study could not capture this but there were hints that automation can and should have a place in a pharmaceutical warehouse. Here lies the main issue of validation and trusting the solution that must be solved. This poses an interesting question, not only is answering the what and who enough, but you must also solve the cultural aspect. What are the key success factors that enable you to successfully implement and run an automation solution? As previous discussion has shown, automation seems to be a key to unlock opportunities for efficiency.

Lastly, KPIs are tools that can be used for the measuring of a warehouse performance for instance and for managers to manage their staff. In this study it was difficult to articulate KPIs or an incentive system that would align with warehousing performance and goals. The standard, of the shelf sort of, KPIs would not work because of the strict requirements of the context. This would also provide an area of research that probably should answer the question on what to actually measure to manage operations in a rational, effective and efficient way.

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Appendix

Appendix A – Interview guide

Not all questions were asked for every single interview, these were however the questions we wanted to have answered. Do note that the interview guide is in Swedish.

Introduktion
Presentera vilka vi är, var vi kommer ifrån, vad för forskning vi gör och vilket syfte den har, förklara vilken ungefärlig längd intervju kommer ha

Berätta lite om dig själv
- Vilken befattning
- Utbildning
- Ansvarsområde
- Dagliga uppgifter
- Långsiktiga uppgifter

Förklara hur intervjun kommer gå till
- Flera ämnen som vi kommer diskutera för ökad förståelse
- Ibland kommer vi visa bilder eller låta personen rita bilder
- Om vi under varje ämne missar något som du anser kan vara viktigt så får du gärna lägga till det under diskussionens gång

Nuvarande situation
Övergripande karaktärisering

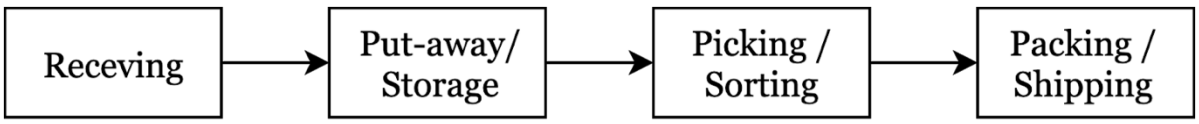
1. Vilket syfte har detta lager?
2. Vilka mål vill ni uppnå genom era WH-operations?
3. Vilka kunder betjänas?
4. Kan du beskriva det inkommande flödet? (Frekvens, typ av leverantörer, antal leverantörer, varifrån kommer godset, volym, typer av fordon som ankommer)
5. Kan du beskriva vilken karaktär godset som kommer hit har? (Storlek, lagringsenheter som hanteras, vilken beskaffenhet godset har (vikt, skrymmande, värde, hållbarhet, staplingsbart),frekvens, ursprung)?

a. Hur stor andel ungefär av total mängd har speciella krav? (Narkotika, farligt gods, ömtåligt, temperatur)

6. Kan du beskriva det utgående flödet? (Ordertyper, frekvens, när på dagen, volym, antal kunder, vilka typer av fordon ankommer?)

Warehouse operations

Vi vill förstå hur detta lager fungerar och hur ni arbetar, för att få en så bra förståelse över era "operations" som möjligt så kommer vi göra nedslag i varje del i den generella warehouse-processen. Så vi kommer börja med mottagning (receiving) och avsluta med utskeppning (shipping). (Visa bilden)



Receiving

7. Skulle du kunna beskriva processen för inkommande gods fram till att lagring ska ske (Föravisering, scanning, kontroller (avsyning), ompackning, ommärkning (labeling), pre-staging/förbereda inlagring)

a. Hur hanteras olika temperaturkrav?

b. Hur hanteras farliga produkter?

8. Varför ser processen ut som den gör?

9. Vilka problem/utmaningar, om du kan komma på några, tycker du finns i processen?

10. Har du några förslag på hur processen kan förbättras eller hur den borde vara?

11. Hur hanteras gods som är narkotikaklassat?

. Behövs det någon särskild behörighet?

a. Hur rapporteras inleveranser?

b. Om ni mottagit felaktig mängd, fel produkt eller att något är trasigt hur hanteras det?

Put-away and storage

1. Kan du beskriva processen för inkommande gods från att mottagningen är genomförd tills att godset är inlagrat? (En förklaring för varje lagringsenhet) (lagringspolicy, fefo/fifo osv…)

a. Hur hanteras olika temperaturkrav?

b. Hur hanteras farliga produkter?

2. Varför ser processen ut som den gör?
3. Vilka problem, om du kan komma på några, tycker du finns i processen?
4. Har du några förslag på hur processen kan förbättras eller hur den borde vara?
5. Hur lagras gods som är narkotikaklassat?

Picking and sorting

1. Kan du beskriva processen för processen från att en order inkommer till att ordern är plockad? (För varje lagringsenhet, logik för plock)

a. Hur lång tid i förväg får ni ordrarna?

b. Hur genereras plocklistan?

c. Behövs det någon sortering av ordrarna efter att de blivit plockade?

d. Hur hanteras gods som är narkotikaklassat?

e. Hur hanteras olika temperaturkrav?

f. Hur hanteras farliga produkter?

2. Varför ser processen ut som den gör?
3. Vilka problem, om du kan komma på några, tycker du finns i processen?
4. Har du några förslag på hur processen kan förbättras eller hur den borde vara?

Packing and shipping

1. Kan du beskriva processen för processen från att en order är plockad och sorterad tills att den avgår? (Varje lagringsenhet/lastbärare)

a. För Öckerög.: Hur påverkas det dagliga arbetet av att ni enbart levererar till Limhamn?

b. Hur hanteras olika temperaturkrav?

c. Hur hanteras farliga produkter?

d. Hur hanteras gods som är narkotikaklassat? (Särskild behörighet för hantering?)

2. Varför ser processen ut som den gör?
3. Vilka problem, om du kan komma på några, tycker du finns i processen?
4. Har du några förslag på hur processen kan förbättras eller hur den borde vara?

KPI (vilket/vilka är målen för lagret)

1. Hur jobbar ni med KPI

a. Vad mäter ni?

b. Varför?

2. Använder ni fler metrics bortsett från KPIerna?

Extraprocesser

Lagerverksamheten idag inkluderar fler processer än de vanliga traditionella. Dessa kan kallas value-added (värde-adderande) eller extraprocesser. Vilka processer utförs här som kan anses vara separat från de vanliga processerna? (se bild). Vi har också fått lite förhandsinformation om vilka processer som kan utföras i lagret och vi vill därför fråga om dessa.

1. Behöver ankommande gods någonsin rengöras innan de lagras?

a. Vilken utrustning används för detta?

b. Vilka krav ställs på processen?

2. Hur hanteras gods som måste kasseras?

. Förvaras spillmaterial på lagret när det väntar på kassering?

3. Utförs någon form av provtagning/vägning av startmaterial på lagret?

. Görs det på ett avskilt område för att undvika kontaminering?

4. Händer det att förpackningsmaterial blir utdaterat/överflödigt?

. Finns det särskilda processer för att kassera detta?

5. Finns det något som du vill tillägga vad gäller extraprocesser?

a. Produktionskit är något som nämnts

Innan vi lämnar processerna så tänkte vi avluta med och fråga om det finns några målkonflikter mellan de olika processerna och hur hanteras dessa?

Warehouse design and resources

Fysisk layout

1. Enligt WHO:s föreskrifter är det viktigt med segregation i lagret för att undvika kontaminering och mix-ups. Hur arbetar ni med detta?
2. Det står också att lastplatser för mottagning och skeppning ska vara avskilda från varandra, men ni använder samma port för båda syften eller hur?

a. Bör detta tas i beaktande nu när ett nytt lager byggs?

3. Färdiga produkter och inkommande material ska bli satta i karantän direkt efter bearbetning eller mottagning, tills de är “released” för användning eller distribution. Finns det delar av lagret som har karantän-status (fysisk karantän) eller har ni något annat system med motsvarande säkerhet (informationssystem)?
4. Hur stor del av lagret har särskilda lagerförhållanden?
5. Anser ni att det i dagsläget är för liten eller för stor del av lagret som har “särskilda” egenskaper?

Utrustning (materialhantering/lagring)

1. Vilken utrustning använder ni i era materialhanteringasprocesser? (Trucks, palletizers, pallvändare, racks, hyllor). Alltså materialhanterings- och lagringsutrustning?
2. Hur övervakas och kontrolleras förhållanden (ex. temp) i dessa speciella zoner?

Informationssystem

1. Kan du beskriva er informationssystems setup?
    d. Hur används ert IS/WMS i de olika processerna?

e. Tycker du att ert WMS är anpassat de processerna?
f. Är det någon funktion eller systemstöd som du tycker saknas?
2. Rita möjligen ett flödesschema på kopplingar
3. Rita möjligen en processhierarki för order/IT

Arbetskraft och liknande aktiviteter

1. Kan du beskriva aktiviteter relaterat till arbetskraft (ergonomi, shift, rotation)?

Automation

1. Beskriv er(a) automationslösning(ar) om ni har någon

a. Varför valde ni den?
b. Upplevda för och nackdelar?

2. Har ni undersökt någon automationslösning?
    - Om ja
        - Vad har ni undersökt?
        - Vad beslutade ni?
    - Om nej,
        - Varför inte?

3. Finns det något område/uppgift/process där ni tycker att en automationslösning skulle vara lämplig?

a. Har ni undersökt detta?
        - Om nej, varför?
        - Om ja, vad beslutaden ni?

Diskussion om eventuell vinst med olika automationslösningar:

- *Paternosterverk (ha bild)*
- *Miniload*
- *Carousel*
- *Vertical buffer module*
- *Network video*

Avslutande frågor

Förpackningsmaterial

Förtryckt förpackningsmaterial (labeling) benämns ofta som särskilt viktigt att ha koll på på lagret. Hur arbetar ni med detta?

Myndighetskontroll

1. Vad tittar man på när man bedömer lagerverksamheten?

a. Myndigheter
b. Kunder
c. Internt

2. Vad är det främsta ni fokuserar på inför en kontroll?
3. Har det någon gång uppstått problem vid en kontroll som gjort att ni fått anmärkning?

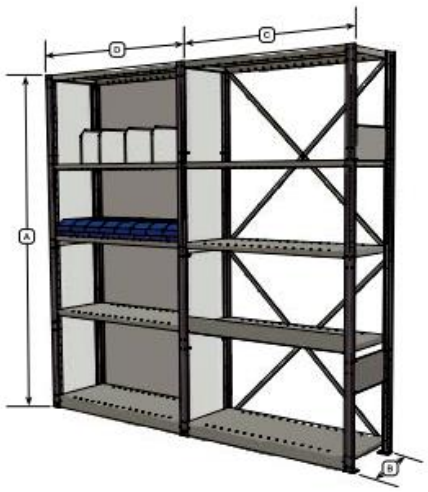
Dokumentation

1. Vilken dokumentation förs på lagret?
2. Uppdaterar ni fysiska etiketter på godset eller sköts det via datoriserat informationssystem?

Appendix B - Specifications of equipment

Single racks: EAB, “Alfa” pallet racks	Shelves: EAB, “Hyllställ”

TEKNISKA DATA	PALLSTÄLL	
	MÅTT	BELASTNING
A Gavelhöjd	1500 - 8000 mm	
B Gaveldjup	500, 800, 1100 mm	
C Stolpbredd	90 mm	8000 kg, 12000 kg
Stolpbredd	110 mm	14000 kg, 18000 kg
Gaveldistans	100, 150, 200, 250, 300, 400 mm	
D Bärbalk längd / profil,	950 mm / Z100 mm	1x1000 kg
(för kortsideshantering av pall)	1850 mm / Z100 mm	2x1000 kg
	2300 mm / Z100 mm	2x1000 kg
	2750 mm / Z100 mm	3x550 kg
	2750 mm / Z115 mm	3x750 kg
	2750 mm / Z140 mm	3x1000 kg
	3600 mm / Z160 mm	4x800 kg
	3600 mm / Z160 mm	4x1000 kg
D Längd / profil	1350 mm / Z100 mm	1x1000 kg
(för långsideshantering av pall)	2650 mm/ Z115 mm	2x1150 kg

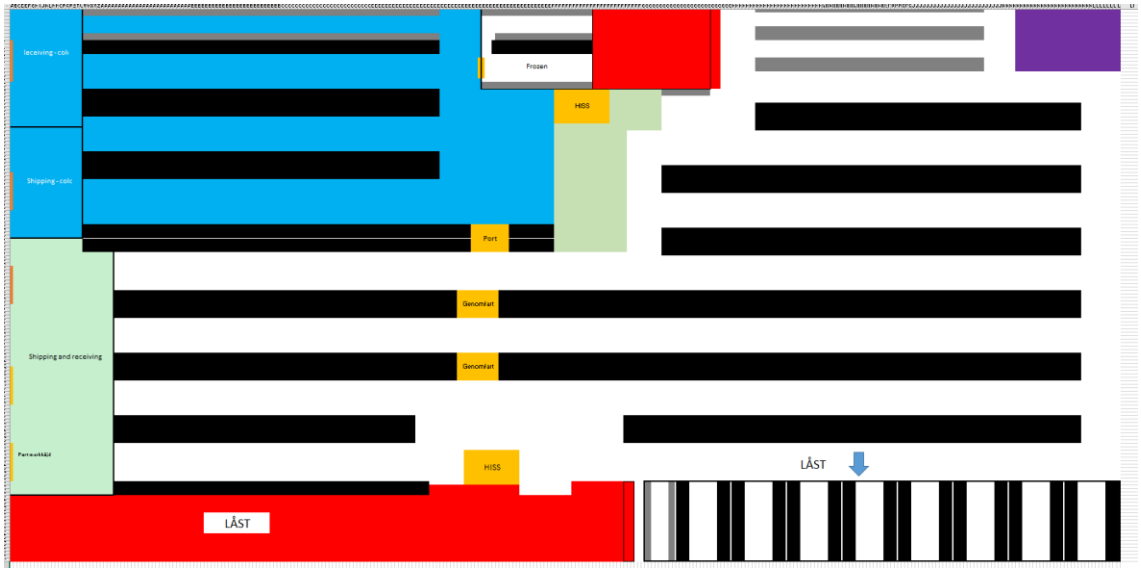


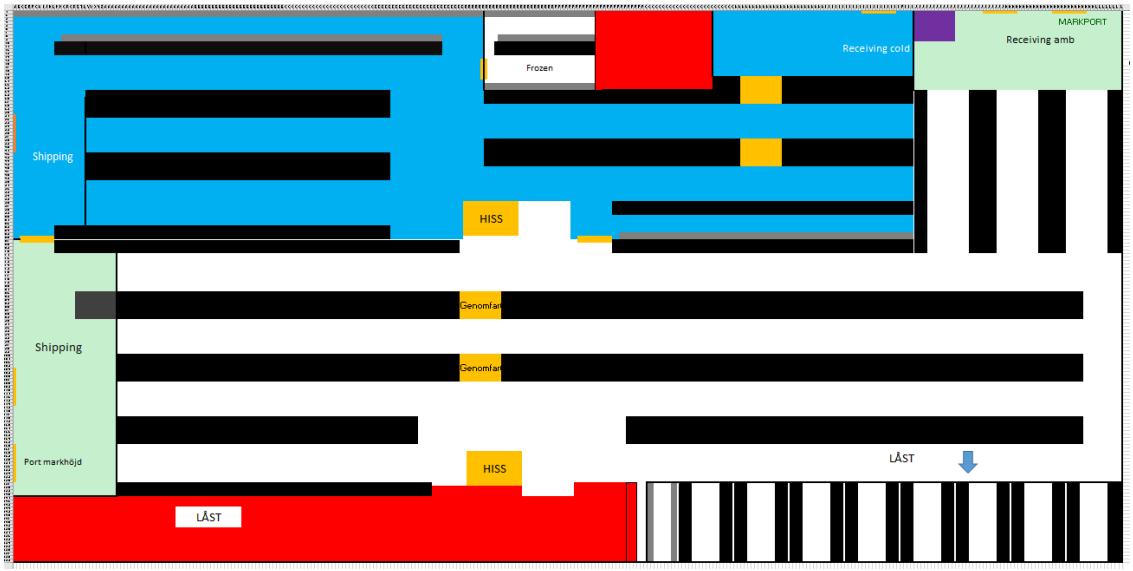
TEKNISKA DATA	HYLLSTÄLL	
	MÅTT	BELASTNING
A Gavelhöjd	2000, 2500, 3000 mm	
B Hyllplansdjup	300, 400, 500, 600 mm	
C Grundsektion	1060 mm (vid hyllplansbredd 1000 mm)	
D Påbyggnadssektion	1010 mm (vid hyllplansbredd 1000 mm)	
Hyllplan, bredd / belastning	750, 1000 mm	200 kg, jämnt fördelad last
Hyllplan, bredd / belastning	1300 mm	120 kg, jämnt fördelad last
Hyllplan, höjd	30 mm	
Belastning per sektion		1500 kg vid standardstagning
Gavelplåt, höjd	2000, 2500, 3000 mm	
Ryggplåt, höjd	2000, 2500, 3000 mm	
Delningsplåt, höjd	200 mm	
Sockelplåt, höjd	40 mm	
Raskant, höjd	55 mm	
Dörrsektion, höjd*bredd	2000 * 1000 mm	
Utdragslåda, höjd*bredd*djup	95 * 915 * 400/500 mm	

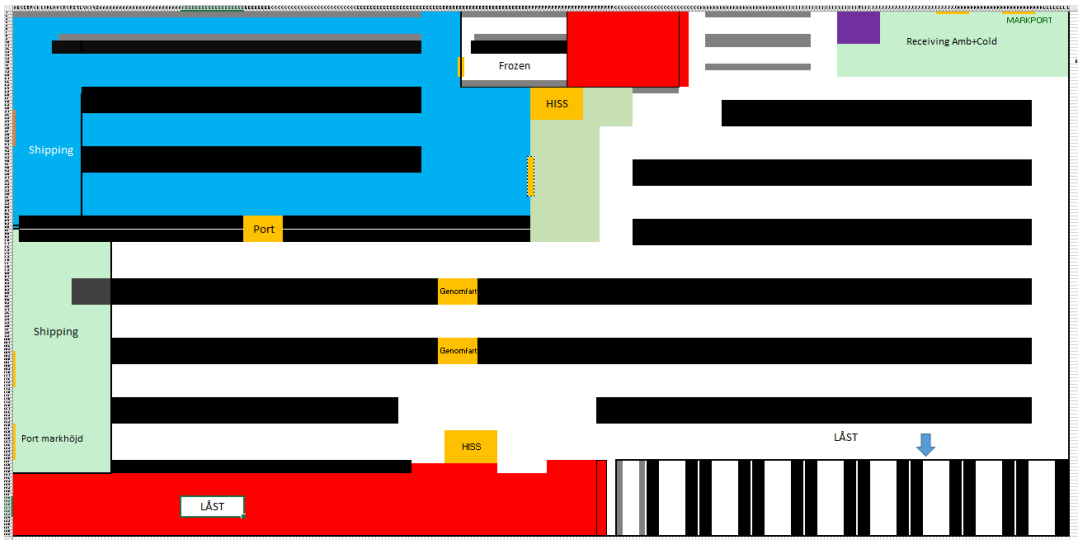
Specification of robot:

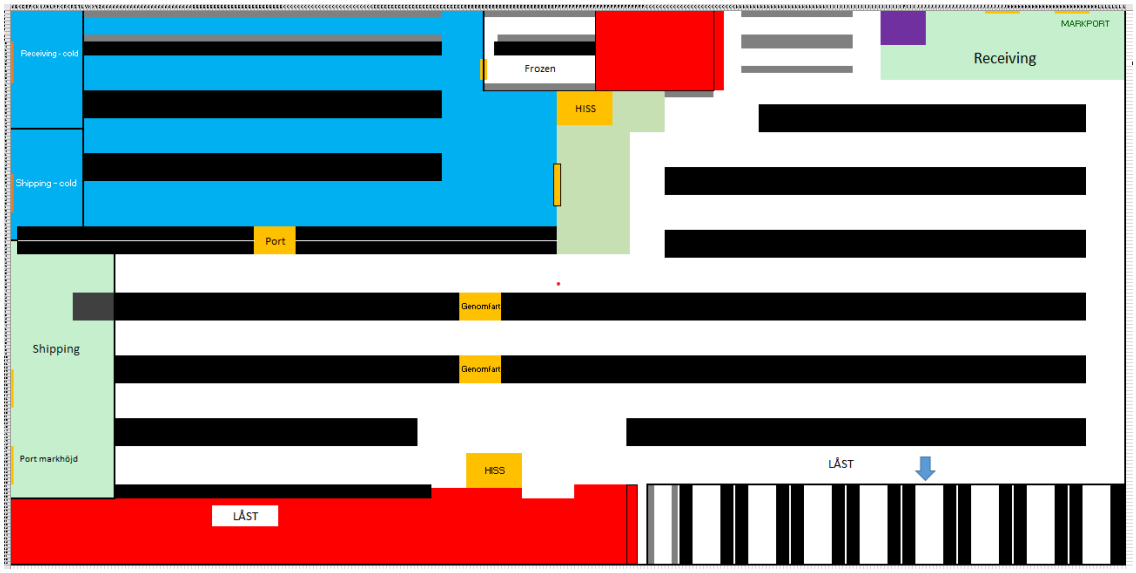
Robopac, Robot S6, Stretch Wrapping Machine	

Appendix C - Developed and considered layouts








Receiving - cold
Shipping - cold
Frozen
HISS
MARKPORT
Receiving
Port
Genomfart
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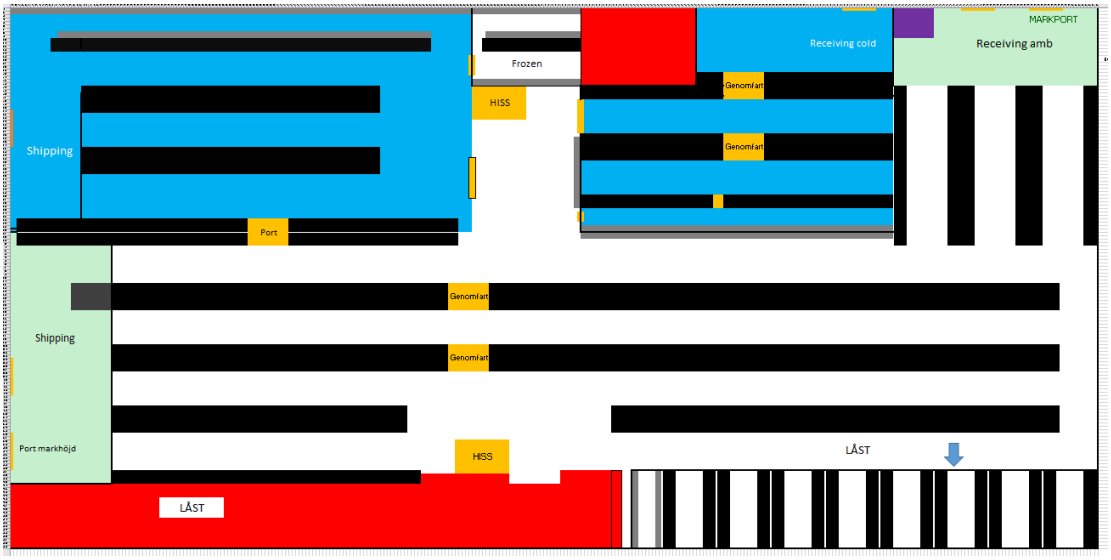
Frozen
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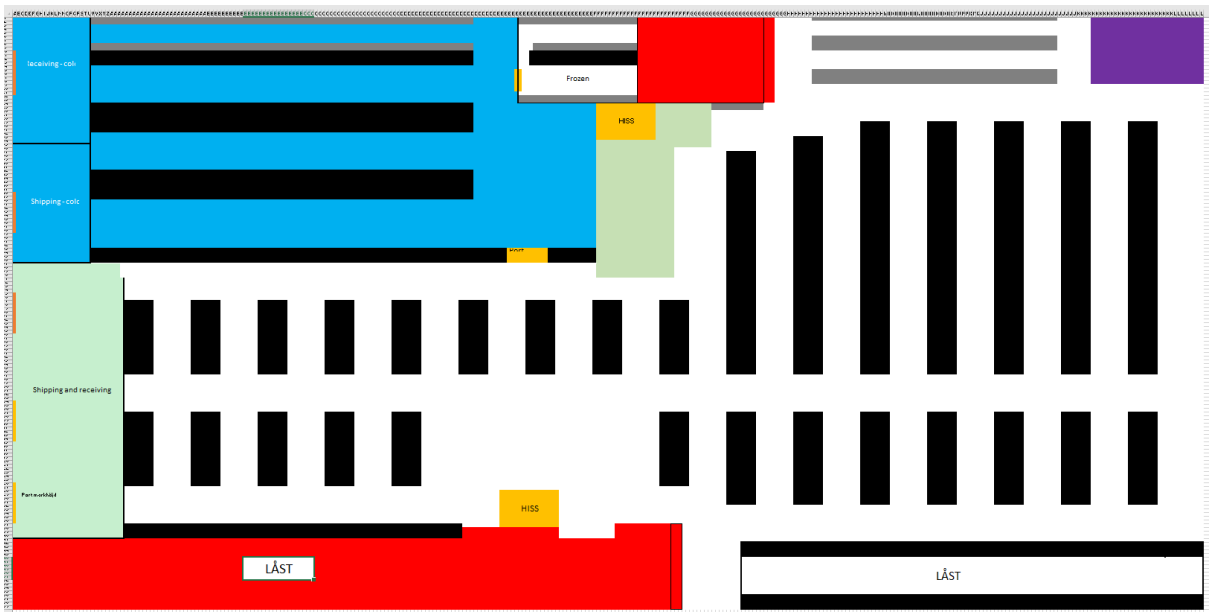
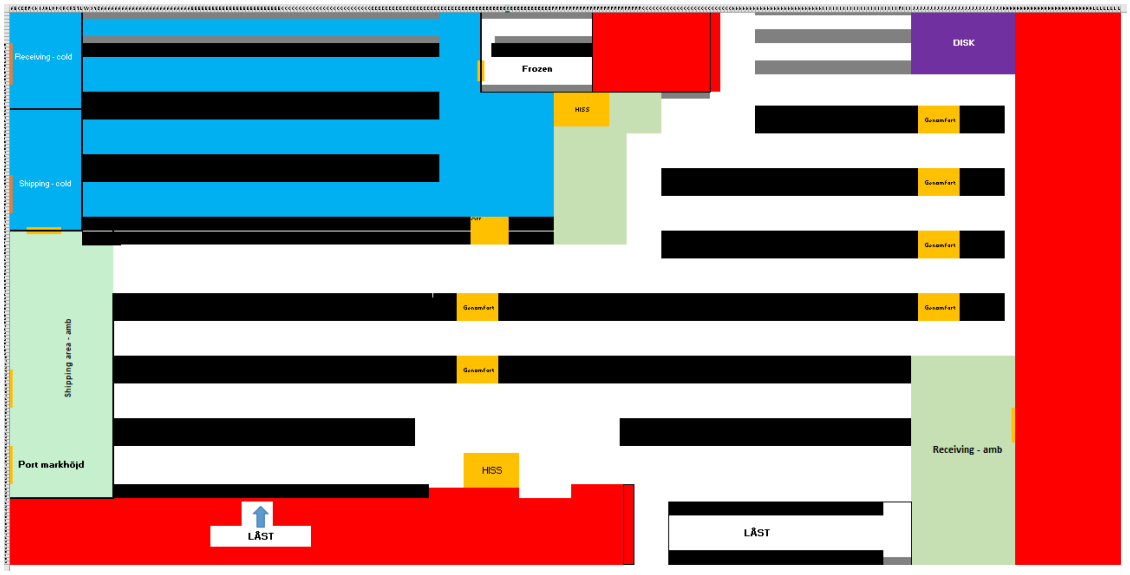

Frozen
HISS
Shipping and receiving
HISS
LÅST
LÅST


Receiving - cold
Shipping - cold
Frozen
DISK
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Gasamfart
Shipping area - amb
Port markhöjd
Receiving - amb
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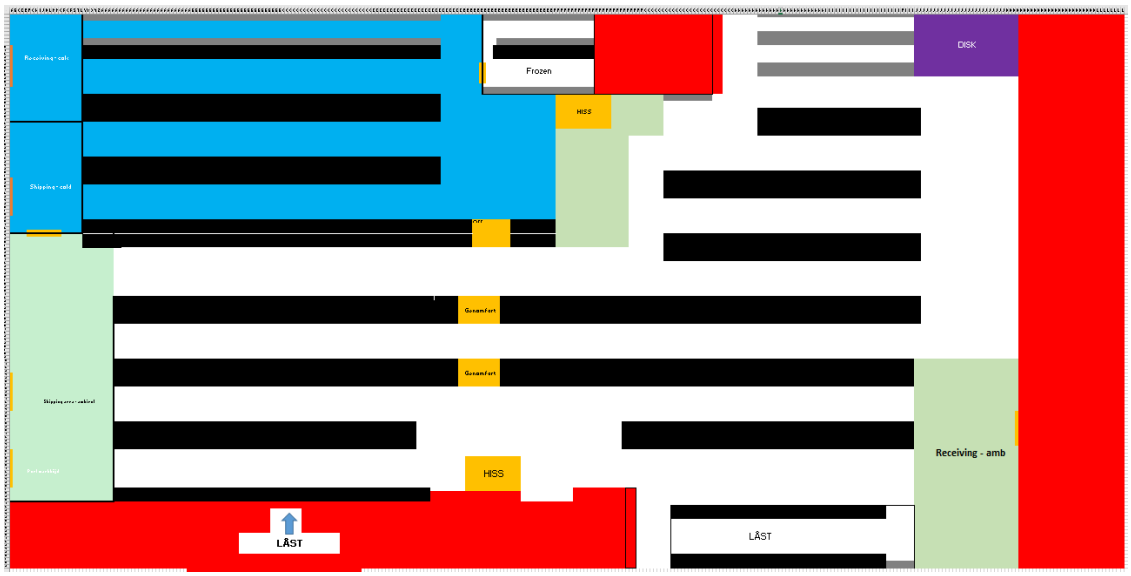
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