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# LEAN IMPLEMENTATION BENEFITS FOR THE PHARMACEUTICAL COMPANY - FROM PROJECT TO IMPLEMENTATION

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**Abstract.** The primary purpose of this paper is to identify the benefits of LEAN methods implementation for the pharmaceutical company from theoretical and practical points of view. The methodology employed in this study is a qualitative content analysis with open coding of the selected literature followed by identifying a consensus view across employees using the Delphi method. The research started as a study project and has identified several LEAN implementation benefits, such as reduced losses, improved document, and systems effectiveness, improved processes, and reduced manufacturing errors. The selected LEAN methods were applied, and immediate improvements were demonstrated. The study results are based on the employees' opinions and the practical application of LEAN methods in only one pharmaceutical company. This study could be beneficial for the top and middle-level pharmaceutical company managers considering improving their operational activities by applying LEAN methods. This paper identifies the benefits of LEAN methods implementation considering the specifics of pharmaceutical manufacturing. The study also demonstrates how the theoretical findings can be applied in a real manufacturing environment.

***Keywords:*** *drug manufacturing, efficiency, improvement, lean manufacturing, lean methods, pharmaceutical industry.*

**JEL Classification:** L65, O14

## INTRODUCTION

In the pharmaceutical business, significant losses are caused by various factors, such as waste, errors, poor process management leading to low-quality products, and the associated risks.

The request for high-quality medicine increases yearly; therefore, manufacturing companies increase their capacities. Considering the increasing costs, especially the current increase in energy resource prices, minimizing the number of production deviations resulting in losses is necessary.

Standby time and waiting are classified as production waste that generates financial losses and eliminates opportunities for the company to make a profit (Indrawati, 2019). Reducing losses by improved efficiency is critical for companies to be more competitive than others.

The introduction of LEAN methods into production focuses on improving processes and the quality of the final product by reducing process variations and

unnecessary activities and avoiding product defects (Lokpriya, et al., 2022). The usage of the Poka Yoke method can lead to the reduction of human mistakes that often happen in manufacturing. Jidoka method excludes the possibility of quality defects, stopping processes where an error occurs. LEAN methods implementation can help to enhance both production and laboratory processes by improving productivity and efficiency (Durakovic, et al., 2018, Szczepaniak, 2019).

The research question in this study is what are the benefits of LEAN methods implementation for the manufacturer of pharmaceutical products? The methodology employed in this research was qualitative content analysis with open coding of the scientific literature and consensus view across employees using the Delphi method. The research period was from February to May 2022. During this period, an analysis of 15 literature sources was carried out; certain LEAN methods were implemented, ten pharmaceutical company employees were involved in the survey.

The research is a part of a study project with Master level studies in the field of Quality management.

# 1. LITERATURE REVIEW

The literature search used the following keywords: Lean, manufacturing, approach, methodology, lean manufacturing, pharmaceutical industry, and drug manufacturing.

Three scientific databases were used for the literature search: Scopus, EBSCOhost, and ScienceDirect. These databases were chosen because of a large number of literature sources related to the pharmaceutical industry and production.

The following exclusion criteria were applied: the publications in the English language only. The keywords were combined, using Bull operators *AND* and *OR*. As a result, 15 scientific literature sources in the English language were selected for further analysis. The list of the literature sources selected for the qualitative content analysis is in Appendix 1. The authors of the publications are from different countries – the United Kingdom, India, Indonesia, Thailand, and Malaysia.

A qualitative content analysis was used for the systematization and analysis of the scientific literature sources. From the selected literature, the text fragments that answered the research question were highlighted. The information was summarized and analyzed in Excel tables. Codes were written out from the source fragments (answers to the research question). The results of the qualitative content analysis are represented in Figure 1.

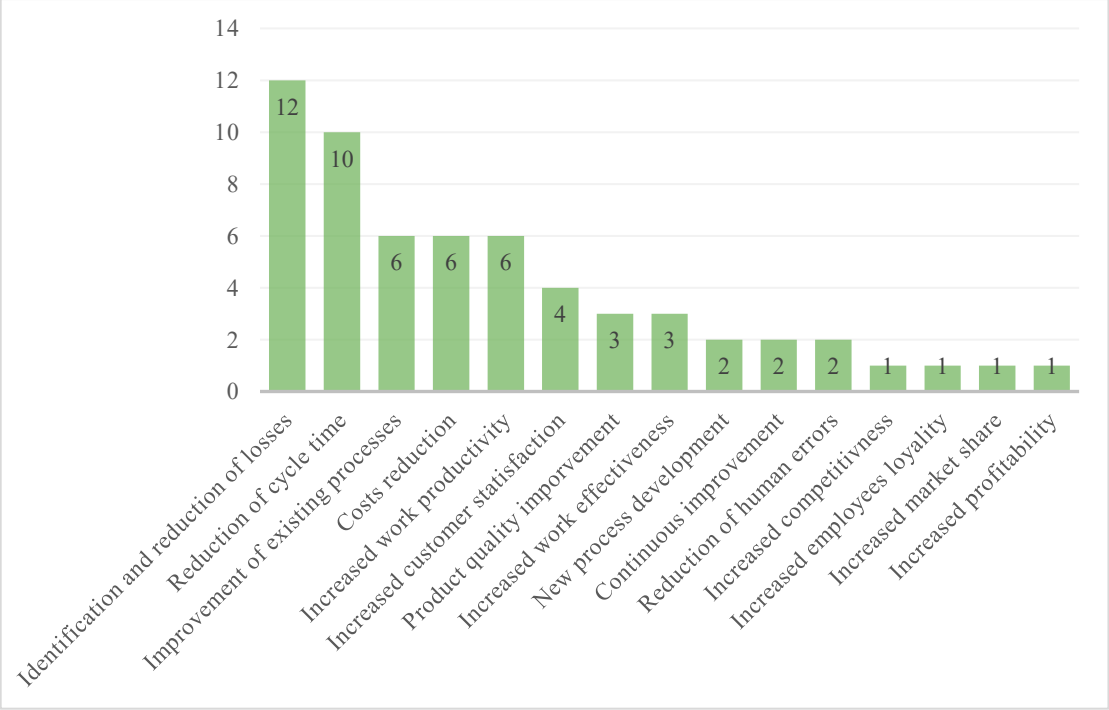


**Fig. 1.** Lean implementation benefits identified in the literature.

The codes were then systematized and categorized into two categories – benefits for the company and benefits for employees, as shown in Table 1.

**Table 1.** Lean implementation benefits categories

| Benefits for the company | Benefits for employees |
|---|---|
| 1. Identification and reduction of losses (*n*=12) | 1. Increased work productivity (*n*=6) |
| 2. Reduction of cycle time (*n*=10) | 2. Increased work effectiveness (*n*=3) |
| 3/4.Costs reduction (*n*=6) | 3. Reduction of human errors (*n*=2) |
| 3/4. Improvement of existing processes (*n*=6) | 4. Increased employees' loyalty (*n*=1) |
| 5. Increased customer satisfaction (*n*=4) | |
| 6. Product quality improvement (*n*=3) | |
| 7/8. New process development (*n*=2) | |
| 7/8. Continuous improvement (*n*=2) | |
| 9/10/11.Increased competitiveness (*n*=1) | |
| 9/10/11.Increased market share (*n*=1) | |
| 9/10/11.Increased profitability (*n*=1) | |

"Identification and reduction of losses" is the category mentioned the most in the literature. Waste reduction and efficiency improvement are the main objectives of improving processes (Durakovic et al., 2018). The company should establish a dedicated team of employees who have been in-house trained on LEAN methods implementation to focus on waste elimination (Ismail et al., 2014).

The production cycle is a control mechanism to evaluate production efficiency and capability. This cycle time includes all activities related to production, starting with resource planning, supply of excipients, and production and delivery of the finished

product to the client. Reducing cycle time in production has many benefits – the shorter the cycle time, the fewer losses (Ismail et al., 2014). Reducing the cycle time results in product quality improvement. Since all unnecessary activities in the manufacturing process are eliminated, the possibility of mistakes and errors is also diminished. Reducing cycle time requires teamwork and management involvement to prioritize those critical points that are the causes of the most significant waste (Narottam et al., 2020).

The publications also stress the importance of reducing non-value-added activities in production to improve processes and increase customer satisfaction (Durakovic et al., 2018). The reduced cycle time, improved planning processes, and the elimination of standby lead to increased productivity, improved quality, and reduced costs (Adly Ishak et al., 2018).

After LEAN implementation in manufacturing processes, employees' efficiency and productivity are increased since less time is required for equipment changeover and retooling, increasing equipment availability and performance (Purwanto et al., 2020). LEAN implementation in pharmaceutical manufacturing improves productivity, quality, and customer orientation while eliminating waste and reducing costs (Dixit et al., 2022).

## 2. EMPIRICAL RESEARCH

The empirical research was performed in Latvian pharmaceutical manufacturing company operating on the market for over 70 years. The company is well known for its qualitative and innovative products. The company already have integrated management system according to ISO 9001, ISO 14001, ISO 50001 and ISO 45001 standards requirements. The company constantly strives for the development implementing new production and quality improvement methods. The empirical part of the study consists of a questionnaire followed by the application of the Delphi method. Experts who participated in the questionnaire and whose opinion was used in applying the Delphi method are the employees of the pharmaceutical company. The expert group consisted of ten pharmaceutical company employees who have worked for at least ten years in the company. The average employment time in the company is seven and a half years; therefore, the employees who have worked the longest time have experience in the company processes and accepted the company's culture. The experts were also the employees who participated in the early stages of the LEAN implementation in the company.

Both female (70 %) and male (30 %) representatives were selected as experts. All experts have obtained at least master's degrees in either chemistry, pharmacy, quality management, or business management

The majority of experts are female; however, it shall not significantly impact the study results, according to the authors. As previously mentioned, all selected experts have worked at the company for at least ten years and have at least a master's degree. Figure 2 shows the education level of the experts. Several experts have obtained more than one master's degree; the most common combination is a master's degree in Chemistry or Pharmacy and a master's degree in Quality Management. Experts were chosen specialists from different divisions who are familiar with the company's processes (both manufacturing and quality control).

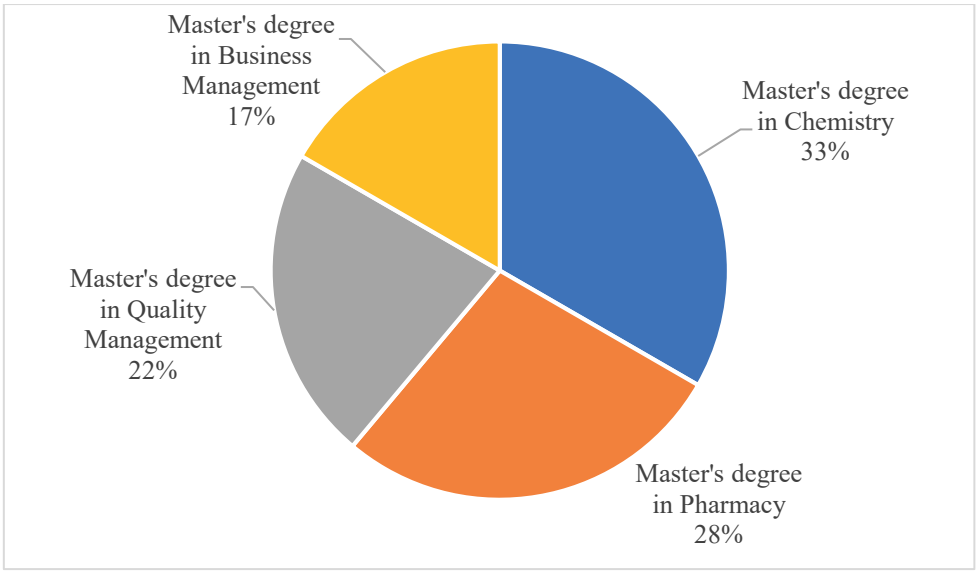


**Fig. 2.** Education level of the experts.

The questionnaire consisting of one open-ended question was sent to the experts, who were asked to name at least two major areas in pharmaceutical manufacturing and in a laboratory where the most significant wastes can occur. Figure 3 represents the results. Several experts have named more than two areas for improvement.


**Fig. 3.** Major areas in pharmaceutical manufacturing and laboratory where the most significant wastes can occur.

According to the experts, the most significant waste occurs due to the system's inefficiency; for example, in a document management system – several documents contain the same information, and the update of documents must be done for each document resulting in a waste of time. In process management – no efficient procedures and instructions result in more time spent on employees' training, or the training is inefficient, resulting in production mistakes and human errors. Insufficient training and

an unproductive work environment were mentioned as the areas for concern. The goals not being defined leads to confusion among employees.

After the questionnaire was completed and the results analyzed, the practical implementation of LEAN methods was performed in areas where the most significant waste can occur. Theoretical LEAN training, where the application of various LEAN methods and their benefits was taught, was organized in the company for all company employees involved in the LEAN implementation. During the hands-on training, simulations with different LEAN methods were performed to find the suitable method to implement for the specific process.

The practical implementation of LEAN methods was done in various departments. For example, the 5S methodology was applied to one of the laboratory storage rooms. The room was used for the storage of laboratory equipment and tools. There was no formal responsibility for the room and its content and no storage rules. Much time needed to be spent to find the necessary item, for example, glows, in the room, not to mention finding the right size of gloves, as shown in Figure 4.

**Fig. 4.** The storage room before the 5S implementation.

The objective of the 5S method implementation was set as follows: using minimal time and steps, all equipment and tools must be found by any employee who enters the storage room. The five steps of the 5S methodology were followed. At the room entrance, a map shows the location of all equipment and tools. The equipment is sorted by size and functionality and marked by different colors. The visual signs on the floor allow reaching the necessary equipment in the shortest possible time. The improved storage room is demonstrated in Figure 5.

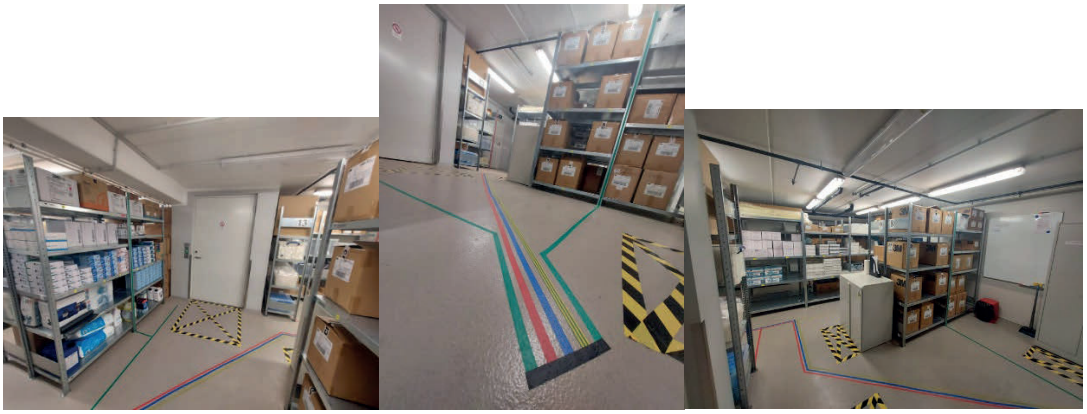

**Fig. 5.** The storage room after the improvement.

With the introduction of LEAN methods in the company, the inventory of documents has been carried out, eliminating unnecessary documentation and duplicates. The process review was performed combined with the update of the process description. With the documentation update, internal system audits have been carried out, resulting in systems improvements. Internal audits and risk analysis have helped identify critical points in the processes – where errors occur, most affecting product quality. As a result of the improvement, it was possible to reduce the number of production errors.

Based on the qualitative content analysis of the selected literature and the results of the experts' survey, a new questionnaire consisting of 15 statements was prepared and sent to the same experts. The statement listed LEAN implementation benefits. The experts were asked to rate the statements from 1 to 15, where 1 marks the most significant benefit of LEAN implementation in the company and 15 marks the least significant benefit. To identify whether the consensus has been achieved by the exerts, Kendall's coefficient of concordance $W$ was calculated using the formula (1).

$$W = \frac{\sum_{j=1}^{m}((\sum_{j=1}^{n} A_{ij}) - \bar{A})^2}{\frac{1}{12} \times n^2 \times m| \times (m^2 - 1)} \quad (1)$$

Where

$\bar{A}$ - arithmetic mean value of the overall evaluation;

$m$ - number of objects (15);

$n$ - number of experts (10).

Kendall's coefficient of concordance $W = 0.84$ in this study, therefore, the authors assumed there was a consensus among the experts, and no further questionnaire rounds were necessary. In theory, a consensus is achieved when all experts are unified in their opinion; however, in practice, the level of consensus $W$ may vary from 0.51 to 0.80 (Chuenjitwongsa, 2017). The anonymous experts' responses were then aggregated and analyzed, as represented in Figure 6. The results were also communicated to the experts and the company's management via management review in July 2022.

| | Reduction of cycle time | Reduction of human errors | Increased employees motivation | Increased document and systems effectiveness | Improved processes | Reduction of waste movements | Improved communication | Improved training system | Reduction of manufacturing errors | Reduction of laboratory errors | Processes are easier to understand | Costs reduction | Improves planning works | An improved environment of the workspace | Clearly defined goals |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| *Expert 1* | 6 | 7 | 8 | 2 | 1 | 9 | 14 | 11 | 3 | 10 | 4 | 5 | 12 | 13 | 15 |
| *Expert 2* | 3 | 9 | 8 | 1 | 4 | 7 | 15 | 14 | 5 | 10 | 6 | 2 | 11 | 12 | 13 |
| *Expert 3* | 5 | 4 | 11 | 2 | 1 | 8 | 10 | 12 | 3 | 9 | 7 | 6 | 13 | 14 | 15 |
| *Expert 4* | 5 | 6 | 9 | 2 | 3 | 4 | 11 | 12 | 1 | 13 | 8 | 7 | 10 | 14 | 15 |
| *Expert 5* | 4 | 10 | 15 | 1 | 3 | 8 | 13 | 12 | 2 | 5 | 7 | 6 | 14 | 11 | 9 |
| *Expert 6* | 4 | 9 | 11 | 3 | 1 | 6 | 15 | 10 | 2 | 7 | 8 | 5 | 14 | 13 | 12 |
| *Expert 7* | 3 | 10 | 13 | 1 | 2 | 8 | 15 | 9 | 5 | 6 | 4 | 7 | 14 | 12 | 11 |
| *Expert 8* | 4 | 12 | 13 | 3 | 2 | 8 | 14 | 7 | 6 | 9 | 1 | 5 | 10 | 11 | 15 |
| *Expert 9* | 5 | 4 | 11 | 1 | 2 | 9 | 15 | 10 | 3 | 8 | 7 | 6 | 13 | 12 | 14 |
| *Expert 10* | 5 | 6 | 13 | 2 | 1 | 7 | 15 | 14 | 3 | 9 | 8 | 4 | 11 | 10 | 12 |
| ***Total points*** | 44 | 77 | 112 | **18** | **20** | 74 | 137 | 111 | **33** | 86 | 60 | 53 | 122 | 122 | 131 |

**Fig. 6.** LEAN implementation benefits ranked by the experts.

According to the experts' opinion, the benefits of LEAN implementation in the pharmaceutical company are (in the importance decreasing order):

1. Increased document and systems effectiveness.
2. Improved processes.
3. Reduction of manufacturing errors.
4. Reduction of cycle time.
5. Costs reduction.
6. Processes are easier to understand.
7. Reduction of waste.
8. Reduction of human errors.
9. Reduction of laboratory errors.
10. Improved training system.
11. Increased employees' motivation.
12./13. Improved planning works.
12./13. An improved environment of the workspace.

14. Clearly defined goals.
15. Improved communication.

The most significant LEAN implementation benefits are increased document and systems effectiveness, improved processes, and reduced manufacturing errors. Comparing the answers to the questionnaire with the answers of the experts' evaluation, the authors conclude that the area where the most improvement was necessary is the ineffectiveness of the processes and systems, like documentation; therefore, the most significant benefits of LEAN implementation was noted in relation to the improvement in this particular area.

## 3. DISCUSION AND CONCLUSIONS

According to the consensus opinion of the experts obtained by the Delphi method, the most significant benefit is that the effectiveness of documents and systems has improved. The second most significant benefit from LEAN implementation mentioned by the experts is improved company processes, followed by the reduction of production errors. The production errors resulted from the inefficiency of the system and process deficiencies. The experts' opinion and the results obtained in the literature content analysis differs – the most important LEAN implementation benefits identified in the content analysis of the literature are the identification and reduction of losses, reduction of cycle time, cost reduction, improvement of existing processes, and increased work productivity. While according to the experts, the most improvements and, therefore, the benefits for the pharmaceutical company are increased document and systems effectiveness, improved processes, and the reduction of manufacturing errors. Process improvement is the only LEAN implementation benefit identified in the literature and by the experts.

The results of the research are limited by the fact that the empirical study was conducted in only one pharmaceutical manufacturing company. The future research could be expanded to several pharmaceutical manufacturing companies implementing LEAN methodology as well as other production improvement methodologies contributing to the sustainable development of the companies, like green or circular manufacturing.

# APPENDIX 1
## The list of literature sources used in the qualitative content analysis

| No. | Authors | Title | Year | Source | Reference |
|---|---|---|---|---|---|
| 1. | Adly Ishak, F., Khudri Johari, M., & Dolah, R. | A case study of LEAN application for shortest lead time in composite repair shop. | 2018 | International Journal of Engineering & Technology | Adly Ishak, F., Khudri Johari, M., & Dolah, R. (2018). A case study of LEAN application for shortest lead time in composite repair shop. *International Journal of Engineering & Technology*, *7*(4.13), 112. https://doi.org/10.14419/ijet.v7i4.13.21341 |
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