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Integration of Machine Learning into Lean Six Sigma: A Systematic Review for Enhancing Predictive Analytics in the Pharmaceutical Industry

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Abstract: This study reviews research on integrating machine learning within Lean Six Sigma for predictive analytics in pharmaceutical manufacturing. It targets three operational priorities reported across the literature, predictive maintenance, quality control, and process optimisation. The review follows a systematic design guided by PRISMA and Saunders' Onion Model, with Scopus and Web of Science as the primary sources. The search applied 2014 to 2024 publication filter and selected peer reviewed journal articles written in English and aligned to the defined scope. Data analysis used thematic analysis with NVivo 15 to code and synthesize evidence across thirty-four studies. Four themes emerged. First, Lean Six Sigma supports productivity and compliance through waste reduction, variation control, and standardised quality practices in pharmaceutical operations. Second, machine learning strengthens the DMAIC cycle by improving pattern recognition, anomaly detection, forecasting, and monitoring, with clear relevance to Analyse, Improve, and Control activities. Third, three dominant framework strategies appear in the literature, model centric designs that embed specific algorithms, process centric designs that align analytics to DMAIC phase objectives, and platform-based designs that combine IoT or cloud infrastructure with continuous data processing and feedback. Fourth, case evidence reports practical gains in documentation and audit readiness, equipment failure prediction, process and batch optimisation, and sustainability-oriented improvement, with recurring benefits reflected in lower rejection risk, reduced downtime, and stronger traceability. The review also identifies persistent constraints. Studies report weak standardisation in model selection and evaluation, limited empirical validation across settings, and recurring implementation barriers such as fragmented data, legacy IT constraints, limited skilled personnel, and low interpretability in regulated contexts. Future work should develop phase specific guidance for ML embedded LSS, expand real time deployment studies using live manufacturing data, strengthen governance and validation practices aligned to GMP and data integrity, and adapt frameworks to plant level constraints and product specific risk profiles.

Keywords: Machine Learning, Lean Six Sigma, Predictive Analytics, Pharmaceutical Industry, Process Optimization, Continuous Improvement, Data-Driven Decision Making, Operational Efficiency

INTRODUCTION

Background and Context

The pharmaceutical industry is under continuous pressure to enhance operational efficiency while complying with rigorous regulatory standards. Lean Six Sigma (LSS) has gained traction as a robust methodology in this sector, facilitating waste reduction, quality enhancement, and productivity optimization. LSS integrates Lean principles, which focus on eliminating waste, with Six Sigma's emphasis on reducing process variation and defects (Olutade, 2023; Francescatto et al., 2022). This hybrid approach has been shown to yield significant improvements in various pharmaceutical processes, as evidenced by case studies demonstrating its effectiveness in enhancing operational performance (Yamamoto et al., 2010; Alkunsol et al., 2019). However, the increasing complexity of pharmaceutical manufacturing necessitates advanced predictive capabilities that traditional LSS methodologies may not fully address. The integration of machine learning (ML) into LSS offers a promising solution by providing real-time insights and enhancing decision-making processes through data-driven analytics (Alhakimi, 2024; Huang et al., 2023). This synergy not only streamlines operations but also aligns with the industry's shift towards Industry 4.0, where data analytics plays a crucial role in driving efficiency and compliance (Nwamekwe et al., 2025; Arcidiacono & Pieroni, 2018). Thus, the combination of LSS and ML represents a significant advancement for the pharmaceutical sector, enabling it to meet both operational and regulatory demands effectively.

ML, with its data-driven approach to pattern recognition and predictive analytics, aligns seamlessly with the objectives of LSS by providing advanced tools for anticipating maintenance needs, enhancing quality control, and optimizing processes. The integration of ML within LSS frameworks offers an innovative pathway for the pharmaceutical industry to improve operational efficiency, reduce costs, and ensure compliance with stringent regulatory demands (Nadeau, 2017; Nwamekwe et al., 2025). For instance, ML algorithms can analyse historical data to predict equipment failures, thereby facilitating proactive maintenance strategies that align with LSS's focus on waste reduction and efficiency (Nwamekwe & Nwabunwanne, 2025; Okechukwu et al., 2025; Okeagu et al., 2024). Moreover, the fusion of ML and LSS necessitates a systematic approach to identify, evaluate, and synthesize existing frameworks and methodologies within this integrated landscape. This integration not only enhances the capabilities of traditional LSS methodologies but also addresses the growing complexity of pharmaceutical manufacturing processes (Chugani et al., 2017; Francescatto et al., 2022). As industries increasingly adopt Industry 4.0 principles, the combination of ML and LSS becomes crucial for leveraging real-time data analytics to drive continuous improvement and operational excellence (Nwamekwe et al., 2020; Okpala et al., 2025). Thus, the strategic incorporation of ML into LSS represents a significant advancement for the pharmaceutical sector, enabling it to meet both operational and regulatory challenges effectively.

Problem Statement

Despite the promising potential of integrating ML into LSS methodologies, the pharmaceutical industry faces several challenges in adopting this advanced framework. Current LSS frameworks often lack the capability to provide real-time predictive insights, which are essential for proactive decision-making in a highly regulated environment (Vitalis et al., 2024; U-Dominic et al., 2025, Onyeka et al., 2024). This limitation can lead to inefficiencies in operations, as timely data-driven decisions are crucial for maintaining compliance and optimizing processes (Munir et al., 2021; Shah et al., 2019).

Moreover, there is a notable absence of consolidated research that systematically reviews and synthesizes existing frameworks and methodologies for implementing ML within LSS. Such a gap in the literature restricts the ability of pharmaceutical organizations to leverage best practices and insights that could enhance operational efficiency and product quality (Igbokwe et al., 2025; Okpala et al., 2025). Addressing this gap is vital, as it would empower the industry to harness ML's predictive capabilities effectively, ultimately leading to improved regulatory compliance and operational performance (Karimi et al., 2020). Therefore, a comprehensive exploration of the integration of ML into LSS is essential for advancing the pharmaceutical sector's capabilities in the face of evolving challenges.

Aim and Scope of the Review

The primary aim of this study is to systematically review existing research on ML-embedded LSS frameworks within the pharmaceutical industry, focusing specifically on their application for predictive analytics. The scope encompasses frameworks and studies that utilize ML algorithms in LSS applications within pharmaceutical manufacturing. By focusing on predictive maintenance, quality control, and process optimization, this review seeks to identify the benefits, challenges, and gaps in current frameworks and propose future directions for enhancing these integrated methodologies.

METHOD

Research Design

This study employs a systematic review approach grounded in thematic analysis, utilizing Saunders' Onion Model (figure 1) to ensure methodological rigor throughout the research process while adhering to PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) principles. The Onion Model serves as a structured framework that guided this research through various stages of research design, encompassing research philosophy, approaches, strategies, choices, time horizons, and techniques (Johnson et al., 2020). By following this model, the study aims to enhance the clarity and coherence of the research methodology, thereby improving the overall quality of the findings.

The systematic review design is particularly suitable for identifying patterns, trends, and themes across multiple studies, allowing for a comprehensive synthesis of existing literature (Sena et al., 2014). This approach not only facilitates the identification of gaps in the current body of knowledge but also aids in the formulation of new research questions that can advance the field (Jimenez et al., 2023). Furthermore, employing rigorous methodologies in systematic reviews is essential for ensuring the reliability and validity of the conclusions drawn from the analysed studies (Donovan et al., 2011). Thus, the integration of Saunders' Onion Model within a systematic review framework underscores the commitment to methodological rigor and the pursuit of high-quality research outcomes.

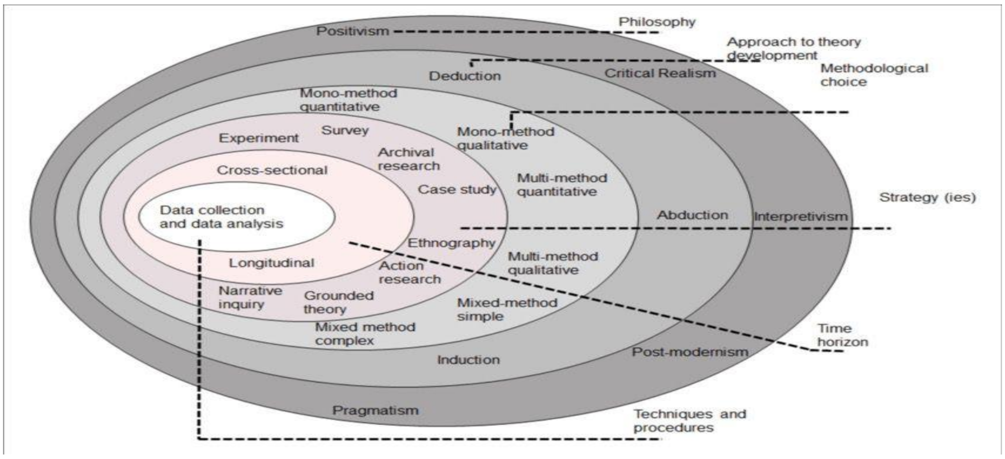

Figure 1: Research Onion (Saunders et al., 2019)

Data Collection Process

Data for this systematic review was meticulously collected from reputable academic databases, including Scopus and Web of Science, ensuring access to high-quality, peer-reviewed articles. The selection of these databases is critical, as they are recognized for their comprehensive coverage of scholarly literature, particularly in the fields of science and technology (Nwamekwe & Chikwendu, 2025). The search terms employed "Lean Six Sigma," "Machine Learning," "Predictive Analytics," and "Pharmaceutical Industry" were tailored to capture relevant research within the specific focus of this review, thereby enhancing the relevance and specificity of the findings.

To ensure the review's comprehensiveness, filters were applied to include studies published within the last ten years (2014 to 2024). This time frame is essential for capturing recent advancements and trends in the integration of machine learning with Lean Six Sigma methodologies in the pharmaceutical sector (Ezeanyim et al., 2025; Igbokwe et al., 2025, Udu et al., 2025). The systematic review design is particularly advantageous for identifying patterns, trends, and themes across multiple studies, allowing for a robust synthesis of existing knowledge (Emeka et al., 2025; Chidiebube et al., 2025). By adhering to established guidelines such as PRISMA, this review aims to maintain methodological rigor and transparency throughout the research process (Nwamekwe & Chikwendu, 2025; Akl et al., 2015).

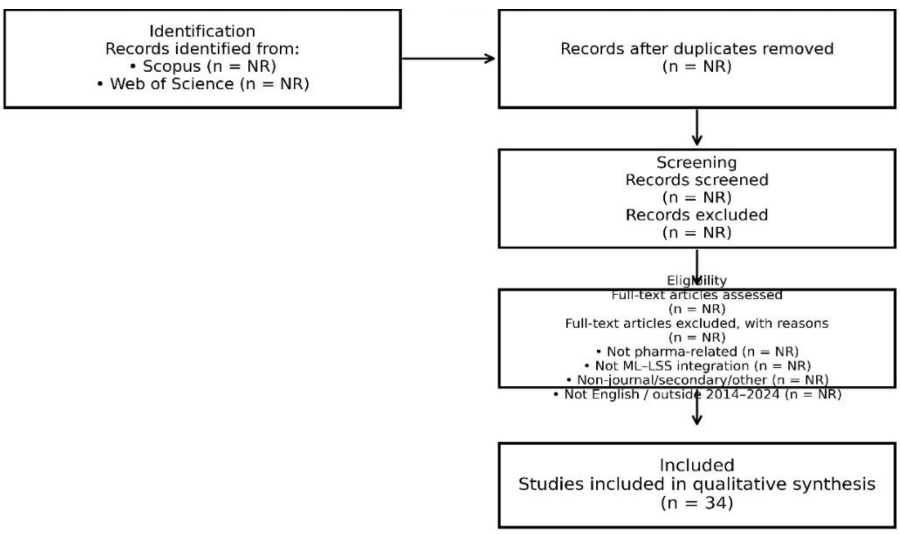

Figure 2: PRISMA Flow Diagram

Table 1: Study Characteristics

S/N	Title	Authors	Publisher/Journal	Year
1	Leveraging AI and Machine Learning in Six-Sigma Documentation for Pharmaceutical Quality Assurance	R. Bhaskar, S. R. Mohanty	Chinese Journal of Applied Physiology	2024
2	Harnessing Artificial Intelligence and Machine Learning in Six-Sigma Documentation Processes within the Pharmaceutical Industry	Aisha Hamzah, Manik Sharma, Nada A. Aljarbou, Anubha Jain, Akshat Gaur	Journal of Chemical Health Risks (JCHR)	2024
3	Applying Lean Six Sigma Methodology to a Pharmaceutical Manufacturing Facility: A Case Study	Brian Byrne, Olivia McDermott, John Noonan	Processes (MDPI)	2021
4	Artificial Intelligence and Internet of Things Integration in Pharmaceutical Manufacturing	Anandram Venkatasubramanian, Aishwarya Srivastava	Pharmaceutics (MDPI)	2023
5	The Implementation of Machine Learning Methods in Six Sigma Projects – A Literature Review	Paula Kolbusz, Katarzyna Antosz	Advances in Manufacturing IV (Springer)	2024
6	Potential Integration of Machine Learning Algorithm and Manufacturing Execution System in the Lean Six Sigma Method to Improve Operational Excellence at ABC Farma Company	Feri Setyowati, Teguh S. Sampurno, Nur Fadila Rahmawati, Syifa Fauziah	Eduvest Journal	2023
7	Optimizing Green Lean Six Sigma using Industry 5.0 Technologies	B.B. Gupta, Chanchal Kumar, Lalit Mohan Goyal	Cleaner Engineering and Technology (Elsevier)	2024
8	The Future of Six Sigma: Integrating AI for Continuous Improvement	Prerna Mangal, Garima Sharma	International Journal of Innovative Research in Engineering & Management (IJIREM)	2023
9	Artificial Intelligence-Driven Pharmaceutical Industry: A Paradigm Shift in Drug Discovery, Formulation Development, Manufacturing, Quality Control, and Post-Market Surveillance	K. Huanbutta, K. Burapapadh, P. Kraisit, P. Sriamornsak, T. Ganokratanaa, K. Suwanpitak, T. Sangnim	European Journal of Pharmaceutical Sciences (ScienceDirect)	2024
10	Leveraging Natural Language Processing (NLP) and Machine Learning for Quality Control Using Lean Six Sigma	Anilesh Mukherjee, Om Sharma	International Journal of Science and Research (IJSR)	2024
11	Role of Lean Six Sigma in Manufacturing Setting: A Systematic Literature Review and Agenda for Future Research	Humiras Hardi Purba	International Journal of Production Management and Engineering	2021
12	The r-evolution of Lean Six Sigma from Industry 4.0 to Society 5.0: Excellence 5.0	Gabriele Arcidiacono, Andrea Antonacci, Jiju Antony	International Journal of Quality & Reliability Management (Emerald Insight)	2024
13	Unveiling the nexus of Industry 4.0 and Lean Six Sigma for sustainable development: insights from bibliometric and structural topic modeling analysis	Vishal Ashok Wankhede, Rohit Agrawal	International Journal of Lean Six Sigma (Emerald Insight)	2024

14	Design for green lean six sigma to improve sustainability in the pharmaceutical industry – a case study	McGlinchey, Y., Iqbal, J., Trubetskaya, A., Thenarasu, M., & McDermott, O.	Production & Manufacturing Research (Taylor & Francis)	2025
15	Machine learning and lean six sigma for targeted patient-specific quality assurance of volumetric modulated arc therapy plans	Nicola Lambri, Damiano Dei, Giulia Goretti, Leonardo Crespi, Ricardo Coimbra Brioso, Marco Pelizzoli, Sara Parabicoli, Andrea Bresolin, Pasqualina Gallo, Franceso La Fauci, Francesca Lobefalo, Lucia Paganini, Giacomo Reggiori, Daniele Loiacono, Ciro Franzese, Stefano Tomatis, Marta Scorsetti & Pietro Mancosu	Radiotherapy and Oncology (ScienceDirect)	2024
16	Artificial Intelligence in Pharmaceutical and Healthcare Research	Bhattamisra, S. K., Banerjee, P., Gupta, P., Mayuren, J., Patra, S., & Candasamy, M.	Big Data and Cognitive Computing (MDPI)	2023
17	Lean Six Sigma Implementation: A Systematic Literature Review	S. Tampubolon, H.H. Purba	International Journal of Production Management and Engineering	2021
18	Analyzing the Impact of Combining Lean Six Sigma Methodologies with Sustainability Goals	Amjad Hossain, Md Rabbe Khan, Md Tahmidul Islam, Kazi Saiful Islam	Journal of Science and Engineering Research	2024
19	Pharmaceutical Sales Forecasting with Machine Learning: A Strategic Management Tool for Decision-Making	Fajar Saranani, Ruby Dahiya, Shetty Deepa Thangam Geeta, P Hameem Khan, Razia Nagina	International Journal of Intelligent Systems and Applications in Engineering	2024
20	Leveraging Artificial Intelligence to Revolutionize Six Sigma: Enhancing Process Optimization and Predictive Quality Control	Muhammad, Syed & Bukhari, Syed Muhammad Shakir & Akhtar, Rehman	Russian Social Science Review	2024
21	Lean Six Sigma in Healthcare: A Systematic Literature Review on Challenges, Organisational Readiness and Critical Success Factors	McDermott, O., Antony, J., Bhat, S., Jayaraman, R., Rosa, A., Marolla, G., & Parida, R.	Processes (MDPI)	2022
22	Machine Learning Algorithms for Manufacturing Quality Assurance: A Systematic Review of Performance Metrics and Applications	Kausik, Ashfakul & Rashid, Adib & Baki, Ramisha & Maktum, Md.	Array (Elsevier)	2025
23	Analysis of Lean Six Sigma Use in Pharmaceutical Production	Beatriz Maria Simões Ramos da Silva, Vicente Aguilar Nepomuceno de Oliveira & Jorge Lima Magalhães	Brazilian Journal of Pharmaceutical Sciences	2023
24	Artificial Intelligence (AI) in Pharmacy: An Overview of Innovations	Raza, M. A., Aziz, S., Noreen, M., Saeed, A., Anjum, I., Ahmed, M., & Raza, S. M.	Innovations in pharmacy (NIH)	2022
25	Applying Lean Six Sigma Methodology to a Pharmaceutical Manufacturing Facility: A Case Study	Brian Byrne, Olivia McDermott, John Noonan	Processes (MDPI)	2021
26	Artificial Intelligence and Internet of Things Integration in Pharmaceutical Manufacturing	Anandram Venkatasubramanian, Aishwarya Srivastava	Pharmaceutics (MDPI)	2023

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29	Optimizing Green Lean Six Sigma using Industry 5.0 Technologies	B.B. Gupta, Chanchal Kumar, Lalit Mohan Goyal	Cleaner Engineering and Technology (Elsevier)	2024
30	Integration of Lean Green and Sustainability in Manufacturing: A Review on Current State and Future Perspectives	Elemure, I., Dhakal, H. N., Leseure, M., & Radulovic, J.	Sustainability (MDPI)	2023
31	Artificial Intelligence: Future Aspects in the Pharmaceutical Industry an Overview.	Aakash Bairagi, Akhlesh K. Singhai, Ashish Jain	Asian Journal of Pharmacy and Technology	2024
32	Advanced Artificial Intelligence Technologies Transforming Contemporary Pharmaceutical Research	Kumar, P., Chaudhary, B., Arya, P., Chauhan, R., Devi, S., Parejiya, P. B., & Gupta, M. M.	Bioengineering (MDPI)	2025
33	Artificial Intelligence in Pharmaceutical Technology and Drug Delivery Design	Vora, L. K., Gholap, A. D., Jetha, K., Thakur, R. R. S., Solanki, H. K., & Chavda, V. P.	Pharmaceutics (MDPI)	2023
34	The Future of Six Sigma- Integrating AI for Continuous Improvement	Anitej Chander Sood & Konika Singh Dhull	International Journal of Innovative Research in Engineering and Management	2024

Inclusion and Exclusion Criteria

The meticulous formulation and rigorous implementation of inclusion and exclusion criteria are pivotal in executing a systematic literature review, particularly within the context of integrating Machine Learning into Lean Six Sigma for predictive analytics in the pharmaceutical industry. These criteria function as a structured framework for identifying, screening, and selecting studies that align closely with the research objectives, thereby enhancing the analytical rigor and validity of the review outcomes. By explicitly delineating these parameters, studies that meet predefined standards are systematically curated, ensuring the review process maintains high relevance and methodological quality.

The review included peer-reviewed studies that specifically focus on the applications of ML integrated with LSS within the pharmaceutical sector. This targeted approach was essential to ensure that the findings would be directly relevant to the research objectives. Studies were excluded if they lacked empirical data, were outside the focus area ML or LSS applications without integration), or did not address predictive analytics. This exclusion criterion was critical in maintaining the integrity and applicability of the review, ensuring that only studies contributing meaningful insights into the integration of ML and LSS were considered.

By concentrating on empirical studies that demonstrate the practical application of ML within LSS frameworks, the review aimed to highlight successful case studies and methodologies that could serve as benchmarks for future research and practice. The systematic exclusion of non-empirical studies and those not directly addressing predictive analytics allowed for a more focused analysis of the current landscape of ML-integrated LSS applications in the pharmaceutical industry. This approach not only enhances the relevance of the findings but also provides a clearer pathway for identifying gaps in the literature and opportunities for further research.

Inclusion criteria

Year range: Articles published between 2014 and 2024 were included. This timeframe was selected to focus on recent research and developments in assessing the integration of ML into LSS framework, particularly in the pharmaceutical sector.

Subject areas: The review concentrated on articles related to Machine Learning applications in manufacturing processes, Lean Six Sigma frameworks and methodologies, Predictive analytics for operational efficiency, Process optimization and waste reduction strategies and Data-driven decision-making in production environments. This focus ensured that the selected studies provided relevant insights from disciplines such as machine learning and artificial intelligent applications, lean six sigma methodologies, predictive analytics in pharmaceutical industries.

Document type: Only peer-reviewed journal articles were included in the review. This criterion aimed to ensure the selection of primary research studies, empirical analyses, case studies, and theoretical papers that provided in-depth insights on integrating ML into LSS framework in the pharmaceutical industries.

Keywords: The review considered articles that included specific keywords related to the research topic. These keywords included terms such as ("Machine Learning" OR "ML" OR "AI" OR "Artificial Intelligence") AND ("Lean Six Sigma" OR "LSS") AND ("Pharmaceutical industry" OR "Pharmaceutical manufacturing") AND ("Predictive analytics" OR "forecasting models"). Articles that featured these keywords in their titles, abstracts, or main text were included in the review.

Language: Only articles published in English were considered. This criterion ensured that the research team could efficiently access, comprehend, and analyse the chosen studies. The use of English also facilitated clearer communication and more effective dissemination of the findings.

Publication stage: The review included only final articles that had undergone the complete publication process. This criterion ensured that the selected articles had passed rigorous peer review and were considered completed research contributions.

Table 2: Search Strategy

Database	Exact query string	Fields searched	Date searched	Year filter
Scopus	("Lean Six Sigma" OR LSS) AND ("Machine Learning" OR ML OR "Artificial Intelligence" OR AI) AND ("Predictive Analytics" OR "predictive analytics" OR forecasting) AND (pharmaceutical OR "pharmaceutical industry" OR "pharmaceutical manufacturing")	Title/ Abstract/ Keywords	NR (add exact date)	2014–2024
Web of Science	("Lean Six Sigma" OR LSS) AND ("Machine Learning" OR ML OR "Artificial Intelligence" OR AI) AND ("Predictive Analytics" OR "predictive analytics" OR forecasting) AND (pharmaceutical OR "pharmaceutical industry" OR "pharmaceutical manufacturing")	Title/Abstract/Keywords	NR (add exact date)	2014–2024

Exclusion Criteria

Year range: Articles published before 2014 were excluded. This criterion focused the review on recent research developments, capturing the latest advancements in ethical compliance within multi-tier supply chains.

Subject areas: Articles unrelated to machine learning and artificial intelligent applications, lean six sigma methodologies, predictive analytics in pharmaceutical industries were excluded. This criterion ensured that only studies directly related to the research topic were included.

Document type: The review excluded conference papers, book chapters, conference reviews, and general literature reviews. This focus on primary research studies and empirical analyses ensured that the review was grounded in original research contributions.

Language: Articles published in languages other than English were excluded to maintain consistency in the interpretation and communication of the findings.

Publication stage: Articles labelled as "Articles in Press" were excluded. This criterion ensured that only completed and peer-reviewed research contributions were considered.

By employing these inclusion and exclusion criteria, the systematic literature review aimed to select a focused set of relevant articles from the fields of Industrial Engineering, Production Engineering, Pharmaceutical Sciences, Data Science, and Operations Management, published between 2014 and 2024. These criteria ensured that only high-quality, English-language research articles focused on machine learning and artificial intelligent applications, lean six sigma methodologies, predictive analytics in pharmaceutical industries were included in the review.

Data Analysis Method

Data were analysed using thematic analysis to identify key themes, which were then categorized according to the layers of Saunders' Onion Model using NVivo 15. This model provides a structured framework that facilitates a comprehensive understanding of research design by breaking down the analysis into distinct layers, including research philosophy, approaches, strategies, and techniques (Vaismoradi et al., 2013). Thematic analysis, as a flexible and widely used qualitative research method, allows for the identification and interpretation of patterns within qualitative data, making it particularly suitable for this study (Altınbaş & Gıersbergen, 2021).

By employing thematic analysis, the research enabled a deeper understanding of how different studies conceptualize and implement ML-embedded LSS frameworks within pharmaceutical settings. This approach not only highlights the common themes across various studies but also uncovers unique insights specific to the integration of machine learning and Lean Six Sigma in the pharmaceutical industry (Liu et al., 2012). The systematic categorization of themes according to Saunders' Model layers further enhances the clarity of the findings, allowing for a nuanced exploration of the methodologies and practices that characterize ML-integrated LSS applications (Mundagowa et al., 2021). Ultimately, this rigorous analytical framework contributes to a more comprehensive understanding of the current landscape and future directions for research in this evolving field.

Table 3: Inclusion Exclusion

Criterion category	Inclusion rule	Exclusion rule	Rationale (1 line)
Year range	2014–2024	Before 2014	Focus on contemporary ML/AI and Industry 4.0-era integration
Subject area	ML/AI + Lean Six Sigma integration in pharma	Unrelated to ML/AI or LSS; unrelated sectors	Keeps scope aligned to ML-embedded LSS in pharmaceuticals
Document type	Peer-reviewed journal articles	Conference papers, book chapters, review articles, editorials	Ensures rigor and primary empirical evidence
Keywords presence	Core keywords present in title/abstract/text	No relevant integration/predictive analytics keywords	Improves retrieval precision for the research topic
Language	English	Non-English	Ensures consistency in

			interpretation and reporting
Publication stage	Final published articles	Articles in Press / incomplete reports	Ensures complete peer-reviewed evidence base

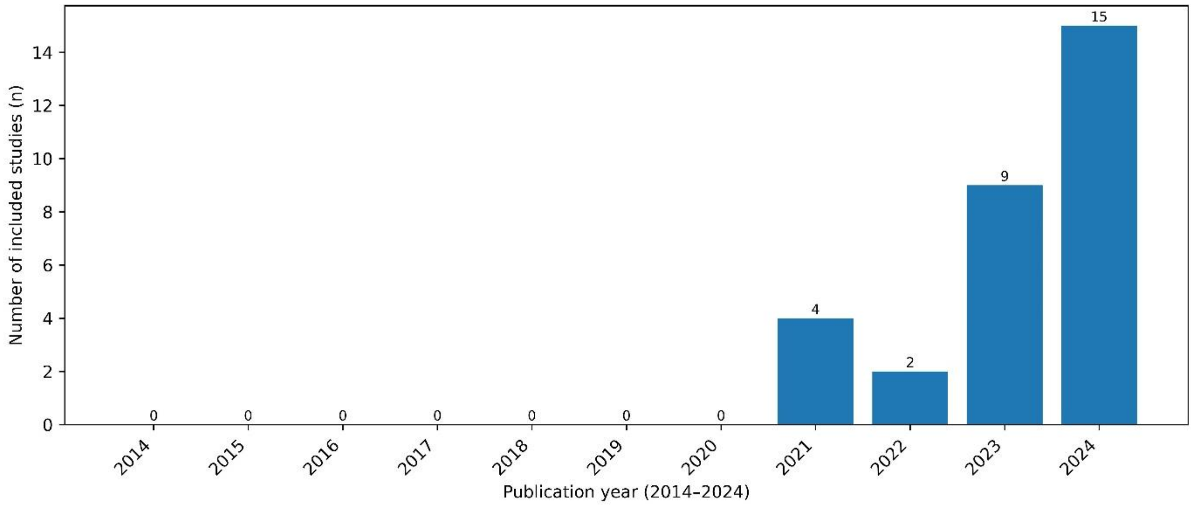

Figure 3: Study Selection Timeline 2014 - 2024

Findings and Thematic Analysis

This section presents the synthesized findings from the reviewed literature using thematic analysis, focusing on four major themes: (1) Lean Six Sigma in the pharmaceutical industry, (2) integration of ML with LSS for predictive analytics, (3) framework development strategies, and (4) key applications and case studies. These themes emerged from a systematic review of 34 peer-reviewed articles selected using rigorous inclusion and exclusion criteria.

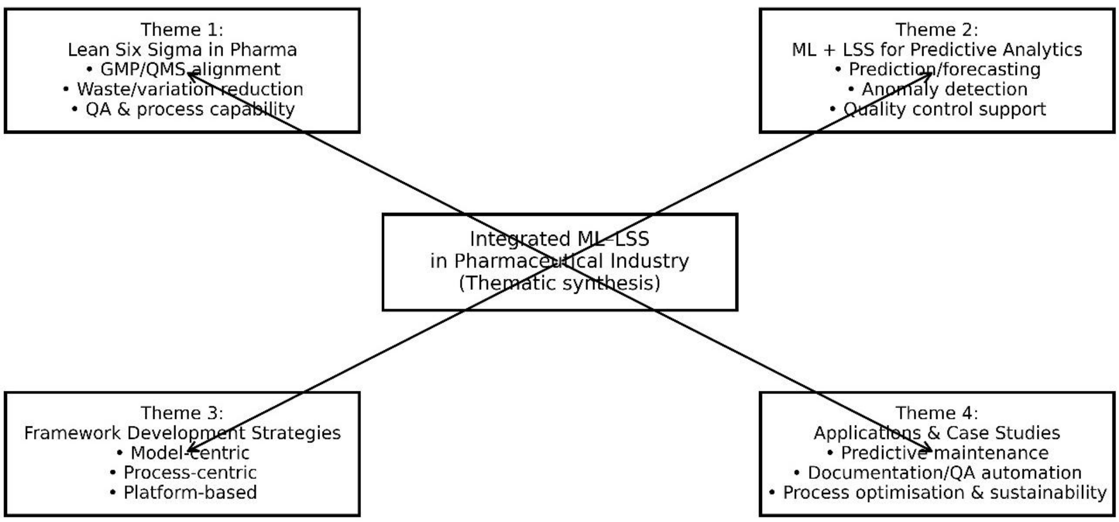

Figure 4: Thematic Map

Lean Six Sigma in the Pharmaceutical Industry

LSS has gained considerable recognition in the pharmaceutical industry as a structured methodology for driving operational excellence. The integration of Lean principles that focused on waste reduction and Six Sigma tools which is targeting the process variability and defect minimization, has been shown to yield measurable improvements in productivity and compliance (Olutade, 2023; Francescatto et al., 2022). Numerous studies underscore the value of LSS in enhancing pharmaceutical manufacturing outcomes. For example, Byrne et al. (2021) demonstrated how LSS methodologies led to a significant reduction in production cycle times and improved throughput in a pharmaceutical facility. Similarly, Purba (2021) and Simões Ramos da Silva et al. (2023) emphasized that LSS enhances regulatory adherence by standardizing quality control measures across complex production chains. Despite these benefits, traditional LSS approaches face limitations in dynamic environments. Their reliance on historical data and linear process models limits responsiveness to real-time variability. This gap has prompted researchers and practitioners to explore more adaptive, intelligent tools that can complement and enhance the traditional LSS structure.

Integration of Machine Learning with LSS for Predictive Analytics

The convergence of ML and LSS represents a pivotal advancement in process optimization, particularly in complex and data-rich industries such as pharmaceuticals. ML algorithms bring the power of pattern recognition, anomaly detection, and predictive modelling to LSS frameworks, thereby addressing LSS's limitation in real-time responsiveness (Alhakimi, 2024; Huang et al., 2023). Thematic analysis revealed a strong convergence between ML algorithms and the DMAIC (Define, Measure, Analyse, Improve, Control) cycle of Six Sigma. For instance:

a. In the Analyse phase, ML enables identification of hidden patterns and process inefficiencies;
b. In the Improve phase, optimization algorithms propose data-driven adjustments;
c. In the Control phase, ML supports dynamic monitoring and feedback control systems.

Many of the studies highlighted the synergistic potential of ML and LSS. For instance, Mukherjee and Sharma (2024) leveraged Natural Language Processing (NLP) and ML within an LSS framework to enhance pharmaceutical quality control. Similarly, Kolbusz and Antosz (2024) reviewed multiple implementations of ML within Six Sigma projects, illustrating improved forecasting of equipment failures and proactive maintenance planning. This integration enables pharmaceutical firms to shift from reactive to proactive quality and operations management. And studies by Nwamekwe et al. (2024) and Francescatto et al. (2022) highlighted that ML-enhanced LSS frameworks support proactive rather than reactive decision-making, improving responsiveness to critical variables in pharmaceutical production, such as temperature stability, equipment utilization, and material traceability. Through supervised learning and other predictive techniques, ML enriches LSS by providing foresight into potential process deviations, reducing wastage and enabling better resource allocation. Furthermore, the alignment of this integrated approach with Industry 4.0 initiatives strengthens its value proposition in future-ready manufacturing systems (Arcidiacono & Pieroni, 2018; Nwamekwe et al., 2025).

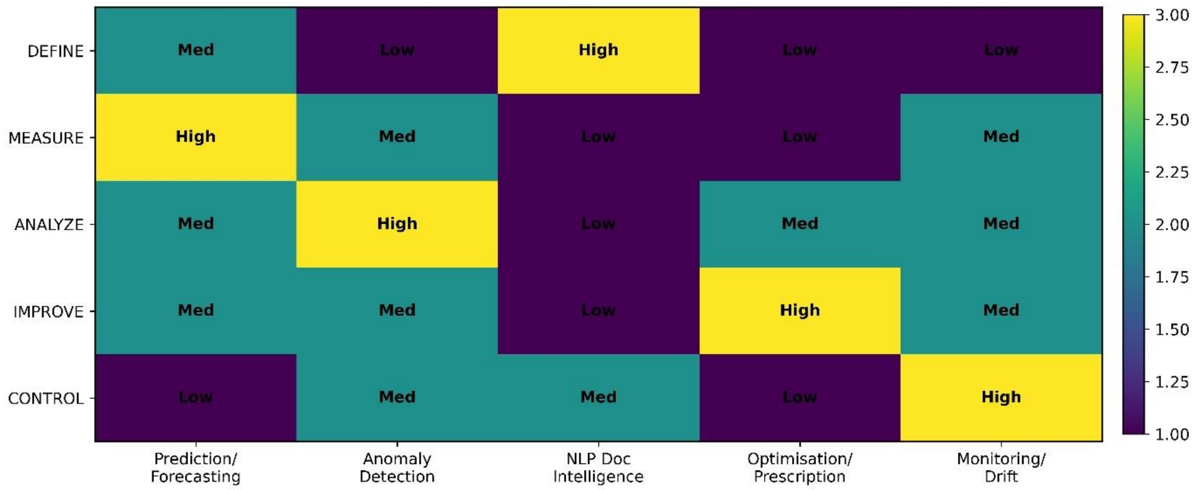

Figure 5: DMAIC x ML Capability Heatmap

Framework Development Strategies

A prominent theme in the literature is the strategic development of integrated frameworks that blend ML tools with established LSS methodologies. These hybrid models often employ algorithms such as decision trees, support vector machines, and neural networks within the DMAIC (Define, Measure, Analyze, Improve, Control) cycle of LSS. Setyowati et al. (2023) proposed an integrated framework involving ML algorithms and Manufacturing Execution Systems (MES) within the LSS architecture to improve operational excellence at a pharmaceutical company. Similarly, Mangal and Sharma (2023) developed a continuous improvement model that utilizes AI-based predictive feedback loops within the traditional LSS framework. However, the review also revealed a lack of standardization in these frameworks. Variability in algorithm selection, data preprocessing strategies, and performance evaluation metrics makes it challenging to generalize findings or replicate results across different pharmaceutical settings. This underscores the need for consolidated guidelines or industry benchmarks to support broader adoption of ML-enhanced LSS systems.

However, multiple studies proposed different strategies for embedding ML into LSS frameworks. Thematic analysis identified three dominant approaches:

1. Model-Centric Frameworks: These emphasize the deployment of specific ML models (e.g., Random Forests, SVM, Neural Networks) at various stages of LSS projects to support classification, regression, or clustering tasks (Kolbusz & Antosz, 2024).
2. Process-Centric Frameworks: These align ML capabilities with each phase of the LSS methodology, ensuring integration from project definition to control and monitoring (Setyowati et al., 2023; Mangal & Sharma, 2023).
3. Platform-Based Frameworks: These use cloud-based or IoT-enabled platforms to continuously gather, process, and analyse data within the LSS lifecycle (Venkatasubramanian & Srivastava, 2023).

A common theme across these strategies is the need for modular and scalable designs, enabling pharmaceutical companies to integrate ML at their own pace, depending on digital maturity and data availability. Frameworks also emphasized the necessity of cross-functional collaboration between data scientists, quality engineers, and regulatory experts.

Key Applications and Case Studies

Empirical studies serve as a strong validation for the practical applicability of ML-integrated LSS frameworks in the pharmaceutical sector. These case studies span diverse functional areas such as quality control, production planning, drug development, and regulatory compliance. For example, McGlinchey et al. (2025) conducted a case study on applying green LSS principles integrated with ML to enhance sustainability in pharmaceutical manufacturing. Another study by Bhaskar and Mohanty (2024) demonstrated how AI-enhanced Six Sigma documentation tools streamlined quality assurance processes, reducing errors and approval cycle times. A recurring benefit reported in these applications is the improvement in key performance indicators (KPIs) such as reduced batch rejection rates, lower operational costs, and increased equipment utilization. However, the implementation of such systems is not without challenges. Data fragmentation, lack of skilled personnel, and integration with legacy IT infrastructure are commonly cited hurdles (Wankhede & Agrawal, 2024).

These case studies not only validate the theoretical underpinnings of ML-LSS integration but also highlight the contextual and organizational factors that influence successful implementation. As the pharmaceutical industry continues to evolve, the insights from these real-world applications will be instrumental in shaping best practices for future initiatives. In summary, the thematic analysis underscores the transformative potential of integrating Machine Learning into Lean Six Sigma methodologies. While the reviewed literature affirms significant benefits in predictive analytics and process optimization, the findings also call for greater standardization and empirical validation to fully harness the capabilities of this integrated approach within pharmaceutical manufacturing.

However, the practical implementation of ML-integrated LSS frameworks was documented in several real-world case studies. Notable applications include:

a. Quality Assurance and Process Control: Bhaskar & Mohanty (2024) demonstrated the use of Natural Language Processing (NLP) and ML to automate Six Sigma documentation and reduce audit preparation time.
b. Predictive Maintenance: Nwamekwe et al. (2024) reported success using historical sensor data to forecast equipment failures, reducing unplanned downtime.
c. Batch Process Optimization: Lambri et al. (2024) applied ML models to optimize dose accuracy in volumetric modulated arc therapy, improving patient-specific pharmaceutical outcomes.
d. Green Manufacturing: Gupta et al. (2024) discussed the application of Industry 5.0 technologies, including AI, to enhance the sustainability of Lean Six Sigma operations.

Thematically, these case studies demonstrate the versatility of ML-enhanced LSS systems in addressing diverse operational challenges from compliance and documentation to sustainability and quality consistency.

Table 6: Application KPI Template

Application type	**Typical KPIs**
QA/QC automation	Deviation rate; audit preparation time; documentation cycle time
Predictive maintenance	Downtime; MTBF; maintenance cost; OEE
Batch/process optimization	Yield; batch rejection rate; cycle time; energy intensity
Green manufacturing / sustainability	Energy use; waste rate; emissions proxy; cost per batch

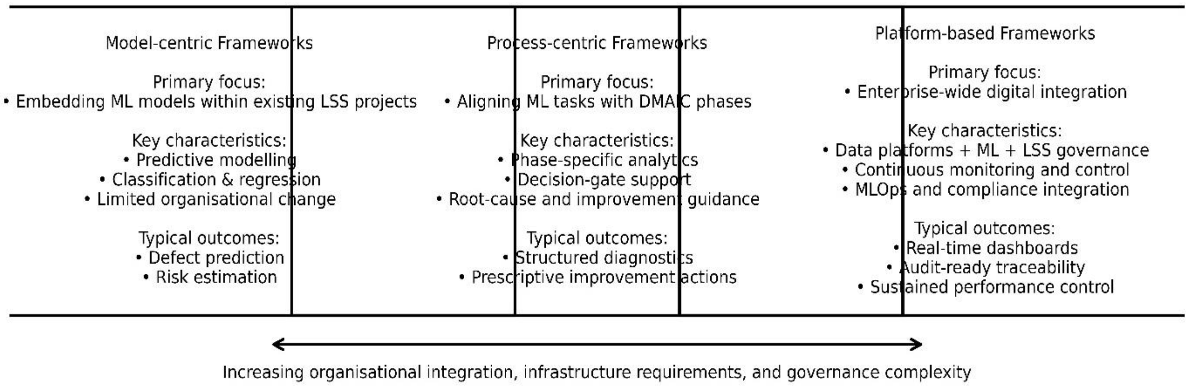

Figure 6: Framework Taxonomy 3 Class

Discussion

Analysis of the Thematic Findings

The findings highlight the multifaceted benefits of incorporating ML within LSS frameworks, including enhanced process optimization and predictive capabilities. However, challenges such as data management complexities, algorithm interpretability, and the need for a skilled workforce present obstacle. A synthesis of these benefits and challenges provides a foundation for future enhancements in ML-embedded LSS frameworks.

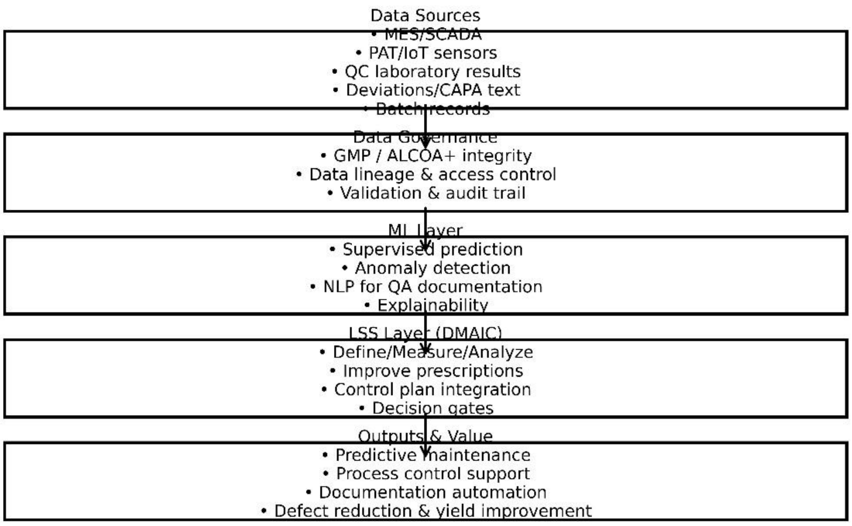

Figure 7: Reference Architecture of ML Embedded LSS

Implications for the Pharmaceutical Industry

The integration of ML into LSS frameworks has practical implications for pharmaceutical companies, especially concerning regulatory compliance and competitive positioning. The ability to predict maintenance needs and optimize production processes can lead to significant long-term cost savings and operational resilience. By adopting these frameworks, pharmaceutical companies can better navigate regulatory landscapes and enhance their adaptability to market changes.

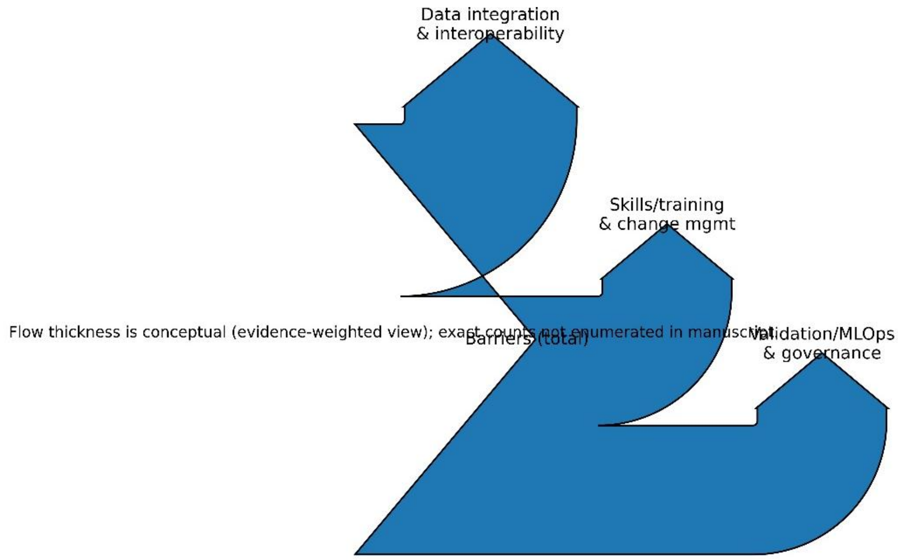

Figure 8: Barriers vs Enablers Sankey

Limitations and Research Gaps

While the reviewed literature provides valuable insights, it reveals several research gaps, such as the need for empirical validation of ML-embedded LSS frameworks. Additionally, there is a lack of studies focusing on real-time applications and customized frameworks that address specific pharmaceutical manufacturing challenges.

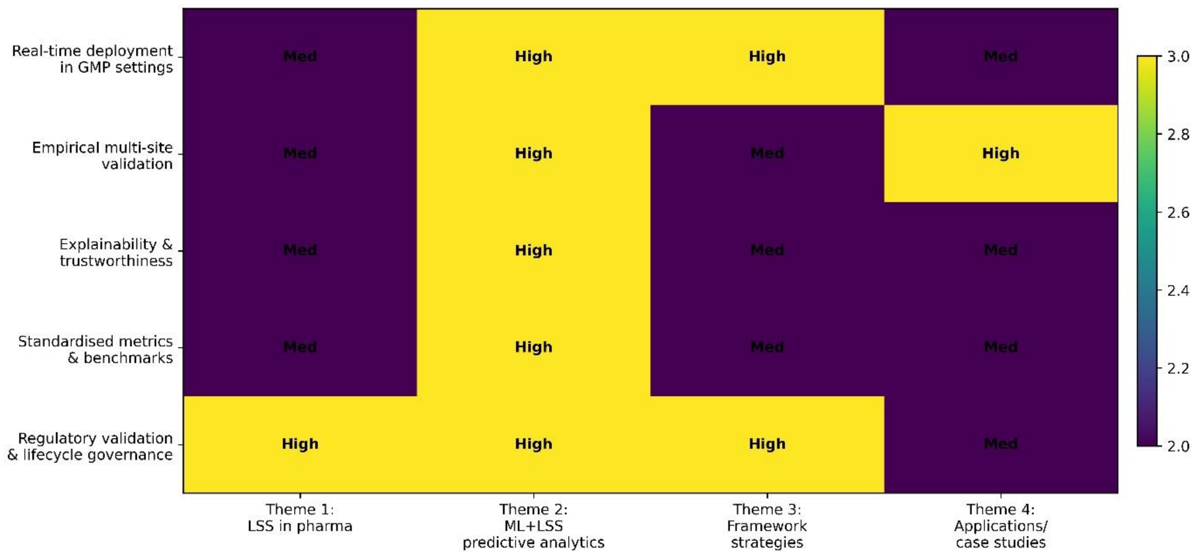

Figure 9: Research Gaps Heatmap with Severity Coding

CONCLUSION

Summary of Key Findings

This review synthesizes evidence from thirty-four peer reviewed studies on the integration of machine learning within Lean Six Sigma in pharmaceutical settings. The findings show strong alignment between ML techniques and the DMAIC structure, especially in the Analyse, Improve, and Control phases. Studies report consistent gains in predictive maintenance accuracy, quality monitoring, and process stability. ML strengthens LSS by enabling early detection of deviations, improved forecasting of equipment and quality risks, and continuous monitoring of critical process variables. Case evidence links ML embedded LSS to reduced batch rejections, shorter quality review cycles, better equipment availability, and stronger data traceability. The review also shows that most frameworks remain fragmented, with limited standard metrics, uneven validation practices, and weak attention to interpretability and regulatory readiness. These gaps constrain transferability across pharmaceutical operations.

Future Research Directions

Future research should focus on structured integration of advanced ML models within clearly defined LSS decision points. Priority areas include model transparency, validation logic, and alignment with GMP and data integrity principles. Researchers should develop phase specific ML guidance tied directly to DMAIC objectives, rather than standalone model demonstrations. Real time deployment studies using live manufacturing data deserve focused attention, especially for process control and deviation prevention. Comparative studies across plants and product types would strengthen generalizability. Research should also address workforce readiness, cross functional collaboration, and governance structures that support sustained ML use within LSS programs. These directions support practical adoption and long-term value creation in pharmaceutical manufacturing.

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