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To Optimize Product Scheduling in Multi-Pharmaceutical Product in Pharmaceutical Industry

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ABSTRACT: Efficient product scheduling in pharmaceutical manufacturing is a critical operational challenge due to the high complexity of processes, frequent changeovers, and stringent delivery requirements. Unlike other industries, pharmaceutical scheduling prioritizes on-time delivery to avoid costly stock-outs and regulatory repercussions. In a multi-product setting, manufacturers must continuously adapt schedules to fluctuating demand, resource availability, and the intricacies of production across different product lines. This involves harmonizing market-driven requirements, process constraints, and plant capacities to maximize responsiveness and minimize costs.

Advanced optimization techniques, such as demand-driven scheduling, finite capacity scheduling, and MILP models, are increasingly applied to create flexible schedules that can respond effectively to evolving circumstances. Digital tools and centralized decision support systems further enhance coordination between production stages and improve overall resource utilization. Incorporating simulation models and automated scheduling can significantly improve control over operations, reduce idle time, and facilitate faster, more reliable transitions between product runs.
Ultimately, the optimization of multi-pharmaceutical product scheduling enables manufacturers to lower costs, boost customer service levels, and maintain compliance with industry regulations—supporting the competitiveness and resilience of pharmaceutical supply chains.

I. INTRODUCTION

In the following section, the studied problem area will initially be presented. The problem area studied is then summarised in the problem formulation, which then culminates in the study's aim and research questions. Finally, the scope of the study are presented to concretely present the area that has been studied.

1.1. Background

The pharmaceutical industry can be considered as a complex system consisting of processes, operations, and organizations that work with manufacturing, discovering, and developing medicines (Moniz et al., 2015; Marques et al., 2017). Consequently, the pharmaceutical industry has some exceptional challenges that are not as common in other industries (Kaylani & Atieh, 2016). Some of the challenges presented include a huge product mix with a variation in process times, batching of various lots that share common resources, industry standards that contain huge cleanliness and sterilisation regulations that incorporate campaign lengths, and can differ in accordance with product sequencing (Ghousi et al., 2012; Kaylani & Atieh, 2016; Hering et al., 2021). Production planning- and scheduling activities are thus two of the primary challenges in pharmaceutical industries (Ghousi et al., 2012). On the other hand, due to the growth in global competitiveness and the commitment to meet customer demand in a timely aspect, the pharmaceutical industry is compelled to improve their production planning- and scheduling and develop the utilisation of resources (Wattitham et al., 2015; Kaylani & Atieh, 2016).

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1.2. Problem statement

The pharmaceutical industry is characterised by complex systems, operations, and development phases that are deeply linked with planning- and scheduling problems, leading to a low utilisation of resources (Moniz et al., 2015; Eberle et al., 2016; Marques et al., 2017). Some challenges that are common in the pharmaceutical industry and need to be addressed are large product mixes, batches that share resources, high regulatory demands, and sanitation procedures that can vary according to each specific product (Ghousi et al., 2012; Kaylani & Atieh, 2016; Eberle et al., 2016; Hering et al., 2021). However, one of the greatest challenges for any production company, including pharmaceutical productions, is the composition of a product mix (Badri et al., 2014; Sobreiro et al., 2014).

Aim and Research questions

The aim of this study is to investigate the optimisation of production planning- and scheduling in a pharmaceutical facility using DES. Thus, the following research questions shall be answered:

II. THEORETICAL FRAMEWORK

In the following section, previous research and theories that will be useful for further development in the study will be presented.

2.1. Production planning- and scheduling in a pharmaceutical industry

The pharmaceutical industry performs in an extremely dynamic, highly regulated, and competitive business condition, being one of the main producing branches in Europe (Moniz et al., 2015; Eberle et al., 2016; Marques et al., 2017). The liberalisation of global trade with pharmaceuticals and the coercion from regulatory authorities to lower the price of medicine has led to an increase in generic competition. The price of imitation in the pharmaceutical industry is low in contrast to the price of innovation, which results in generic competition turning progressively harsh, especially concerning financial issues. Regarding that, the pharmaceutical industry is very contingent on patent effective life, being required to provide medicines rapidly and productively (Marques et al., 2017). Aside from this, the pharmaceutical industry has further exceptional challenges that are not as common in other industries (Kaylani & Atieh, 2016). Some of the challenges presented incorporate a huge product mix with a variation on process times, batching of various lots that share common resources, industry standards that contain huge cleanliness, and sterilisation regulations that include campaign lengths, that differ in accordance with product sequencing (Ghousi et al., 2012; Kaylani & Atieh, 2016; Eberle et al., 2016; Hering et al., 2021). Production planning- and scheduling activities are thus one of the primary challenges of pharmaceutical industries (Ghousi et al., 2012). Furthermore, Moniz et al. (2015) and Eberle et al. (2016) state that time-to-market is the most censorious problem in the pharmaceutical industry. To efficiently meet customer demand and sales order, improved and developed production planning and utilisation of resources is therefore necessary (Wattitham et al., 2015; Kaylani & Atieh, 2016). Production planning- and scheduling activities are intended to lower the costs and develop responsiveness of the manufacturing systems (Moniz et al., 2015). Kaylani and Atieh (2016, p. 412) define production planning- and scheduling as “allocating of shared resources during a planning period to competing products in order to meet production requirements.”

2.2. Demand forecasting and production planning

Forecasting methods are used to develop decisions associated to production planning. Demand forecasting has an impact on several practical operations within an organisation including production planning and resource allocation (Ghousi et al., 2012). Production planning that is successful is contingent on the modelling quality of various problem-related features, involving demand uncertainty, production lead times, and capacity. Numerous types of research within inventory literature includes information about demand forecasting (Albey et al., 2015). On the other hand, there is limited information on demand forecasting in production planning research although demand forecasting is a crucial part within production planning (Bóna & Lénárt, 2014; Albey et al., 2015). Forecasts are reconsidered as added information and becomes accessible over the years (Aouam & Uzsoy, 2015). A time series is the primary source of information for forecasting, where this time series consists of a sequence of examinations obtained at frequent periods. The modelling simplifies system synthesis, involvement, and verification, while its forecast benefit planning operations (Box et al., 2015).

2.3. Building the simulation model

The simulation model was built in ExtendSim10 since this was already in use at the studied company. ExtendSim10 is well suited for the situation as it is an established tool for conducting process simulations (Strickland, 2012). The

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approach used in this study was heavily influenced by the twelve steps provided by Banks et al. (2015) with some inspiration from Hering et al. (2021), see Table 1 and Figure 1.

Steps	Description
1. Problem formulation	*The study was defined and clear goals for the simulation were set up. This discussion was held with the supervisor together with the head of production at the site.*
2. Creating a project plan	*A Gantt Chart was created where larger checkpoints were included and described in detail.*
3. Conceptual model	*Inputs, assumptions, basic functionality, and goals were represented in a conceptual model for guidance throughout the study.*
4. Data collection	*By collecting data with Discoverant and organising it in Microsoft Excel the study could extract a Median, First- and Third Quartile of the production times that was used in the simulation model. This step was executed along with the process engineer expert at the company.*
5. Building the model	*Reoccurring meetings with the production team were scheduled once a week for continuous explanation and iteration of the progress. Through these checkpoints the simulation model grew forth over a few months. As a further support this step was performed with help of the supervisor from the company.*
6. Verification of the model	*Verification of data occurred through several test runs, along with an analysis of the simulation model logic, processing times and scheduling together with the supervisor from the company.*
7. Validation of the model	*Validation of the simulation model occurred by the supervisor together with the head of production from the company. Validation has been present to some degree in most steps of building the simulation model.*
8. Production run and analysis	*Test runs were made and analysed for further validation and comparison.*

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9. Implementation as an analysis tool	*The simulation model could be used to analyse production runs and predict future improvements in the production set up.*
10. Implementation as a scheduling tool	*The simulation model could be used as a tool to find an optimised production schedule.*

Table 1 Action plan for the simulation (Source: Own construction)

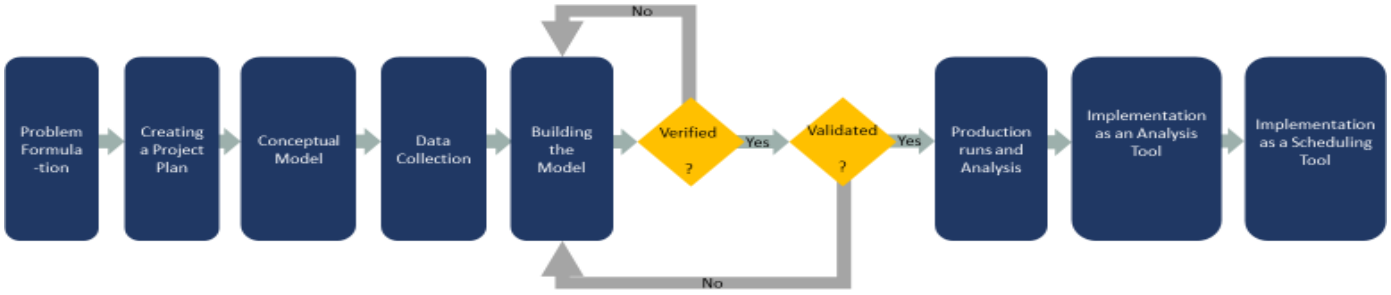

Figure 1 Simulation Process Flow (Source: Own construction)

Analysis implementation

The analysis was based on the results from the simulation runs. Each simulation scenario was aimed to explore different aspects of the production hence they were not all analysed in the same way and each scenario had specific demands for their reliability. The scenarios were run between several times depending on the expectations on the result. For example, the first scenario was run more times than scenario 3, since scenario 1 was more reliant on a statistical average that later could be used as a validation for the simulation. The simulation exported every scenario into a Microsoft Excel sheet after each run where the data was organised in tables, averages and totals were used to study the results. The most studied areas were the queues and the resources, since these areas could give a lot of information about how the production performed (see section 2.3). Queues that grew indicated a bottleneck and low utilisation of operators could indicate an ineffective use of the resources.

2.4. The production environment

The studied production produces medicines in tablet form in a production environment based on a cell layout. Three different APIs divided into 20 different variations are being processed by three production flows consisting of two or four steps depending on the medicine being produced. Each medicine and production step includes specific sanitation and production regulations including sequencing of products, campaign lengths, production times and lead times. In total there are 22 main processes and three preparatory processes that are included in the study where three are supporting activities, six granulation activities, two blending activities, ten compression activities, and four coating activities, see Figure 2 and Table 2. The three production flows are in this study called Medicine A, Medicine B and Medicine C and do not share any operators amongst each other in the current system.

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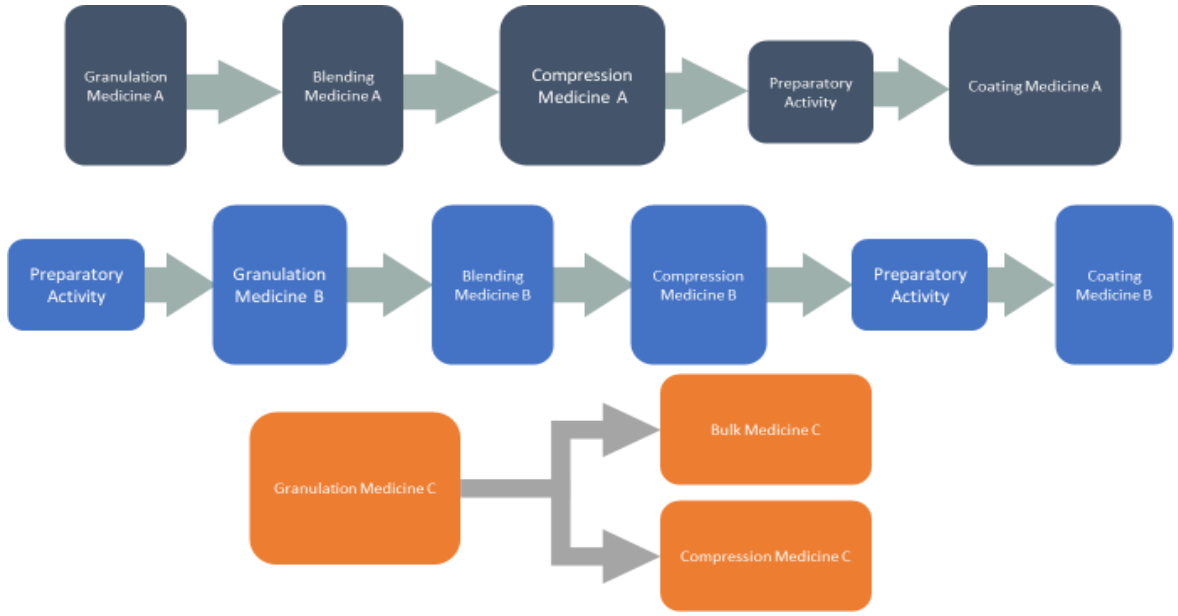

Figure 2 Schematic view of the production (Source: Own construction)

Process step	*Granulation*	*Blending*	*Compression*	*Coating*
Medicine A	*2*	*1*	*4*	*3*
Medicine B	*3*	*1*	*2*	*1*
Medicine C	*1*	*-*	*3 or 4*	*-*

Table 2 Number of machines for each process flow (Source: Own construction)

In the production environment there are three types of sanitation measures depending on the intensity of the sanitation. A- B- and C-sanitation, where A-sanitation is the highest level of sanitation and the longest process. C-sanitation is the lowest level of sanitation measure and the quickest process.

	Medicine A	*Medicine B*	*Medicine C*
Granulation	*4*	*6*	*2*
Blending	*2*	*2*	*-*
Compression	*3 or 4*	*2*	*2*
Coating	*3*	*3*	*-*

Table 3 Number of operators in every step (Source: Own construction)

The number of operators required varies for the different steps in the process. The granulation step requires two operators each for the granulating machines and two operators for the blending machine, see Table 3. One operator is required for each compression machine and one operator each for the coating machines where the supporting activity is included.

2.4.1. Flow for Medicine A

The Medicine A flow consists of two separate variations that are being produced, with most of the demand being for the stronger variation. The granulation requires two operators per facility throughout the entire process, and there are

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four operators stationed in this area to handle two facilities. In this step, there are no regulations on the production sequence between the two variations. However, there are regulations constricting the process to only be operating for 21 days before a major sanitation, A-sanitation, is needed with a duration of 20 hours, see Table 4.

Medicine Type A	*A-Sanitation (h)*	*B-Sanitation (h)*	*C-Sanitation (h)*
Granulation	*20*	-	-
Blending	*6*	-	-
Compression	*24*	*7*	*0.5*
Preparatory	*2*	-	-
Coating	*5*	*0.75*	-

Table 4 Sanitation process times Medicine A (Source: Own construction)

After granulation there is a need for a final blending in the next step. The blending step serves under no specific requirements regarding sequence, but similarly to the previous step, there is a constriction so that every 14 days there is a mandatory A-sanitation for 6 hours and there is one single blender in this flow handled by two operators. Following this step is the compression step consisting of four tabletting machines that require one operator each, thus there are four operators stationed in this area. There are three types of sanitation measures depending on the input of products and time in this area. There is an A-sanitation that takes place every 28 days and lasts for 24 hours. If the medicine changes from one batch to another there is a requirement for a larger sanitation which includes changes of punches. This takes 7 hours to perform and is referred to as a B-sanitation. Because of this there is a need to schedule the production and avoid sanitation as much as possible. Lastly, there is a small C-sanitation measure of 0,5 hours that needs to be done after every batch if no changes are made. Finally, the Medicine A flow enters the coating step

which consists of a preparatory activity and three coating machines. The preparatory activity restricts by an A-sanitation with a duration of 2 hours every 26 hours. The three coating machines are on the other hand restricted by A- and B-sanitations. An A-sanitation takes place every 4 days and occupies 5 hours. The B-sanitation takes place every time there is a change of product and entails 0,75 hours of cleaning.

2.4.2. Flow for Medicine B

The Medicine B flow is very similar to the Medicine A flow. There are two variations of the medicine, and the more potent one is the more demanded product. Firstly, in this production flow there is a mandatory preparation step operated by one operator and every 7 days there is a mandatory A-sanitation with a 7-hour process time, see Table 5.

Medicine Type B	*A-Sanitation (h)*	*B-Sanitation (h)*	*C-Sanitation (h)*
Preparatory	*7*	-	-
Granulation	*20*	-	-
Blending	*6*	-	-
Compression	*24*	*7*	*0.5*
Preparatory	*2*	-	-
Coating	*5*	*0.75*	-

Table 5 Sanitation process times Medicine B (Source: Own construction)

After this follows the granulation step with three facilities to handle the products and two operators are required to run each facility. The preparatory step and the granulation step share the same operators, and thus this could become a restriction in the process. Thirdly there is a final blending step where the three granulation facilities need to share one blending facility which requires two operators. In the blending there is a requirement for sanitation every 14 days that takes 6 hours to perform. The following step is the compression step that consist of two facilities and two operators

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required per facility. The compression of Medicine B is restricted by three kinds of sanitation measures. The A-sanitation has a duration of 24 hours and is required every 28 days. The B-Sanitation is required when there is a shift in variation of the medicine from weak to strong variation, or the other way around. A B-sanitation is 7 hours long, and between every batch there is a shorter C-sanitation with a duration of 0,5 hours. Before the coating there is a need to prepare the solution. Also, once every 24 hours there is a need for a sanitation measure of 2 hours. Finally, the coating step is restricted by one A-sanitation every 4 days that has a duration of 5 hours, and a B-sanitation that is required when changing the recipe where this action is 0,75 hours long. The process is operated by one person and when this step is finalised the medicine can be sent to the lab for a final approval of the batch.

2.4.3. Flow for Medicine C

The Medicine C flow differs more from the other two production flows and includes its own set of constrictions. In the Medicine C flow there are two main types, one with only one API and one with two APIs combined, referred to as the Medicine C1 and the Medicine C2. These are also produced in different size tablets, which will affect the production flow. Medicine C1 has five variations whilst Medicine C2 has seven different variations, both products are also produced in Bulk, with two variations each all of which affects the production flow. The flow itself exists of two activities. Firstly, there is the granulation step, where one machine handles the entire flow of products and is operated by two operators. The granulation step has no restrictions that affect the sequence however, the process is often adapted to the restrictions of the following compression step. The granulation is restricted by an A-sanitation that occurs every 10 days and occupies 14 hours of time, see Table 6.

Medicine Type C	*A-Sanitation (h)*	*B-Sanitation (h)*	*C-Sanitation (h)*
Granulation	*14*	-	-
Compression	*14*	*4*	*1 or 1,5*
Bulk	*14*	-	-

Table 6 Sanitation process times Medicine C (Source: Own construction)

The following step, and the last step in the production flow is the compression. In this cell there are three compression machines and one Bulk blender. The Bulk material is shipped in a powder form, and thus not compressed. This activity requires two operators and has a C/T of 2,5 hours. The other three machines have a compression element and because of this they run slower. These activities require two operators to start the activity and after this one operator can monitor the process alone. The compression machines have complex sanitation regulations that to a high degree affect the production. When handling the Medicine C1 type there is an A-sanitation and a B-sanitation. The A-sanitation is required when the colouring of the tablet is changed, which is between all but two tablets, and this A-sanitation has a duration of 14 hours. Between the two strongest variants there is a requirement for a B-sanitation, this is preferred to the A-sanitation since the process is shorter. A B-sanitation takes 4 hours to perform. If the same medicine is run in sequence, there is a required C-sanitation between each batch with a duration of 1 hour. For the Medicine C2 API there is another set of rules, and they include an A- and a C-sanitation. The seven variants are separated by variations, colouring and size. The ones with the least colour are required to go first in any production sequence. If the same medicine is run in sequence a C- sanitation is required with a duration of 1,5 hours, but if the medicine changes there is a need for an A-sanitation which has a duration of 14 hours. The Bulk process is restricted by an A- sanitation with a duration of 14 hours. This is required whenever the API is changed but can otherwise shift freely between the variations of the tablets.

Conclusion: Optimizing product scheduling across multiple pharmaceutical products is key to achieving operational efficiency, regulatory compliance, and enhanced customer service in pharmaceutical manufacturing. By leveraging advanced scheduling models, integrated digital tools, and data-driven decision-making, manufacturers can minimize downtime, reduce inventory costs, and rapidly respond to market fluctuations. The implementation of these strategies strengthens supply chain resilience, supports timely delivery, and maintains high quality standards—ultimately driving the competitiveness and sustainability of pharmaceutical operations in an increasingly complex and regulated industry

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