



Production Planning and Order Fulfilment in Hybrid Make-to-Order / Make-to-Forecast Production System

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Thesis of 30 ECTS credits
Master of Science in Engineering Management

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Thesis of 30 ECTS credits submitted to the School of Science and Engineering
at Reykjavík University in partial fulfilment
of the requirements for the degree of
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June 2015

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Abstract

In this thesis the pharmaceutical industry, a highly competitive industry that requires great level of quality, low costs and high customer satisfaction is examined. The main objective is to identify aspects that can be improved in a production process. It explains a current production process which aims to allocate the correct resources at the correct time in the correct quantities. This includes all tasks from campaign setup, raw material procurement to production allocation, packing and sales to the end customer. One of the ways of examining customer satisfaction is order fulfilment rate. A high order fulfilment rate can result in higher customer satisfaction levels and profit margin. First results from evaluation of the overall planning process according to supply chain and lean practices are presented, where implementation of same working standards, simplification of workflow among others are proposed. Second, order fulfilment is examined and solutions proposed for a shared data file and optimization model could be used as a tool when allocation production quantities to predefined production campaigns. The proposed solutions could help increasing order fulfilment and profit margin.

Key words: Supply chain management, Lean management, Pharmaceutical industry, Order fulfilment, Optimization

Áætlanagerð og afgreiðsluhlutfall í blönduðu framleiðslu kerfi

Valgerður Helga Einarsdóttir

Juní 2015

Útdráttur

Í þessari meistararitgerð er fjallað um framleiðslu og áætlanagerð í lyfjaiðnaði, iðnaði sem lifir í samkeppnisríku umhverfi þar sem gæði, lágur kostnaður og ánægja viðskiptavina eru megin krafa. Meginmarkmiðið er að bera kennsl á þætti sem hægt er að bæta í núverandi framleiðsluferli. Ritgerðin skýrir núverandi framleiðsluferli sem miðar að því að úthluta réttum vörum á réttum tíma í réttum magni. Í þessu felast allir þættir framleiðsluferilsins, allt frá uppsetningu á framleiðsluáætlunum og hráefnainnkaupum til framleiðslu úthlutunar, pökkunar og endanlegrar sölu til viðskiptavina. Eitt af því sem skoðað er hve hátt pantana hlutfall er afgreitt til viðskiptavinanna. Því herra hlutfall af pöntuðu magni sem viðskiptavinurinn fær afhent, því herra verður ánægjustigið og framlegð fyrirtækisins eykst. Í fyrsta lagi eru kynntar niðurstöður er varða framleiðsluferilinn í heild með áherslu á aðferðir lean stjórnunar og aðfangakeðjunnar, þar sem stöðlun og einföldun vinnuaðferða er kynnt. Síðan er afhendingarhlutfall pantana skoðað og lausnir í formi sameiginlegra gagna skráa og bestunarlíkans kynntar. Niðurstöður gefa til kynna að fyrirhugaðar lausnir gætu hjálpað til þess að auka afhendingarhlutfall pantana og hækka framlegð.

Efnisorð: Aðfangakeðjustjórnun, Lean stjórnun, Lyfjaiðnaður, afgreiðslu hlutfall pantana, Bestun

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List of Abbreviations

5S	Sort, Set in order, Shine, Standardize, Sustain
API	Active Product Ingredient
AW	Art Work
GMP	Good Manufacturing Practices
JIT	Just In Time
MTF	Make To Forecast
MTO	Make To Order
QRA	Quality Risk Analysis
QRM	Quality Risk Management
RCCP	Rough Cut Capacity Planning
SKU	Stock Keeping Unit
TQM	Total Quality Management
VSM	Value Stream Mapping

1 Introduction

In this thesis the pharmaceutical industry, a highly competitive industry that requires great level of quality, low costs and high customer satisfaction is examined. The main objective is to identify aspects that can be improved in a production process. It explains a current production process which aims to allocate the correct resources at the correct time in the correct quantities. This includes all tasks from campaign setup, raw material procurement to production allocation, packing and sales to the end customer. One of the ways of examining customer satisfaction is order fulfilment rate. A high order fulfilment rate can result in higher customer satisfaction levels and profit margin.

This chapter gives a detailed explanation of the problem. The second chapter states the main literature and theoretical concepts focusing on Supply Chain Management, Lean Management and Risk Management as well as presenting related work and showing its relevance. The third chapter states the methods used in conducting the study, introduction to the problem and ideas for ways of improvement. The results of the research are stated in chapter four and finally chapter five states conclusions from previously presented results and discussions.

1.1 Problem Description

The study is based on real data gathered at a pharmaceutical production unit that today schedules all its production processes manually, aided by a production system, all the way from rough campaign and production plans to detailed production and packing plans. Manual planning and production can lead to waste, shrinkage and low order fulfilment ratio. This leaves room for improvement from waste elimination to great financial gain by increasing profit margin and customer satisfaction.

The unit operates as a hybrid Make-to-Order (MTO) / Make-to-Forecast (MTF) production system where one part of the production is motivated by customer orders and the second part is motivated by customer forecasts. A Global Supply Chain Organization uses the proper planning models to support different business segments, focusing on proper information flow from markets to production unit. In both MTO and MTF practices the demand of raw material is based on customer forecasts. It is because the raw material lead times are in most cases longer than customer order lead times. The difference however is that in MTF more decisions have to be made according to forecasts rather than firm orders, for example that production is started according to forecasts in MTF practices whereas MTO needs firm orders to start production.

The unit receives orders every week which all consequently need to be confirmed to the customer. Delays and other updates are sent weekly to the customer according to the production and packing schedules until the orders are sold and delivered. Figure 1-1 shows the overall production process from forecast and order creation by the customer until order delivery. It starts where forecasts orders are uploaded. Then moves to rough demand and production planning and order confirmations and demand planning for raw materials and campaign planning, detailed production and packing plans. Finally it ends at actual production, packing and order delivery. The process is long and complex using resources from different departments and functions that all need to work together to meet the customer demands.

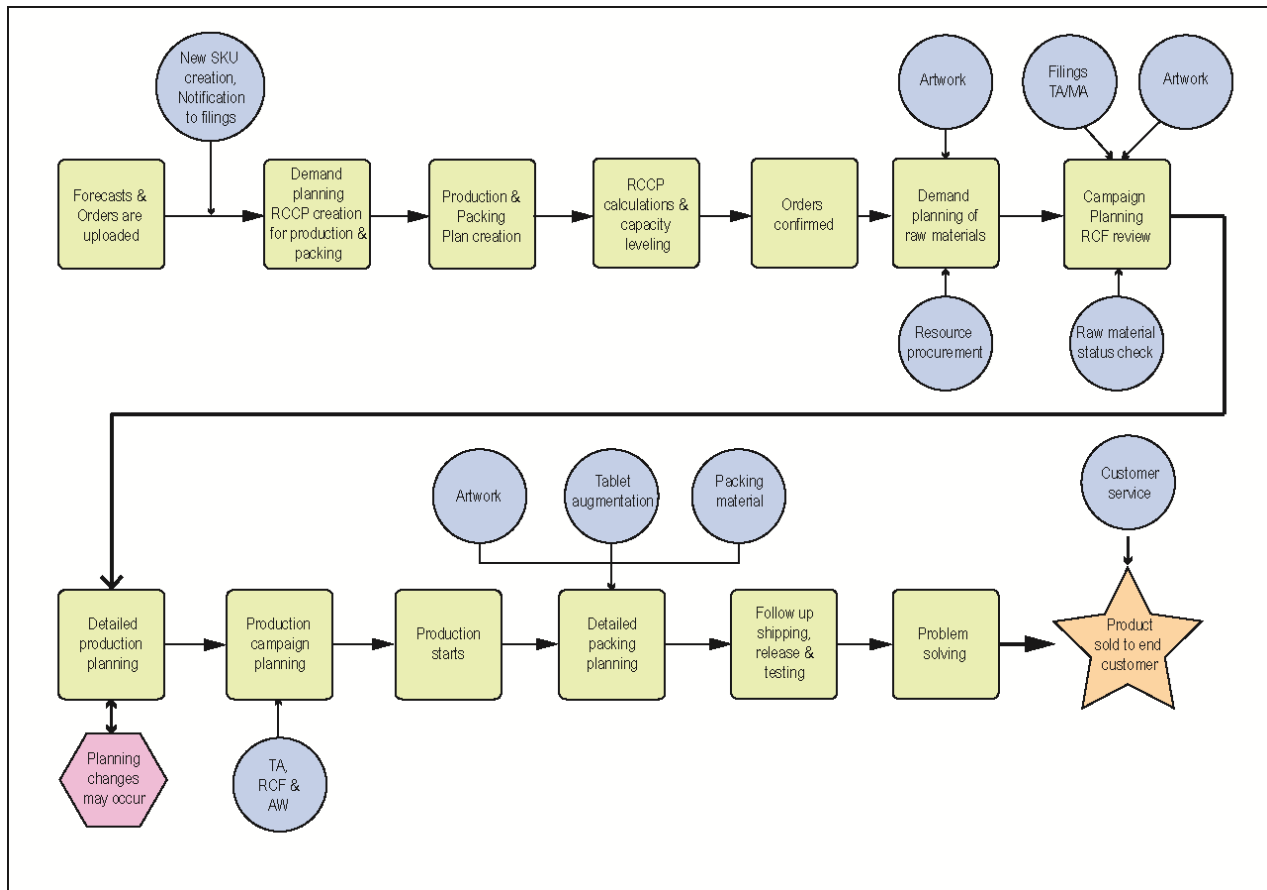


Figure 1-1 – Current planning process

Aside from the main activities of the process there are many different areas that need to be cared for. Including artwork, filings, resource procurement and others which takes place in many different departments working together to reach a common goal. This can result in a time waiting for information before proceeding through the process. The unit is implementing Lean practices. Therefore it is one of the tools used in this study.

Figure 1-2 shows the different rules of the MTF horizon. It is divided into three steps, Liquid 21 month period where plans are totally flexible. Slush period of one month where the plan is still flexible but any changes need to follow certain rule and according to validation process. And the Frozen 98 day period where the forecast cannot be changed in the system and is considered as a firm order, leaving the unit to do a great deal of planning according to forecast period increasing uncertainty factors.

Frozen	Slush	Liquid
Plan is fixed and can't be changed by the system	Plan is still flexible but any changes need to follow certain rule and according to validation process	Plan is totally flexible and can be changed by the system

Figure 1-2 – MTF horizon consisting of Liquid 21 months period, Slush period of one month and Frozen 98 day period

The unit works according to a campaign setup. Which means that all variations of a given product family are produced consecutively to minimize cleaning and setup times in production. This results in lower production cost. Each campaign is made up of production batches which are the smallest production unit of each product. Campaign planning is based on long term forecasts and unknowns that increase uncertainty. However this is a useful step for rough capacity planning as well as raw material estimation. This is because raw material lead times are longer than replenishment order lead times. These forecasts are used to create the initial campaign plans. They are then adjusted once firm orders or updated forecasts become available. Confirmed information is then used to determine production for the orders included in the campaigns.

This kind of production system indicates that production is moving through a Pull System. The planned levels of available capacity and inventory must be used as an outlining of future production instead of the actual amount to be completed. This makes the forecast process more essential to value generation. Resources must be allocated according to forecasts rather than actual data. All forecasting decisions include certain amount of risk, as it is an important decision variable that will influence the optimal schedule and budgets making risk management essential (Roldstadas, 1995). Probably the most difficult thing to deal with in planning is uncertainty (Stadtler and Kigler, 2005).

Forecast errors can cause significant misallocation of resources in inventory, facilities, transportation, sourcing, pricing and even in information management. Utilizing opportunities for demand pooling and increasing responsiveness in the supply chain can reduce forecast errors, mitigate forecast and decrease risk.

As well as managing risk the high competitive industry demands great customer satisfaction levels. However in the current environment order fulfilment is difficult to manage. That is why sold order quantities can vary $\pm 10\%$ of order quantities. It is more common that orders are delivered with less than ordered resulting in loss of sales of up to 20%.

1.2 Aims and Objectives

The aim of this study is to improve the overall production process by using the theoretical tools available by analyzing the current production process with the literature review as a guide. It also aims to examine what is effecting order fulfilment and finding solutions that lead to greater order fulfilment rate without increasing inventory and scrapping cost, leading to higher profit margin. It intends to examine the production process and answer the following questions:

1. How can a pharmaceutical unit with hybrid MTO / MTF production system improve its planning processes and increase reliabilities using supply chain and lean principles?
2. How can tablet allocation process be improved with the goal to increase delivered order quantities?
3. How can the production quantity determination be optimized with the goal of increasing production quantities for better order fulfilment, without increasing scrapping while increasing the overall profit margin?

2 Literature

This chapter reviews the literature and theoretical concepts related to this study. They are Supply Chain Management, Lean Management and Risk Management. Their main focus areas, theories and usefulness are presented as well as introduction to related work.

2.1 Lean Management

Toyota was the first to implement lean practices in their manufacturing process. Their definition of lean management is elimination of waste and respect for humanity (Ohno, 1988). According to Wolmack and Ross (1990) lean practices provide a corporate culture where respect for the employees is significant. The goal of a Lean production system is cost reduction, waste elimination and control, quality assurance and respect for humanity (Shah and Ward, 2007). Standardization of processes, systematic problem solutions, different mindset for problem solving and improvement opportunities are essential part of lean management (Flinchbaugh and Carlino, 2005).

According to Shah and Ward (2003) implementing Lean management practices has many benefits such as improvement in labor productivity and quality, customer lead time and cycle time and manufacturing cost reduction. Lean Management tools can be used to improve production and planning processes and increase reliability. This study focuses only on a small portion of methods available which are explained as follows.

Just In Time (JIT) focuses on having the right product at the right time in the necessary quantity and provides regular feedback on quality and delivery performance (Shah and Ward, 2007). In this kind of system the customer initiates the demand that is then pulled backwards from final assembly back to the raw materials (Abdulmalek and Rajgopal, 2007), fitting to the practices examined in this study. It also aims at keeping inventory at a minimum, decreasing

waste while relying on process stability (Womack, 2006, Garban, 2009). It describes the product as it moves toward completion with time spent waiting in a system up to about 90-95% of the total flow time, therefore lead time reduction can be defined as a result of good implementation (Hopp et al., 1990).

Total Quality Management (TQM) is a continuous process of improvements. It is a way of thinking and managing rather than a methodology where the benefits range from strengthened competitive position, higher productivity, better cost management to increased customer loyalty and others (Chena et al., 2004). It is a system that focuses on continuous improvement, problem solving, statistical methods and long term goals, meeting customer requirements, reducing rework, long range thinking, increased employee involvement and team work, process redesign, competitive benchmarking, team based problem solving, constant measurement of results and closer relationship with supplier (Abdulmalek and Rajgopal, 2007, Shah and Ward, 2007). Zuellig Pharma has successfully implemented TQM in a pharmaceutical logistics organization, resulting in maximization of the organizational profits by improving and managing process flow (Chena et al., 2004).

Value Stream Mapping (VSM) is used to identify opportunities from various lean techniques. It is a collection of all value and non-value added activities of the production system. From raw material to the customer, identifying and eliminate all types of waste in the supply chain (Abdulmalek and Rajgopal, 2007). It focuses on the value added activities of the process. Using VSM means gathering more information than the typical flow chart shows making it better suited for improvement analysis (Rother and Shook, 2003).

Total Productive Maintenance (TPM) can reduce machine breakdown time, and as a result also reduce inventory lead times (Abdulmalek and Rajgopal, 2007). Machine stoppages and breakdowns can account for 20-30% of loss in the overall equipment effectiveness (Suehiro, 1992). The 5S is a standardized work procedure, used to organize work places with the goal of eliminating waste and making problems more visible. Using 5S is often the first step in standardization and waste elimination (Flinchbaugh and Carlino, 2005).

2.2 Supply Chain Management

Stadtler and Kilger (2005) define Supply Chain Management as the task of integrating organizational units along a supply chain to coordinate material, information and financial flows in order to fulfil customer demands with the aim to improve the competitiveness of the supply chain as a whole. In a manufacturing supply chain that includes all functions involved in receiving and filling a customer demands while maximizing the overall value generated. Value is defined as the difference in final product worth to the customer and the cost of fulfilling the customer's request (Chopra and Meindl, 2010).

Chopra and Meindl (2010) define three main focus areas where decisions should be made to raise the overall supply chain surplus. They are supply chain strategy, planning and operations. This study focuses on optimizing the Supply Chain Planning and Operational processes, thus, constraints in which the planning must be done and decisions made to individual customers orders.

Supply Chain Management suggests many forecasting models. For example qualitative, time series, causal and simulation, suggesting that combined forecasts decrease forecast errors and are therefore more effective (Chopra and Meindl, 2010). Forecasting and simulation models predict future developments and explain relationships between input and output of complex systems. Optimizing models can be used to support selection of one or few solutions that are good in terms of predefined criteria from a large set of feasible activities by using objective function to minimize or maximize (Stadtler and Kigler, 2005)

Aggregate Planning is a part of the supply chain that determines capacity levels, production, subcontracting, inventory, stock outs and pricing with the goal of maximizing profits while satisfying customer demand. It is used as a blueprint for operations like determining total production levels in a production plant for a given month, campaign or product family without determining the total quantities for each stock keeping unit (SKU) (Chopra and Meindl, 2010).

Advanced Planning supports decision making by identifying alternatives to future activities and selecting good one. According to the planning horizon there are three levels of planning, long-term, mid-term and short-term planning (Stadtler and Kilger, 2005).

According to Stadtler and Kilger (2005) customer service should be as high as possible at the same time as keeping inventories at a minimum. A common way to deal with multi-objective decision problem is to set a minimum or maximum satisfaction level for each objective except for the one that will be optimized. Example minimize inventories while guaranteeing a minimum customer service level.

This study focuses on planning of regular operations such as rough quantities and detailed instructions for immediate execution, that is mid-term and short-term planning criteria often referred to as operational or tactical level planning.

2.3 Risk Management

Good Manufacturing Practice (GMP) is considered as a quality baseline for all laboratories in pharmaceutical production. However its practices do not start until the final states of Quality Risk Management (QRM). It is a systematic process for the assessment, control, communications and review of risk to the quality of the medical product across the product lifecycle. It makes a frame for making decisions by finding and understanding the problem and its causes, establishing the likely effects of the problem and search for a solution. It provides a common quality baseline for all laboratories in the pharmaceutical industry. This working standard is used in quality of all pharmaceutical products and is essential so they do not put lives at risk with contaminations or deviations (Botet, 2012).

There are three main QRM tools, risk analysis, risk comparison and statistical support. According to Botet (2012), Quality Risk Analysis (QRA) is a new way of looking at things, analyze problems and propose solutions by providing systematic and deep knowledge of the problems. This helps overcoming problems on GMP application and a key element in improvements in the pharmaceutical industry. He also states that risk is no more than an estimation that has to be improved as more experience is collected. Evaluating risk can be

subjective and unreliable. Therefore risk is often used just to get a baseline to work as an indicator of future improvement.

Pareto analysis is a statistical method used to prioritize problem solving to identify the more important elements from the total. It not only shows the most important factor but also gives scoring on how severe the problem really is (Talib et al., 2011). Pareto analysis can be applied to separate the most important factors of a problem from many trivial ones (Chena et al., 2004). Pareto diagrams are used to determine the importance of the data, listing the data elements and determine their frequencies and then classified according to the cumulative frequencies (Botet, 2012).

Ishikawa diagram or cause-and-effect diagram is often used in QRM during root cause identification, as it shows cause relations and how they interact to provoke an effect (Botet, 2012). It is considered one of the seven basic tools of quality control (Ishikawa and Loftus, 1990). The Ishikawa diagram can be used in many different ways from diagnostic tool in medical care to facilitating problem based learning (Wong, 2011).

2.4 Related Work

Malmquist (2009) uses Lean management tools to identify ways to increase efficiency in hospital management in Iceland. According to the study hospital administrations do not use universal management methods and implementing lean tools can standardize management practices throughout the organizational unit making it more efficient while keeping quality as high as possible. However the study emphasizes that implementing can be complicated and must be extremely well planned and coordinated.

In a similar concept study Merscbrock (2009) investigates the construction industry to see if lean management tools can be used. According to his findings implementation of lean practices enhances production efficiency resulting in faster and more productive execution of tasks, however not only lean tools are needed because wasteful or unnecessary tasks are logically useful in the construction industry.

Prior to this study several studies have been carried out with the same production unit as a focus point. First, Stefansson et al. (2006a) focuses on planning and scheduling for a real world continuous and dynamic decision process based on multi-scale hierarchically structured moving horizon that only receives partial information before decisions have to be made. Figure 2-1 shows the hierarchical level presented with representation of uncertainty and information availability with regard to time (Stefansson et al., 2006a, Stefansson and Shah, 2005, Stefansson et al., 2006b).

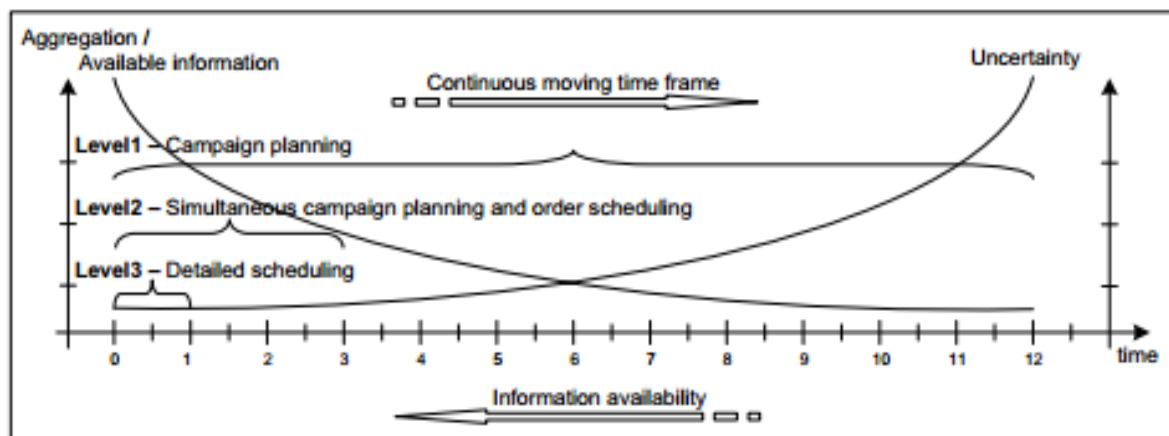


Figure 2-1 – Hierarchical framework with the representation of uncertainty and availability of information with regard to time (Stefansson et al., 2006a)

They developed a dynamic online optimization model used to determine campaign plans and to schedule customer orders within each campaign where the planning horizon is continually moving, decreasing uncertainty as more information becomes available closer to production. They propose three types of models, top level optimization of campaign scheduling and at the lowest level optimization was based on confirmed customer orders, specifying in which campaign which order is produced as well as production sequence. The optimization was found to be more sufficient at the lower level. Stefansson et al. (2009) also proposed a Monte Carlo simulation based approach that can be used to account for uncertainty in the demand information and thereby reduce the risk of creating plans that will prove to be infeasible. Stefansson et al. (2009) had difficulties in solving their optimization models within acceptable solution times and they therefore in later work Stefansson et al. (2011) proposed a solution method based on decomposing the problems into two parts, i.e. first solve for the first four production stages and then solve for the last production stage.

Second, Ásgeirsson et al. (2011) use the same pharmaceutical unit to construct an optimization model for scheduling production. Their approach of optimization is to focus on the scheduling of jobs within the campaigns. There the goal was to create a mixed linear integer optimization model and greedy algorithm for campaign setup with the main focus on tardiness. They found that greedy algorithm is easy to implement and just as good as manually setting up campaigns. The optimization was statistically concluded to be the best option but not as easy to implement.

Third, Guðmundsdottir (2012) aims at improving production scheduling by presenting an optimization model on arranging orders in a campaign plan. The results provide optimization model usable tool in order scheduling in preplanned campaigns, schedule more orders, minimize delays and evaluate the changes. Resulting in usable model, especially when it allows changes to the preplanned campaign plans to include more orders.

All the prior work have in common that the main focus area is on optimizing campaign scheduling or scheduling orders inside the campaigns. They do so by focusing on tardiness in the upper levels of the hierarchy, whereas this study focuses on optimizing the lower level component of detailed scheduling focusing on order fulfilment rate. Also similarly to Malquist (2009) and Merscbrock (2009) this study aims at proposing improvements according to lean management practices to the overall production process.

3 Methods

This chapter explains the approach used in this study. It introduces general information about the methodology and describes the planning and order fulfilment processes in detail and how theory is used to answer the research questions in each case.

3.1 Introduction

In all research it is important to understand the problem and the methodologies applied to answer the research questions in order to obtain reliable and defendable results. In this study data was collected on delivery reliability of a hybrid MTO/MTF production system, where the main focus was on information from the planning and production processes as well as information on delivery reliability. The approach of this study was to examine the processes as it currently is and use the theoretical approaches described in previous chapters to answer the research questions and suggest ways to improve the overall process so that value can be maximized and waste minimized.

The study also focuses on quantity ordered versus quantity delivered using qualitative data gathered in conversations with employees working at different stages in the planning and production process. As well as understanding the problem it is necessary to understand the tools available and choose which ones are the suitable and in line with general organizational practices.

3.2 Planning Process

It is important to understand the overall planning process. This chapter explains in detail the components of the planning process to answer the following research question:

1. How can a pharmaceutical unit with hybrid MTO / MTF production system improve its planning processes and increase reliabilities using supply chain and lean principles?

The planning process is considered as the overall process from the Rough Cut Capacity Planning (RCCP), forecasts, order confirmations, campaign planning to detailed planning in production, packing and customer delivery. Figure 3-1 roughly states the process as the preparations necessary from order to sales.

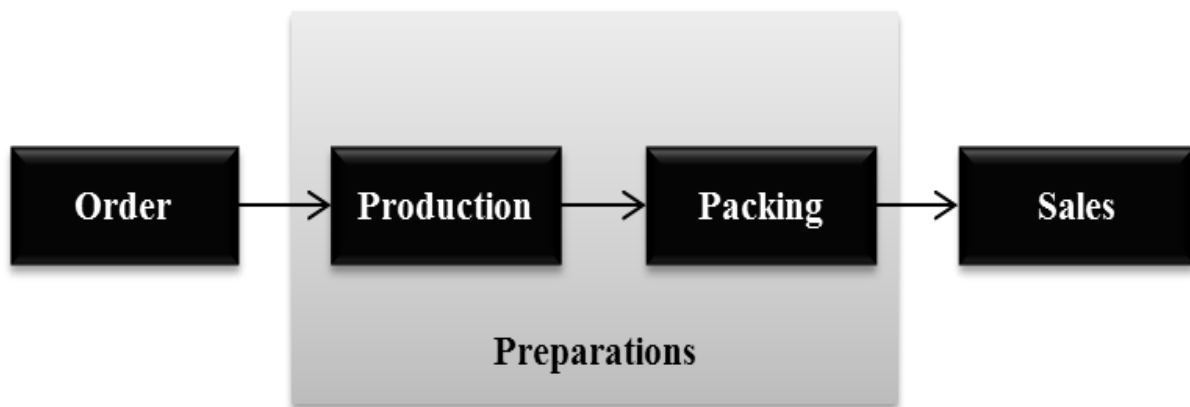


Figure 3-1 – Rough outline of the process from order to sales

First forecasts and firm orders are uploaded to a computer system from the customers. They are then used to evaluate the need for raw materials such as active product ingredients (API), artwork (AW) and others. Next the RCCP is created to evaluate resource requirements and capital equipment requirements. Alongside this process registration documents are checked and approved for each SKU to make order delivery possible. If any information is missing orders may be delayed or cancelled. At the same time first drafts of the packaging masters are created to stimulate detailed raw material demand.

The RCCP is used to calculate the total bulk demand and level capacity load to get maximum usage from the production machines. If necessary plans are adjusted and estimated delivery dates moved before the orders are confirmed to the customer. Once forecasts and orders are confirmed the raw material requirements is rechecked, confirmed and necessary supplies ordered. This process involves collaboration from different departments, making cross functional communication necessary.

Next step in the process is to set up a detailed plan for the bulk production. Each bulk production is set up in a campaign, where each campaign includes one product family in all necessary versions. The bulk is produced in batches where the first production batch started is the first batch to finish production. Each batch is assigned to a specific SKU prior to production where the goal is to fit the SKUs to exactly full batch quantities not considering estimated delivery dates to the customer. Detailed packing plans are formed according to the production schedule once production has started. Batches are then quality released according to first-in/first-out practice. Once batches and packaging masters have been validated tablet augmentation is performed according to the detailed packing plans. Then orders are packed, released and sold to the customer.

3.3 Order Fulfilment & Quantity Determination

It is important to understand in detail the current environment of bulk allocation which is stated briefly in the planning process above. This chapter focuses on explaining the current practices further and highlighting the restrictions to the process to answer the following research questions:

- How can tablet allocation process be improved with the goal to increase delivered order quantities?
- How can the production quantity determination be optimized with the goal of increasing production quantities for better order fulfilment, without increasing scrapping while increasing the overall profit margin?

As stated before the current production batches are assigned to the total order quantity of the specific SKU prior to production. There the goal is to fit the initial production quantities exactly to full production batch quantities. Orders are sorted in the campaign to best fit the full batch quantity, ignoring the estimated delivery dates. This can result in the first batch produced to be allocated to the last order to be delivered and vice versa. This also means that if the current orders do not fulfil the criterion to full production batch quantities they may be adjusted to fit the production. In many cases the orders need to be reduced or increased to fit the exact batch size. This can result in deviations between ordered quantity and quantities

delivered to the customer. As a result of this the production site is allowed to deliver quantities that are $\pm 10\%$ of the total ordered quantities from the customers. More often than not resulting in delivery fulfilment rate of around 90% when order fulfilment of 110% is allowed, leaving a room to increase order fulfilment rate by 20%.

It is a fact that initial maximum production batch quantities reduce during the production processes in the pharmaceutical industry. This does not include shrinkage formed from sampling procedures, deviations and other. However quantity allocation of production to individual campaigns or SKU does not consider this kind of shrinkage. This breaks a fundamental supply chain management rule of delivery reliability and customer satisfaction by delivering less than the customer orders. This leaves room for improvement that can result in increased over all profit margins.

4 Results

In this chapter the results from the study are presented, including theoretical analysis and calculations. Results from the planning process are listed along with risk factor definitions and proposed improvements. As well as explaining results on order fulfilment and quantity determination, results showing risk analysis, calculations and proposed improvements.

4.1 Planning Process

The planning process is composed of both value added and non-value added activities. Therefore it has possibilities to minimize waste according to lean management theory (Shah and Ward, 2007). As the planning process is long and complicated it is necessary to identify a critical path to find the focus areas for the study. This is done by splitting the process into 5 stages and listing critical activities for each stage as Figure 4-1 shows. In stage 1 RCCPs are performed, orders planned for production and confirmations sent to the customer. In stage 2 orders are added to production campaigns and detailed production plans are setup. In stage 3 tablet allocations is performed and bulk production starts. Detailed packing plans are set up and packing starts in stage 4. Finally orders are released and sold to the customer, where sold is defined as ex works or at the place of manufacturing, in stage 5. The focus in this study is optimizing stages 3 and 4 of the planning process.

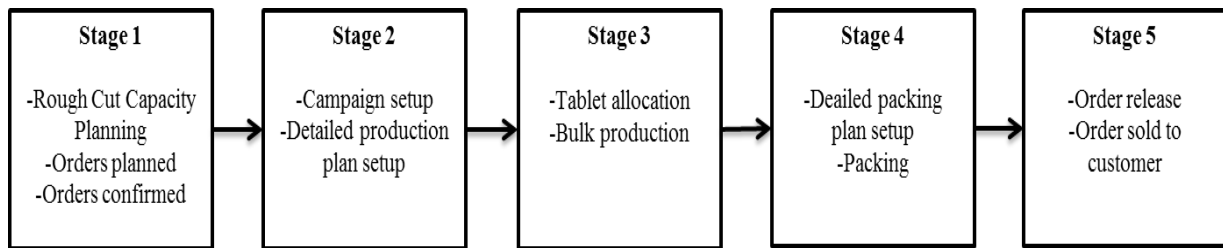


Figure 4-1 – Critical stages of the planning process. Stage 1 RCCPs are performed, orders planned for production and confirmations sent to the customer. Stage 2 orders are added to production campaigns and detailed production plans are setup. Stage 3 tablet allocations are performed and bulk production starts. Stage 4 detailed packing plans are set up and packing. Stage 5 orders released and sold or in transit to the customer.

4.1.1 Current State

A campaign is set up according to estimated delivery dates of the SKUs. Production is setup according to the campaign size and mixture to make production as efficient as possible. The working standard of production is first-in / first-out, which means the first production batch started, is the first batch to finish in production. Batch validation is performed when production has finished also according to first-in / first-out standard.

Tablet allocation of the bulk production occurs once the campaign setup is ready. Each production batch is assigned to a specific SKU prior to production where the goal is to fit the SKUs to exactly full production batch quantity. As stated before it does not consider estimated delivery dates to the customer. The order estimated for earliest delivery could be assigned the last batch in the production and vice versa. This can result in high quantities of work in progress inventories throughout the rest of the process. As well as performance of other non-value added activities necessary to ensure on time delivery to the customer.

A detailed packing plan is set up according to the production campaigns and estimated delivery days of each individual SKU, as well as the preferred packing order which minimize setup times and optimize productivity. Even though there are plans in place stating the optimal packing order they do not guarantee on time packing and delivery. Batches may not be available at the right time due to production timing and tablet allocation in the campaigns.

In addition packing masters need to be verified and approved before packing as well. Only then can tablet augmentation be performed for individual SKUs according to the previous tablet allocation.

Under current conditions data for each of these activities are stored in multiple forms and in multiple files where the data needs to be moved from one file to another. This leads to duplicated data, resulting in numerous non-value added activities that can lead to errors and miscommunication.

4.1.2 Proposed Changes

As described above there is room for improvement. Proposals for changes based on the observations are as follows:

1. All parties to work according to the same working standard.

Production, validation and tablet allocation currently work according to different standards. Production and validation work according to first-in / first-out practices. While tablet allocation works with best fit to production campaign. This means either changing the ways production and validation is performed or changing the way tablets is allocated. By following JIT practices it is proposed that changes should be made to tablet allocation changing it to first needed first produced. Produce first for the orders with first delivery using detailed plans as a reference.

By doing this not only will the working procedures be integrated through the process, it can also decrease waiting times and inventory levels as it increases the likelihood that a full production batch will be used for packing all at once. This can cause a chain reaction that leads to time saved and increased efficiency during the packing process in stage 4. By having the right product ready at the right time as well as keeping inventories at a minimum which are main factors of JIT practices (Shah and Ward, 2007).

For example by doing this batches are more likely to be quality released when needed decreasing likelihood of switching non released batches with already released batches to

ensure packing of the correct SKU on time. This can also have the effect that one full batch will be packed at the same time even though it may be allocated to number of SKUs. Currently orders often are planned in detail for packing without taking into account the production or validation order of the batches. Therefore half batches are often needed to be moved back and forth from the packing machines resulting in unnecessary down times and non-value added activity.

Because this change can decrease the amount of non-value added activities, this means that the change also affects VSM which focuses on value and non-value added activities (Abdulmalek and Rajgopal, 2007), as it decreases the amount of non-value added activities that are currently in the system. However other possible effects of these changes are beyond the scope of this study.

2. Assign batches later.

Assigning batches later in the process or at the time of packing can increase efficiency in the process. This means that the available quality released batches can be assigned to the orders when needed for packing. Reducing the common practice of switching batches when the batch allocated is not quality released in time.

Starting production without allocating batches can make it easier to allocate the batches to the needed SKUs when they are needed as well as making sure that the same batch is used for all consequence SKUs according to detailed plans. This can reduce setup time on packing machines as well as reducing part batch inventories. This may also lead to lead time reductions and over all equipment effectiveness this is in line with practices of TPM theories.

3. Simplify flow of information.

Combing working files into one or two files that contain same or similar information can simplify flow of information. Table 4-1 shows a proposed combination of files according to actives or stages of the process. First files for production campaigns, packing campaigns and detailed packing plans, with the purpose of connecting campaigns and detailed plans closer together, and creating common focus areas should be combined. Secondly is combination of

detailed packing plans, tablet allocation, tablet augmentation and packing master files. This combination could reduce non-value added work as well as establishing greater common goals. Lastly combination of tablet allocation, tablet augmentation and packing master, shipment and order release could also reduce non-value added work and increase efficiency.

Table 4-1 – File combination proposals

Current working files	Combination 1	Combination 2	Combination 3
Production Campaigns	x		
Packing Campaigns	x		
Detailed packing plans	x	x	
Tablet allocation		x	x
Tablet augmentation & packing master		x	x
Shipment & Order release			x

Working with same or almost the same information in many different places at the same time is not only a non-value added according to VSM but also a risk factor for mistakes and deviations. Therefore proposed change are made with TQM thinking as a reference to manage all this information in the same way either in a single file or few files containing the major part of the information. Reducing the amount of non-value added activity from multiple places in the process and to decrease these risk factors, reducing rework as well as increasing cost management and productivity and overall efficiency.

4.1.3 Risk Factors

Implementation of these changes, as for all changes, involves risk. In this case there are few factors that need to be accounted for before implementation. For example deviations as not all productions are a without mistakes. There can be deviations in production, packing and planning that can affect proposed changes of procedure.

For example production deviation can make the first batch out of production to be the last one quality released or allocation of production at a later stage can be more time consuming than switching batches. These and other factors need to be analyzed further before implementation to make sure that changes increase efficiency. At the same time it is essential to make sure

that any changes made are done so with quality as a priority to follow the standards of GMP and QRM which is beyond the scope of the study.

4.2 Order Fulfilment & Quantity Determination

According to sales data the order fulfilment rate was 94% of total ordered quantities for all products in 2013 and 2014. This leaves room for improvement with the objective to increase order fulfilment by at least 6% or even 16% aiming at order fulfilment of 110% which is allowed within the margin of error and optimal fulfilment rate of the production unit.

4.2.1 Root Cause Identification

The first step was to identify the root causes of the difference in sold order quantities versus the ordered quantities before being able to identify corrective and preventive actions. Figure 4-2 shows an Ishikawa diagram that was used to identify the main causes that provoke the final effect which result in the quantity difference.

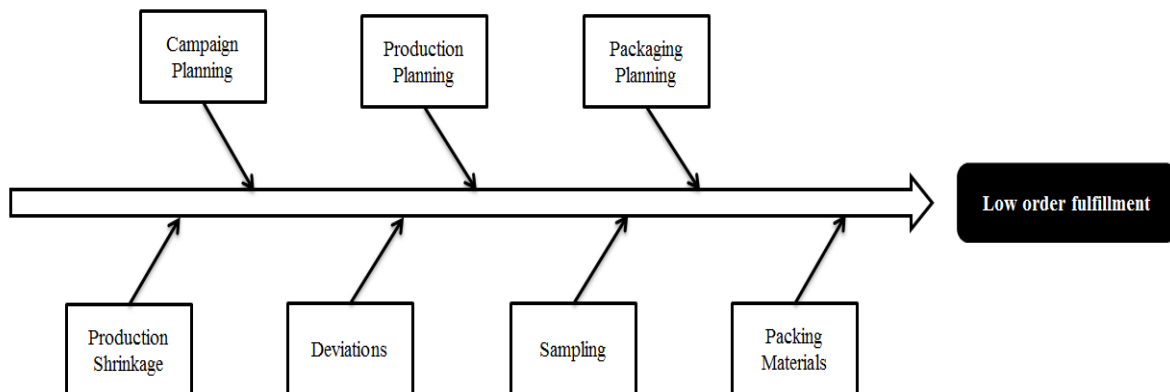


Figure 4-2 – Ishikawa diagram identifies the main causes that provoke the final effect which result in the quantity difference.

Then qualitative evaluation risk ranking was used to determine which factors are more important and viable for improvement, thus, establishing the priorities. Here probability and severity are summarized and used to evaluate the effects of each factor on customer order

fulfilment. High indicates that it occurs frequently and has important effects. Medium indicates that it occurs periodically with moderate effects. And low indicates that it occurs rarely with low effect.

Table 4-2 shows the risk ranking stating all factors that can contribute to decreased order fulfilment rate evaluating the main elements from low to high risk factors. It states only rough approximation of risk for decreased order fulfilment. There are many factors that can affect the order fulfilment rate so it was decided to focus only on the high classified factors of production planning and production shrinkage.

Table 4-2 – Risk ranking stating all factors that can contribute to decreased order fulfilment rate, evaluating the main elements from low to high risk factors

Element	Risk Classification			Evaluation
	Low (1)	Medium (2)	High (3)	
Campaign Planning		x		2
Production Planning			x	3
Packaging Planning		x		2
Production Shrinkage			x	3
Deviations		x		2
Sampling		x		2
Packing Materials	x			1

The production mix used in the study is made of around 60 product families, producing roughly 200 different combinations. By applying Pareto analysis the product families with the highest total order quantities in 2013 and 2014 were determined and used as the main focus for improvement.

Figure 4-3 shows a Pareto diagram where order quantities from last two years are compared to the cumulative ratio, showing the close to 20% of produced product families account for 80% of the total order quantity. The first 10 products families account for 83% of the total order quantities and are therefore classified as the main focus products families of this study. The average order fulfilment rate when looking only at these products families was less than the overall or 87%. The order quantities have been distorted for better presentation and do not show actual order quantities.

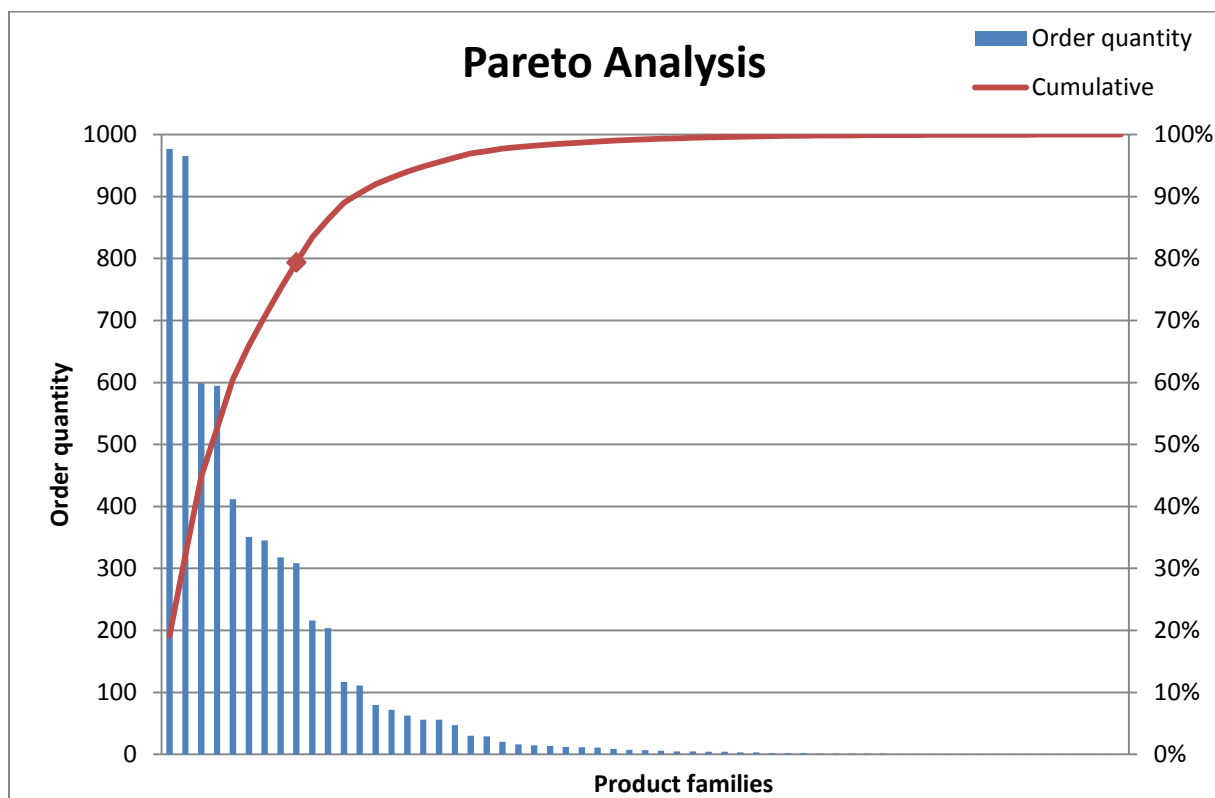


Figure 4-3 – Pareto diagram showing order quantities of each product family from the last two years compared to the cumulative ratio. Around 20% of the cumulative ratio accounts for around 80% of the total order quantity.

Production planning of three of the top ten product families was examined. They are named randomly from 1 to 3. Like stated previously the production is planned with the goal to fill the exact production batches quantity. In all three cases the planned production quantities range from 1-6% above the order quantities. At the same time the sold order quantities are only 93-75% of order fulfilment for the products families.

Figure 4-4 shows shrinkage of ordered quantities to sold quantities. Where 100% represents full order quantity and sold quantity as order fulfilment rate. Product family 1 is stated in red, Product family 2 in blue and Product family 3 in green. Product family 1 has the lowest order fulfilment of the three products families with around 75% in 2013 and 90% in 2014. The low order fulfilment rate can be explained by order cancellations and packing transfer from the production unit. However this is an indicator of shrinkage in the process leaving great room for improvement.

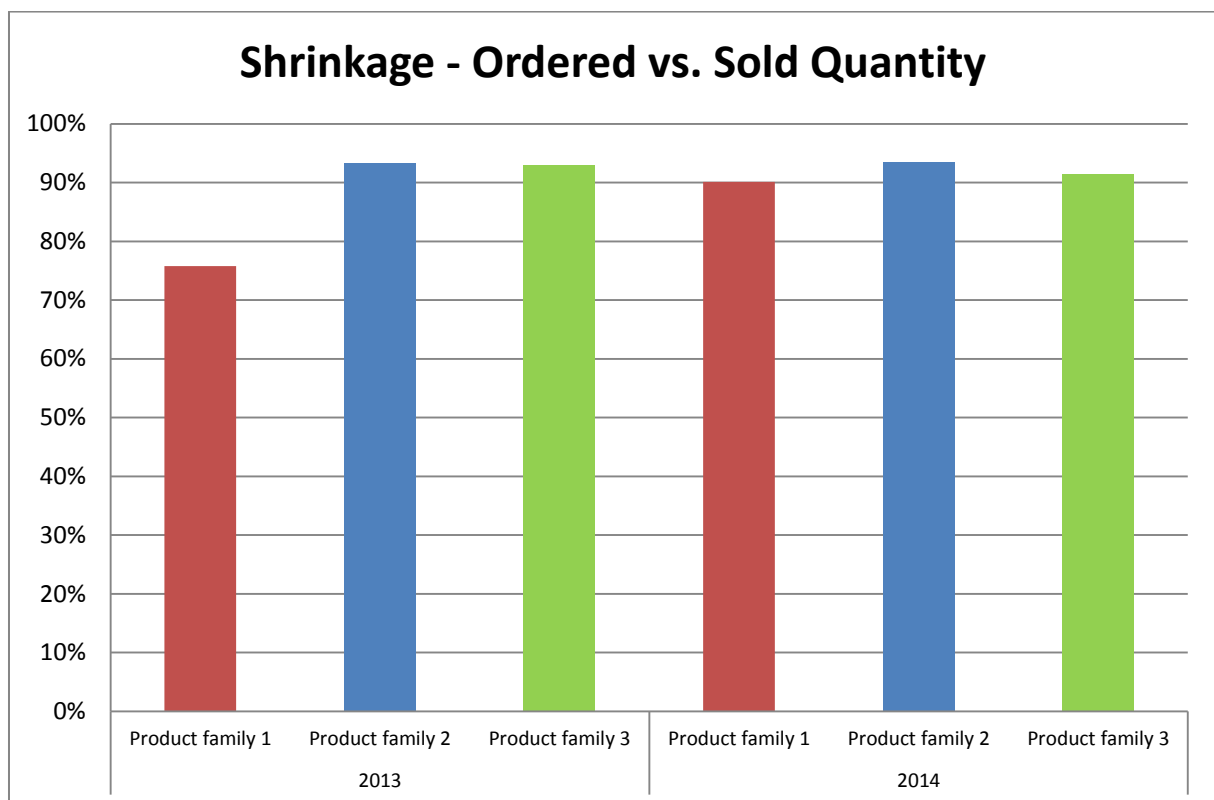


Figure 4-4 - Shrinkage of ordered quantities to sold quantities, where 100% represents full order quantities and sold quantities as order fulfilment rate.

The total production shrinkage for the same three product families was examined and compared to the average shrinkage of all productions in 2013 and 2014. The total shrinkage of all three product families compared to overall average production shrinkage is stated in Figure 4-5. In all cases there is shrinkage in production.

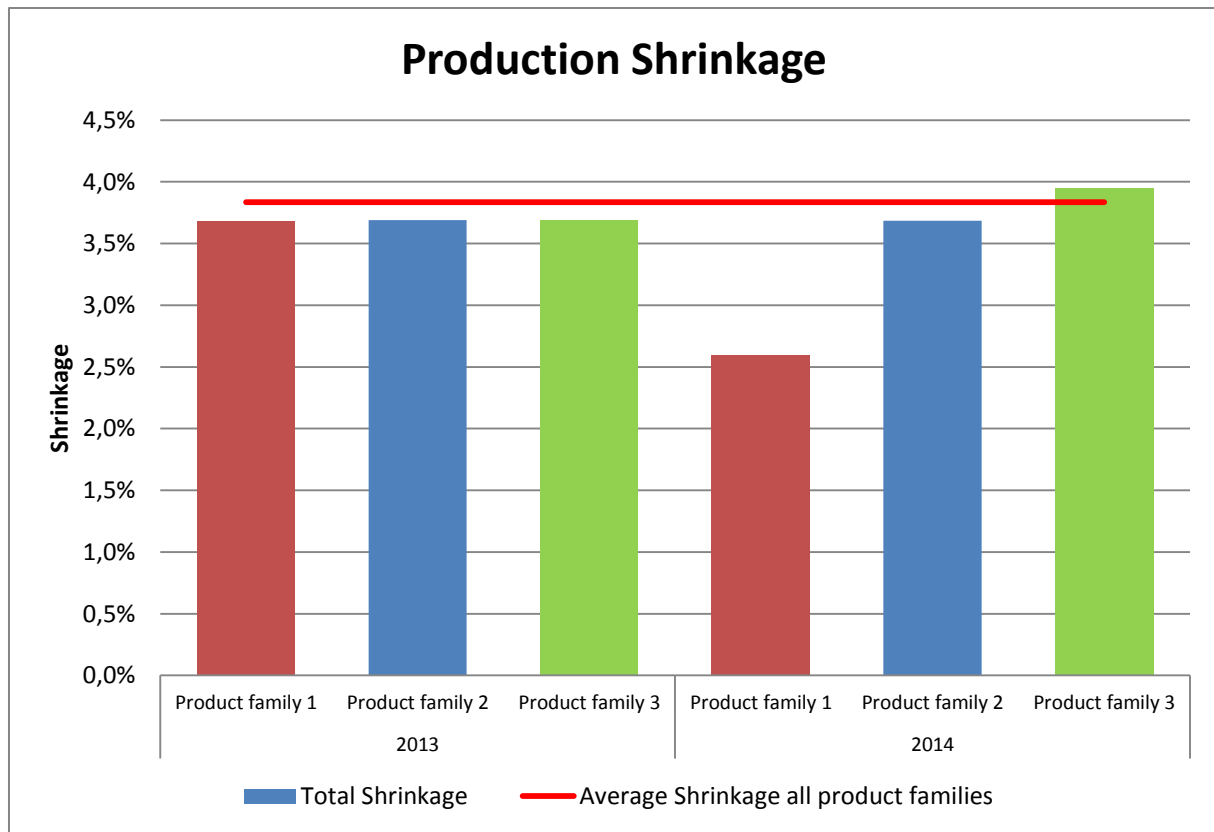


Figure 4-5 –Total production shrinkage for the same three product families was examined, and compared to the average shrinkage of all productions in 2013 and 2014

Comparison of shrinkage of ordered quantities to sold quantities and total production shrinkage in Figure 4-4 and Figure 4-5 shows that Product family 1 has the smallest production shrinkage and the lowest order fulfilment rate.

With order fulfilment rate for all products of average 87% and production shrinkage with the average of less than 4% indicates that not only the production effects order fulfilment rate. The process from after production to sales must account for up to almost 10% of the loss in order fulfilment. This indicates that production shrinkage is not the only factor contributing to order fulfilment rate. Other factor are for example, lack of packing materials, prioritization in packing leading to partial order deliveries as well as deviations and human errors.

Figure 4-6 shows the batch shrinkage trends of the three product families in 2013 and 2014. The shrinkage of each produced batch is stated. Product family 1 has noticeably the smallest and constant shrinkage while there are more fluctuations in Product family 3. Every product

has a fixed maximum batch quantity and even if production starts aiming at this optimum quantity there are factors such as API status or production frailty that can affect the final outcome of the production. However there is something in the process from production to delivery that needs to be examined further.

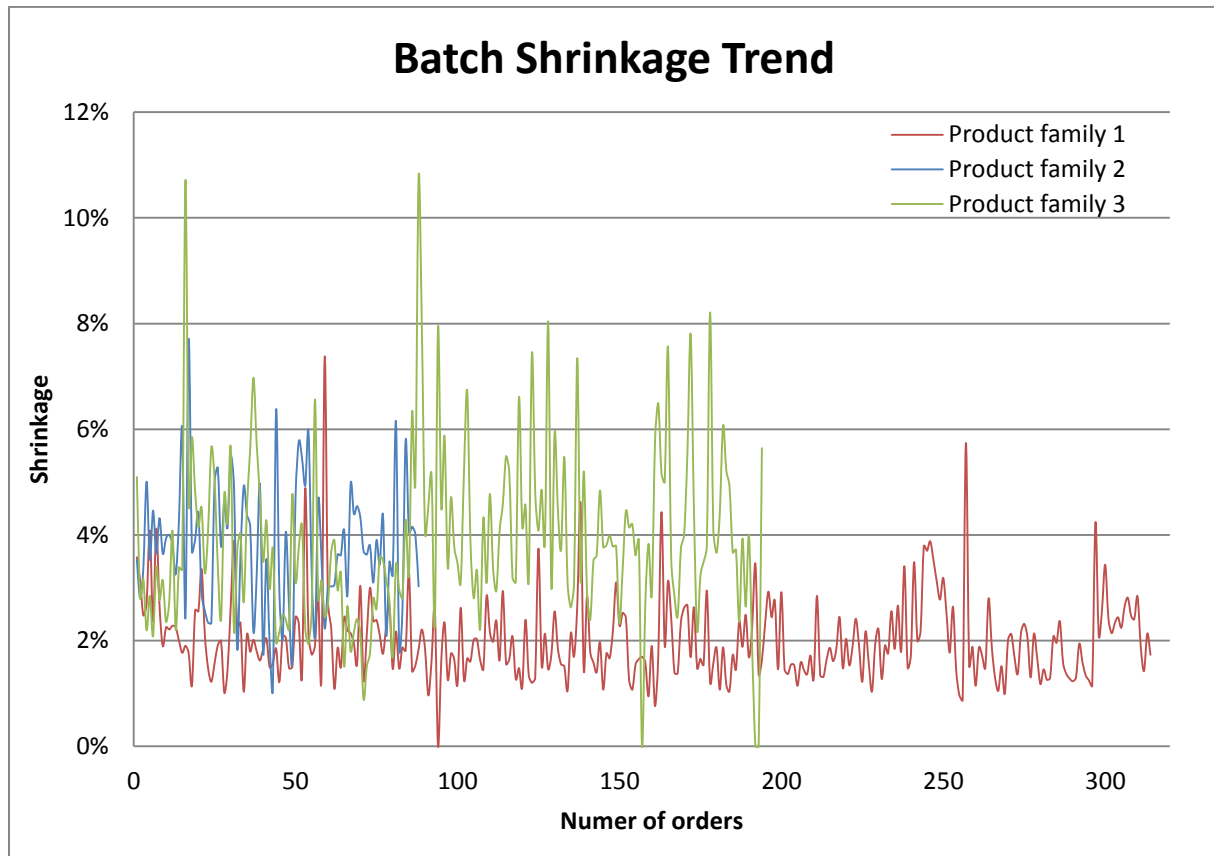


Figure 4-6 – Batch shrinkage trends of three product families in 2013 and 2014, showing shrinkage of every batch produced.

Finally the differences between ordered quantities, sold quantity, production shrinkage were examined. Figure 4-7 shows the difference in fulfilment rate. Where zero represents the total order quantities of each product family, compared to planned production quantities in red, actual production outcome in green and actual sold quantities in purple. As the figure states Product family 1 has only order fulfilment rate of around 75% in 2013. Reasons for this shrinkage can be explained as causes from order combinations late in the process, partial deliveries as well as bulk produced in late 2013 was not packed and sold until beginning of 2014.

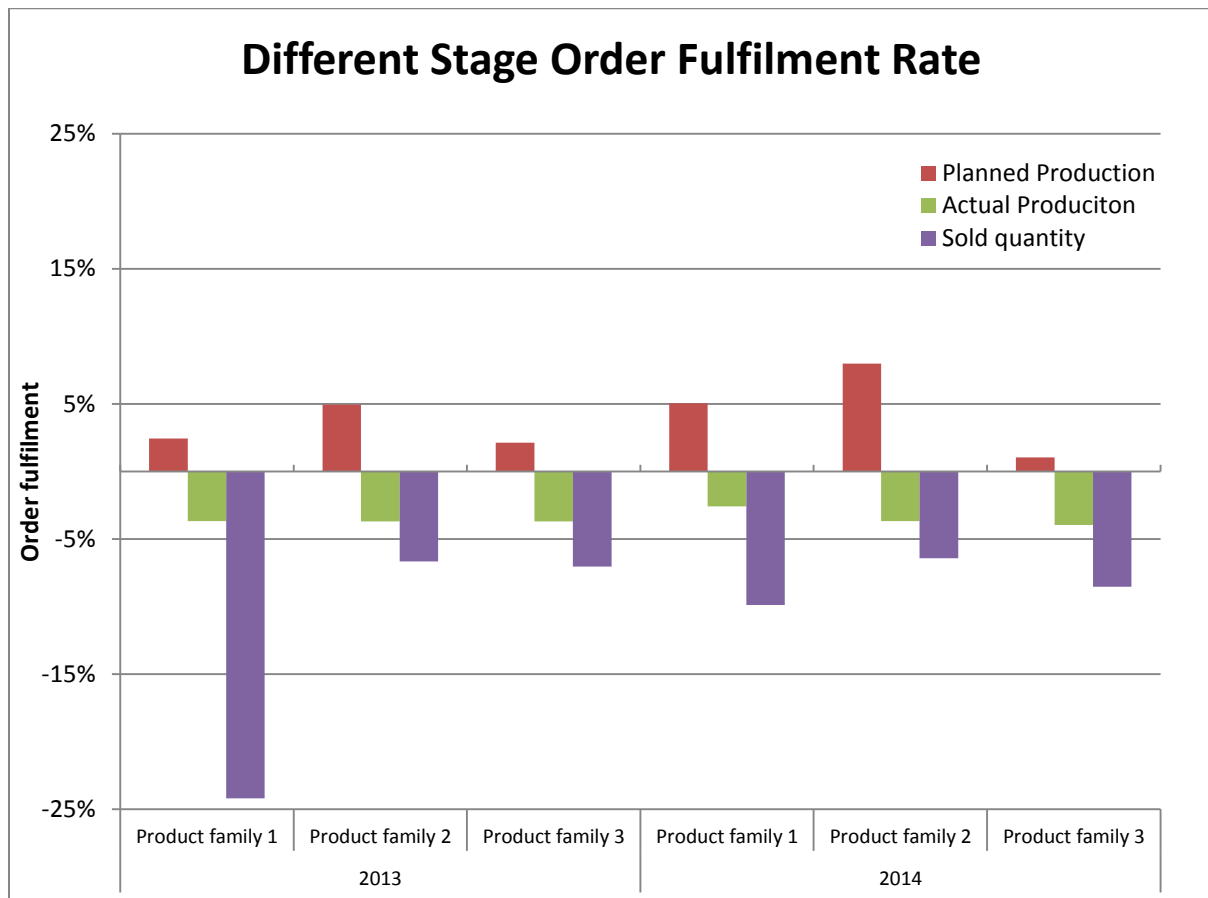


Figure 4-7 – shows the difference in fulfilment rate, where zero represents the total order quantities of each product, compared to planned production quantities in red, actual production outcome in green and actual sold quantities in purple

According to the data there is room for improvement in order fulfilment which consequently can lead to higher profit margin. However production quantities in the last weeks of a year may not be accounted as sold until beginning of the next giving results of less order fulfilment.

Aside from production shrinkage there are also a number of tablets used for sampling purposes for every SKU packed. The sample size can vary depending on how the batch is divided on to individual SKUs, it can be from a couple hundred to tens of thousands of tablets depending on the batch allocation. This may lead to large portion of the production batch used for sampling. Especially if the orders are small and production batches divided between many SKUs. However it is harder to account for shrinkage resulting from unstable products,

deviations and stability sampling or insufficient inventory of packing materials and scrapped production.

4.2.2 Proposed Changes

According to the above findings there is room for improvement. Proposed solutions include finding the optimal production batch quantities which lead to the highest possible order fulfilment rate while keeping work in progress inventories at minimum. Aiming at using aggregate planning tools and focuses on production levels, customer satisfaction and maximizing profits.

1. Implement shared data file used for production quantity determination.

Creation of a functional and shared data file with the main focus on using shrinkage and campaign information to calculate highest possible production quantities. It is easily implemented and was created with the goal of a production resulting in the best possible order fulfilment rate to the customer.

The shared data file was created according to the flowchart in Figure 4-8. First (1) data is manually added into the file and then the data file uses the data to (2) access attached database gathering data which are used to set constraints and boundaries to the calculations. At the same time (3) the method implemented in the spreadsheet uses the data about order quantities to calculate the total ordered quantities and adjusts the total quantity needed for production according to available inventory.

Next (4) the proposed method adjusts the quantities according to the available shrinkage information gathered in the database. The method uses the number of SKU (5) added to the sheet to calculate sample shrinkage and adjusts the quantities once again to the total quantity needed, given all shrinkage factors. Then (6) the sheet accounts for the allowed 110% order fulfilment rate by increase the total production quantities by 10%. At this point (7) it calculates the total number of batches needed to produce that ideal batch quantity. Note that this number can add to part batch quantities and needs to be adjusted to maximum full batch

quantity. If (8) next production campaign is close by and can use extra production from this campaign the batch quantities are rounded up (9) to the next full batch quantity and the extra production is allocated to inventory. However if the extra quantities cannot be used the number of production batches is rounded down to the next full batch quantity. Finally (10) the allowed production is allocated to individual SKU to ensure maximum possible order fulfilment. An example of the shared data file is in the appendix.

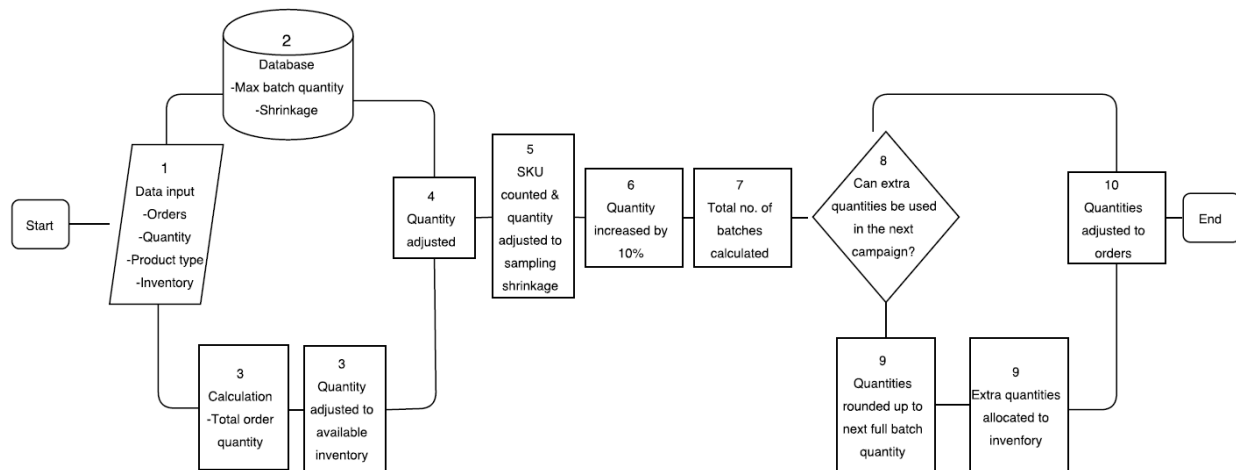


Figure 4-8 – Flowchart representing the main functional elements of a shared data file designed to calculate maximum allowed production batch quantities, given orders, quantities, product type within a product family, inventory and campaign information.

The database holds data about production type, maximum production quantity and average shrinkage. There the average shrinkage for each production type is the average shrinkage for the total product family calculated with production data from the past two years. The sampling shrinkage is also relevant as each SKU requires certain amount of samples with every batch packed. The data used is the overall average sampling size from the last two years. The sheet however only counts the SKU per campaign and does not take into account multiple batches per SKU.

This is a very general model that uses only limited amount of information. For example it can only calculate production quantities of one product at the time not the campaign as a whole. It only allocates tablets to individual SKU not by batch. It assumes that the person using the sheet has already added all orders to the campaign and adjusted their order to best fit the detailed plans as explained in the proposed solutions part of the Planning process results.

Even so it is easily implemented low cost tool which can immediately start increasing order fulfilment.

Figure 4-9 shows order fulfilment rate of each production campaign of product family 1 in 2014, where actual sold quantities are compared to estimated sales when using the shared data file. The order fulfilment increases in almost every campaign resulting in 19% overall estimated sales increase.

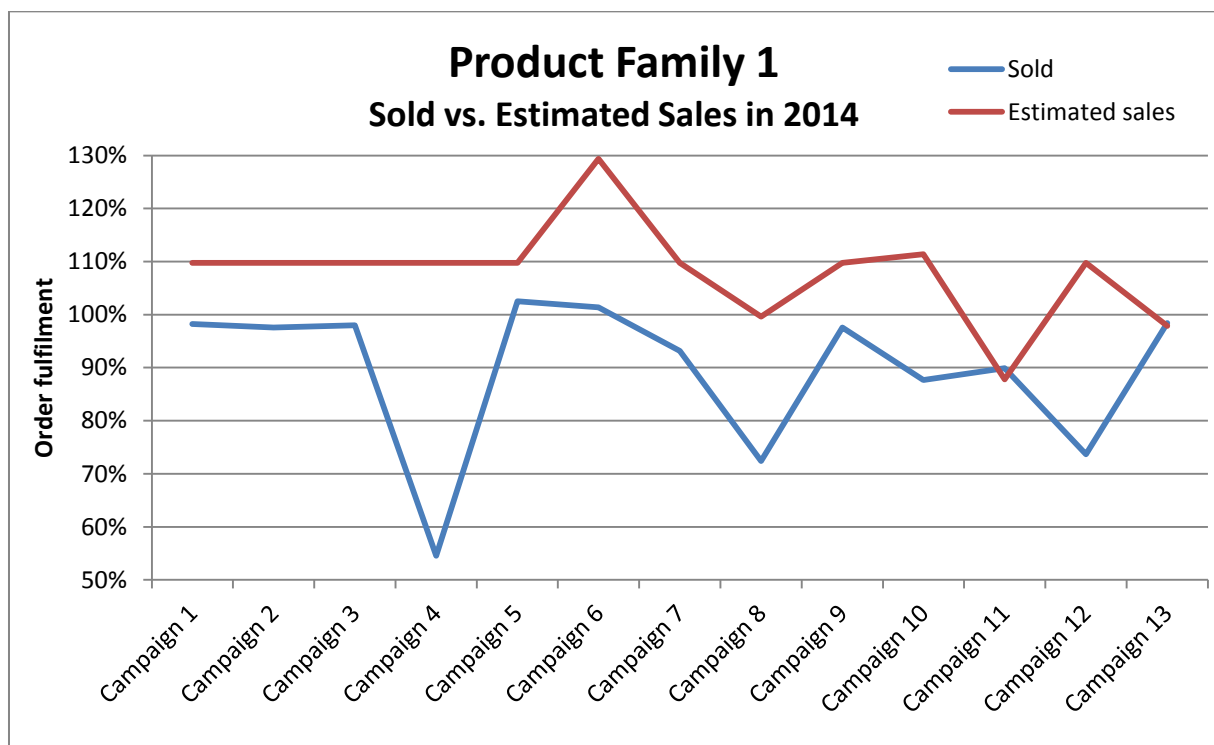


Figure 4-9 - Order fulfilment rate of product family 1 in 2014, where actual sold quantities are compared to estimated sales when using the shared data file.

2. Creating optimization model used for production quantity determination.

Another proposed change is to use an optimization model where the maximized allowed production batch quantities resulting in highest possible profits are determined by using the above criteria of production shrinkage, the less important risk factors as well as costs such as production, inventory and scrapping costs.

The model is based on integer optimization techniques and is designed to assign production quantities (batches) to a predefined campaign setup with the goal to maximize the allowed production quantity and profit, with respect to shrinkage, allowed maximum order fulfilment, inventory and raw material status, campaign schedule as well as including inventory, production and scrapping cost.

Indexes

i : product type

Parameters

α_i : production shrinkage of product type i

β_i : The allowed proportional extra quantity of product type i
(usually equal to 10%)

OQ_i : total order quantity of product type i to be delivered to customers

P_i : profit of product type i

C_i : cost of scrapping and inventory allocation of product type i

M_i : raw material status for product type i i. e. an upper limit due to raw material availability on the number of batches that can be produced of product i

Variables

n : no. of product types in campaign, $i \in n$

Q_i : total no. of production batches produced of product type i

U_i : extra production quantity of product type i either allocated to inventory or to scrapping

I_i : total inventory of product i before production starts

The objective of the model is to maximize profits by increasing number of production batches in a production campaigns depending on inventory status, production and scrapping cost. It (1) is proposed to maximize the total number of batches Q_i allowed in a production campaign, which give the highest possible profit P_i . Where P_i is composed of values of revenues minus cost. The objective function is subject to finding number of batches for each product type i in the production campaign. It uses the variable U_i and parameter C_i to assess if extra production should be assigned as unallocated inventory or if scrapping is feasible of product i . It calculates the cost of scrapping and inventory allocation of the extra production of product i and evaluates whether the profit of sold production quantities make up for the cost of scrapping or allocating to inventory.

$$\max \sum_{i=1}^n P_i Q_i - \sum_{i=1}^n C_i U_i \quad (1)$$

Constraint (2) is used to set the value of the variable U_i equal to the amount of surplus production of product i .

$$Q_i - ((1 + (\alpha_i + \beta_i)) \cdot (OQ_i - I_i)) \leq U_i \quad \forall i \quad (2)$$

Where U_i is a continuous equal to the surplus production of product is i , it can be larger or equal to the total number of production batches Q_i minus updated total order quantity. The updated total order quantity needed is calculated from, the total order quantity of the campaign which is defined as OQ_i because it has an effect on the production needed in the campaign as the quantity differs between campaigns and products. In some cases the campaign can use production already on hand in the inventory I_i . It is used to decreases the production quantity needed. To account for shrinkage the production shrinkage is defined as α_i and the quantity that needs to be produced is increased by the shrinkage. β_i is used to increase the allowed production quantity by the optimal order fulfilment.

To follow the JIT practice of keeping inventories at a minimum and producing to customer demand the extra production U_i is constraint to being greater or equal to 0 and less than 1. The surplus production should be less than single batch as is ensured with constraint (3).

$$0 \leq U_i < 1 \quad \forall i \quad (3)$$

To make sure that the total number of production batches of product i is equal to full batch quantities Q_i can only be an integer number greater than zero as ensured with constraint (4).

$$Q_i \in \mathbb{Z}^+ \quad \forall i \quad (4)$$

And constraint (5) at the same time makes Q_i quantities be less than or equal available raw materials M_i .

$$Q_i \leq M_i \quad \forall i \quad (5)$$

Constraint (6) then makes sure that initial inventory levels can never be less than zero.

$$I_i \geq 0 \quad \forall i \quad (6)$$

Constraint (7) is an alternative constraint that can be used to make sure that the model delivers the minimum required production quantity.

$$Q_i \geq (1 + (\alpha_i + \beta_i)) \cdot OQ_i - I_i \quad \forall i \quad (7)$$

Assumptions and limitations

When creating the model it was assumed that all orders have unit weight to make the model easier to work with. It also assumes that the orders have already been assigned to the production campaign and that the total order quantity is a constant assuming that orders will not be moved between campaigns. It also assumes that unallocated inventory can be used to decrease the production quantities but it does not account for the age or expiry of the production in a direct way as C_i can be both scrapping or inventory cost depending on expiry and how often product i is produced.

4.2.3 Risk Factors

In the case of order fulfilment there are a few risk factors that need to be addressed. These proposals assume that campaigns have already been set up and are only for adjusting the final production quantities within a campaign. Therefore they do not address all issues related, for

example it does not account for if there is capacity available on the production machines or if there is need to increase raw material status for greater optimization.

As the unit has been selling less than ordered quantities for some time it is possible that the customer is aware of this and places orders or forecasts accounting for low order fulfilment. When the orders start to have increased order fulfilment rate the customer will realize the change and adjust their plans resulting in decreased order quantities to the unit, resulting in only short term profit increase.

5 Conclusions

In the pharmaceutical industry it is essential to work according to GMP standards where quality is essential, and as indicated in the above results there are few main areas where improvements are possible for the production unit. According to the results presented in this study there are three changes proposed to the overall production process. Where standardization, elimination of non-value added activities, waste and inventory levels are the main focus areas like stated in lean management theory.

Implementing the same working standard for the overall production process can improve the process efficiency, decrease likelihood of non-value added activities as well as decreasing inventory levels. Assigning batches to SKUs later in the process according to production readiness can consequently lead to non-value added activity reduction. Working file combination leading to reduced working file quantity and waste full work as well as increase overall efficiency between people and departments.

The results from order fulfilment rate examination also indicate that production shrinkage as well as packing, sampling and others can effect order fulfilment. By examining the average shrinkage and depreciation an option of easy functional shared data file was created. There the impacting factors for production setup are used to maximize production quantities to get as much possible order fulfilment rate. This tool could be easy to implement and create higher fulfilment rate and increase profit margin fairly quickly. As well as by combining forces of the production process improvements and implementation of the shared data file, order fulfilment could be increased.

Creation of optimization model however is a more complex process which needs to be examined further as the model presented expects the campaign setup to be ready before execution. Not including criteria such as campaign time, capacity or production machine

availability can lead to incomplete results. It however is a good indicator of how the process could be optimized in the long term.

As this optimization model only focuses on the low hierarchical uncertainty level and not on the higher one it could be beneficial to combine the model with the optimization models from the higher levels by creating optimization model for the total hierarchical framework. Stefansson et al. (2006a), Ásgeirsson et al. (2011) and Guðmundsdottir (2012) built different optimization models focusing on campaign scheduling at the higher hierarchical levels. Collaboration of efforts between results of this study and their previous work could prove beneficial.

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7 Appendix

	client order				allocated from		expected production	expected fulfillment rate
	Orderno	number	SKU	name	order quantity	production		
1	101010		123456	Product 1	10,000	12,257	11,684	116,84%
2	101011		123457	Product 2	25,000	30,642	29,211	116,84%
3	101012		123458	Product 3	150,000	183,852	175,264	116,84%
4	101013		123459	Product 4	300,000	367,704	350,527	116,84%
5	101014		123460	Product 5	50,000	61,284	58,421	116,84%
6	101015		123461	Product 6	750,000	919,261	876,318	116,84%
7						0	0	#DIV/0!
8						0	0	#DIV/0!
9						0	0	#DIV/0!
10						0	0	#DIV/0!
11						0	0	#DIV/0!
12						0	0	#DIV/0!
13						0	0	#DIV/0!
14						0	0	#DIV/0!
15						0	0	#DIV/0!
16						0	0	#DIV/0!
					1,285,000	1,575,000		
					Total order quantity	Total produced quantity		

Product type	2006203
Total order quantity	1,285,000
Inventory level	0
Adjusted quantity 1	1,285,000
Batch size	225,000
Average shrinkage	4.67%
Adjusted quantity 2	1,345,027
SKU quantity in campaign	6
Sampling shrinkage	3000
Adjusted quantity 3	1,348,027
Allowed extra quantity	10%
Adjusted quantity - 4	1,482,830
No. of batches needed	6,59
Is extra production allowed?	Yes
Updated no. of batches	7
Final production quantity	1,575,000
Unallocated / inventory	0
Ratio of production unallocated/inventory	0.00%