

# Productivity Improvement Through Lean Six Sigma in Pharmaceutical Manufacturing: A Narrative Review

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## ABSTRACT

This review examined Lean Six Sigma's (LSS) impact on pharmaceutical manufacturing productivity. 2 databased search engine used which are Science Direct (n= 160) and Google Scholar (n=84) used keywords lean six sigma AND Pharmaceutical manufacturing AND productivity improvement. The search was restricted to English-languange articles and 10 previous years of studied. Five relevant studies were identified, though targeted research in this area was limited. The studies consistently showed LSS's positive influence, highlighting its effectiveness in boosting productivity, reducing inefficiencies and waste, improving delivery, and generating cost savings. The DMAIC cycle's importance and the correlation between Six Sigma and productivity were emphasized. Lean integration (like value stream mapping) was crucial for waste elimination. One study linked lean production with sustainability. While the literature supports LSS benefits, further research is needed to explore implementation strategies and challenges. The studies confirm LSS as a powerful tool for pharmaceutical companies seeking operational optimization, quality enhancement, and productivity improvement.

**Keywords:** Productivity; Lean Six Sigma; Pharmaceutical Manufacturing

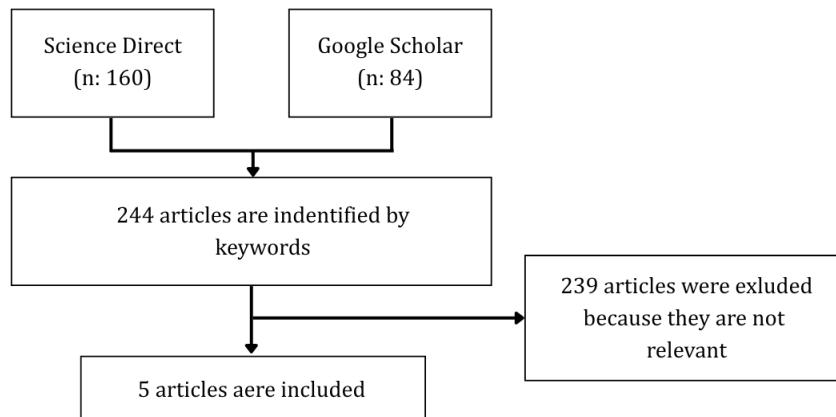
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## INTRODUCTION

The globalization of markets has intensified competition across all sectors, creating a level playing field for organizations worldwide. This heightened competition necessitates the adoption of innovative and competitive strategies by companies, often prioritizing quality, customer satisfaction, and continuous improvement. Furthermore, the increasing emphasis on quality of life, social responsibility, and environmental sustainability has driven organizations to embrace new approaches that go beyond traditional business models (Kartika et al., 2020; Parid et al., 2023).

Moreover, the rapid advancements in technology, evolving social dynamics, and enhanced customer expectations have significantly reshaped the competitive landscape. The easily available information empowers consumers, leading to a greater focus on quality of life, social responsibility, and environmental sustainability. This intense awareness has driven organizations to incorporate these factors into their business strategies to gain a competitive edge. Manufacturing industries play a pivotal role in driving economic and social progress within any nation. To meet the evolving demands of consumers and remain competitive, manufacturers strive to optimize their operations by effectively utilizing human resources and machinery to deliver high-quality products and services efficiently. Recognizing the crucial role of manufacturing, governments actively support this sector through the development and enforcement of policies aimed at enhancing productivity and competitiveness (Eskandari et al., 2022).

The pharmaceutical industry holds a unique position within the manufacturing sector, as it directly impacts human health and well-being. The critical nature of pharmaceuticals necessitates a strong emphasis on quality, safety, and affordability. Consequently, identifying and addressing the challenges faced by pharmaceutical manufacturers is paramount to ensuring the continued delivery of high-quality and accessible healthcare solutions to the global population (Kholil et al., 2021). In the highly regulated and complex pharmaceutical industry, Lean Six Sigma offers a crucial framework for enhancing efficiency, improving quality, and reducing costs. The industry faces numerous challenges, including stringent regulatory requirements, high research and development costs, intense competition, and the need for continuous innovation. Lean Six Sigma principles can be



**Figure 1. Flowchart of the literature searching process**

applied across the entire pharmaceutical value chain, from research and development to manufacturing, distribution, and customer service (Byrne et al., 2021). This review aims to investigate the impact of Lean Six Sigma methodologies on productivity improvement within the pharmaceutical manufacturing sector.

## METHODS

We conducted a narrative review to gain a better understanding of the impact of Lean Six Sigma on productivity improvement within the pharmaceutical manufacturing sector. The researchers chose a narrative review because it is consistent with the research purpose, which is to delve deeper and more specifically the implementation of Lean Six Sigma in pharmaceutical manufacturing field and how it could help the productivity.

### Search Strategy

The following database was searched from literature article by using SUMMON (the powerful engine behind the large search box on the library website) which has been related to Gadjah Mada University Library. The following of keywords was used: lean six sigma AND Pharmaceutical manufacturing AND productivity improvement. The search was restricted to English-languange articles and 10 previous years of studied. We evaluate its applicability to the subject of the implementation Lean Six Sigma among pharmaceutical industry, when we looked for particular terms like "Lean Six Sigma in pharmaceutical industry" we only came across a very small numbers of articles because of Lean Six Sigma could be implemented in many manufacturing sectors.

### Eligibility Criteria

This review focused only on Lean Six Sigma in pharmaceutical manufacturing sector. Pharmaceutical employee completed a questionnaire to measure the implementation of Lean Six Sigma. Must have the concept of lean six sigma such as DMAIC which are Define, Measure, Analyze, Improvement and Control.

## RESULT AND DISCUSSION

### Study selection

Initial literature generated 244 articles from Science Direct 160 and Google Scholar 84 articles. Figure 1 provides an overview of the selection process. Most of these articles did not meet the inclusion criteria. Only 5 articles were assessed for eligibility. We employed inclusion criteria, including the research into productivity in the field using the lean six sigma method in pharmaceutical industry. We used original paper, published over the last ten years, from 2014 to 2024, discuss in englis language. 8 articles about the concepts we discussed in our article were gathered from the two data baseses we used for this research, and they are shown in the Table I.

**Table I. Existing Literature review of Lean Six Sigma in Various Industries**

No	Author & Year	Research location	Research Objectives	Result
1	Brian, et al., 2021	Ireland	applies Lean Six Sigma to pharmaceutical manufacturing, showing how it can boost productivity, reduce backlogs and downtime, eliminate waste, and improve delivery times.	Lean Six Sigma to eliminate waste, solving a problem and saving nearly half a million dollars. These improvements are now being used across the company's global sites, demonstrating Lean Six Sigma's effectiveness in finding root causes and driving continuous improvement for increased productivity.
2	Hayu, et al., 2020	Indonesia	to explore the advantages of implementing six sigmas in the pharmaceutical industry	The results of this study are that the Six Sigma method with stages to determine, measure, improve and control has a positive and significant effect on pharmaceutical industry performance
3	Agus, et al., 2020	Indonesia	This research models and analyzes Six Sigma's impact on pharmaceutical industry performance. It uses the DMIC cycle (Define, Measure, Improve, Control). The goal is to boost productivity.	Six Sigma significantly improves pharmaceutical industry performance. Using the DMIC cycle (Define, Measure, Improve, Control) boosts this performance. This leads to increased productivity
4	Muhammad Kholil, et al., 2021	Indonesia	to address the high reject rate (3.6%) for Tablet Coating A at PT. Medica Indonesia. This high rate threatens productivity. The article aims to identify the causes of waste in the production process. It will use Lean Six Sigma (DMAIC, VSM, VALSAT) to achieve this.	Lean Six Sigma (DMAIC, VSM, VALSAT) analysis revealed waste in Tablet Coating A production. The identified wastes include defects, overproduction, and excess inventory.
5	Mojan, et al., 2022	Iran	for evaluating and improving the performance of pharmaceutical factories, taking into account both efficiency and environmental/social impact.	his framework helps decision-makers consistently evaluate performance and implement improvements, boosting both sustainability and lean production (and thus, productivity).

### Study characteristics

We discovered 5 articles that assessed the productivity improvement in pharmaceutical sectors. Study publication dates range from 2014 to 2024. Three articles were conducted in Indonesia (Kartika et al., 2020; Kholil et al., 2021; Purwanto et al., 2021), one article in Ireland (Byrne et al., 2021), and one in Iran (Eskandari et al., 2022). During the article search process, many articles were

found that used Lean Six Sigma as a tool. However, a large number of these articles were not focused on the pharmaceutical industry, and many of the articles found were review articles. This posed a limitation for the researcher. However, this limitation prompted the researcher to search more deeply until they found the 5 best articles that met the appropriate inclusion criteria.

These studies collectively demonstrate the positive impact of Lean Six Sigma methodologies on productivity and performance within the pharmaceutical industry, albeit with slightly different focuses and approaches. Brian et al. (2021), conducting their research in Ireland, showcased the practical application of Lean Six Sigma, illustrating its ability to directly boost productivity, reduce operational inefficiencies like backlogs and downtime, eliminate waste, and ultimately improve delivery times, resulting in significant cost savings and company-wide implementation. Similarly with Ismail et al. (2014), This study used Lean Six Sigma (specifically the DMAIC cycle, process mapping, and value analysis) to reduce waste and production cycle time in a biopharmaceutical operation. They found 54% of the production cycle was waste. Improvements like new equipment and room renovations were implemented to address this. The study concludes Lean Six Sigma is effective for managing waste and variability, and can help companies achieve profit maximization.

Hayu et al. (2020), based in Indonesia, explored the broader advantages of Six Sigma implementation, confirming its positive and significant influence on overall pharmaceutical industry performance through the structured DMAIC cycle. Similarly, Agus et al. (2020), also in Indonesia, modeled and analyzed the impact of Six Sigma, specifically through the DMIC cycle, finding a strong correlation between Six Sigma application and increased productivity within the pharmaceutical sector. Focusing on a specific operational challenge, Muhammad Kholil et al. (2021), in Indonesia, investigated a high reject rate for a key product, using a combined Lean Six Sigma approach with DMAIC, Value Stream Mapping (VSM), and Value Stream Mapping and Analysis Tool (VALSAT) to identify and address the root causes of waste, revealing defects, overproduction, and excess inventory as key contributors to the problem. Finally, Mojani et al. (2022), conducting research in Iran, took a more holistic approach by developing a lean-production-sustainability framework, which considers both efficiency and environmental/social factors, ultimately providing decision-makers with a tool to consistently evaluate performance and implement improvements that enhance both sustainability and lean production, thereby indirectly boosting productivity.

Pharmaceutical companies use Six Sigma to reduce waste, improve manufacturing processes, and increase efficiency, leading to better product quality and customer service. Process capability, measured by the Cpk index, is key to meeting product specifications. Many pharmaceutical firms use a combined Lean Manufacturing and Six Sigma approach, similar to its successful use in other industries, to improve both quality and operations. Lean Manufacturing is particularly important in pharmaceuticals for minimizing waste and defects, ultimately benefiting customers (Mahajan et al., 2022).

While Six Sigma has been used for a long time, research on it is still relatively new. Its proven track record across industries has fueled research interest. Six Sigma, often seen as a valuable tool, focuses on optimization. Laboratory management should utilize Six Sigma methodologies, supported by data. Lean Six Sigma can be applied to any industry for continuous improvement and better performance. Further research on Lean Six Sigma implementation is needed.

This review explored the impact of Lean Six Sigma (LSS) methodologies on productivity improvement within the pharmaceutical manufacturing sector. Through a systematic literature search, focusing on English-language articles from the past decade related to LSS implementation in pharmaceutical manufacturing and its impact on productivity, five key studies were identified and analyzed. While the initial search yielded a larger number of articles, many were either not specific to the pharmaceutical industry or were review articles themselves, highlighting a limitation in the available targeted research and necessitating a more in-depth search to find relevant material.

The selected studies, conducted across diverse geographical locations including Indonesia, Ireland, and Iran, collectively demonstrate the positive influence of LSS on various aspects of pharmaceutical manufacturing. Several studies showcased the practical application of LSS, demonstrating its effectiveness in boosting productivity, reducing operational inefficiencies like

backlogs, downtime, and waste, and ultimately improving delivery times and generating cost savings. Other research emphasized the importance of the DMAIC cycle in achieving overall performance improvement, with a strong correlation between Six Sigma application and increased productivity.

## CONSLUSION

The integration of Lean principles, particularly value stream mapping and analysis, was shown to be crucial in identifying and addressing specific sources of waste, such as defects, overproduction, and excess inventory. One study took a broader perspective, developing a lean-production-sustainability framework that integrates efficiency improvements with environmental and social considerations, demonstrating that productivity gains can be achieved in conjunction with a commitment to sustainable practices.

While the reviewed literature provides strong evidence for the benefits of LSS in pharmaceutical manufacturing, it also reveals a need for further research to explore specific implementation strategies, address potential challenges, and fully realize the potential of these methodologies in this critical industry. The consistent theme across the studies underscores the importance of LSS as a powerful tool for pharmaceutical companies seeking to optimize their operations, enhance quality, and improve productivity in an increasingly competitive and regulated global market.

## CONFLICT OF INTERENT

The authors declare no conflict of interest.

## LIMITATION

The limitation in creating this narrative review was the researcher's difficulty in finding articles that specifically used Lean Six Sigma in the pharmaceutical industry.

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