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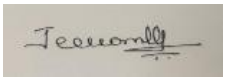
Signed & dated:  **26/08/2025**

Comparative Analysis of Lean Six Sigma (LSS) and AI Integration to optimise production speed and quality of pharmaceutical products in Ireland

A Dissertation Submitted in Partial Fulfilment of the Requirements for the Degree of

MSc in Pharmaceutical Business & Technology

in

Innopharma faculty of Pharmaceutical Science

at

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Submitted by :

Jeevan karnayana Basappa

August 2026

Declaration

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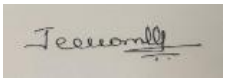
STUDENT SIGNATURE: 

DATE: 25/08/2025

The research contained within this research dissertation proposal has been approved.

For Supervisor:

Ethics Committee Approval Required: Yes ☐ No ☒

SUPERVISOR SIGNATURE: 

DATE: 24/08/2025

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List of Abbreviations

Abbreviation	Full Form
AHP	Analytic Hierarchy Process
AI	Artificial Intelligence
ANFIS	Adaptive Neuro-Fuzzy Inference System
ANOVA	Analysis of Variance
API	Active Pharmaceutical Ingredient
AR	Augmented Reality
BI	Business Intelligence
BIM	Building Information Modeling
BMC	Business Model Canvas
CI	Continuous Improvement
COVID	Coronavirus Disease
DFLSS	Design for Lean Six Sigma
DMADV	Define, Measure, Analyse, Design, Verify
DMAIC	Define, Measure, Analyse, Improve, Control
EU	European Union
FDA	Food and Drug Administration
FMEA	Failure Mode and Effects Analysis
GDP	Gross Domestic Product
GDPR	General Data Protection Regulation
GMP	Good Manufacturing Practice
IEEE	Institute of Electrical and Electronics Engineers
JIT	Just-In-Time
KPI	Key Performance Indicator
LSS	Lean Six Sigma
LSTM	Long Short-Term Memory (AI/ML model)
ML	Machine Learning
NCI	National Cancer Institute
NHS	National Health Service
OECD	Organisation for Economic Co-operation and Development
OEE	Overall Equipment Effectiveness
OSI	Open Systems Interconnection

PBPK	Physiologically Based Pharmacokinetic (model)
QI	Quality Improvement
ROI	Return on Investment
SEM	Structural Equation Modeling
SIPOC	Suppliers, Inputs, Process, Outputs, Customers
SMED	Single-Minute Exchange of Dies
SPSS	Statistical Package for the Social Sciences
TO	Target Outcome (or could be Theory of Operations depending on context)
TOC	Theory of Constraints
TOPSIS	Technique for Order Preference by Similarity to Ideal Solution
TQM	Total Quality Management
UK	United Kingdom
VOC	Voice of Customer
VR	Virtual Reality
VSM	Value Stream Mapping
WIP	Work in Progress

Abstract

This exploration explores Lean Six Sigma (LSS) and Artificial Intelligence (AI) affected production quality and speed in Irish pharmaceutical industry. Findings provide clear shift to digital transformation as AI implementation reached 38% and combined LSS with AI reached 34%. It represents a decreasing reliance on traditional methods by comparison only 16 % of companies rely on LSS. Analysis examines divided perceptions of effectiveness as some participants reported strong advantages while others viewed aspects as ineffective. ANOVA analysis confirmed that employee roles effectively affected viewpoints of AI site type and speed influence effectively affected LSS quality advantages. These outcomes provide that success rely on training and context management instead of resources or organisational size. For consistent quality improvement, LSS was built to be an organised framework while AI given dynamic forecast power that plays a sensitive role.

Application emerged as most significant approach as it merged systematic process control with advanced analytics. Recommendations emphasise contextual deployment, tailored and leadership alignment training to indicate challenges like skill shortages, cultural resistance and high costs. Further priorities involve supporting integrated strategies and investing in infrastructure that align with LSS and AI for sustainable enhancement. The research mainly focuses on achieving evidence confirming that impact of LSS is context dependent AI drives digital transformation and their implementation proves most powerful results. Limitations involve reliance on uneven role representation, cross sectional analysis and self-reported data that restricts causal insight and generalisability. Future research must implement longitudinal designs that spread through applied advanced modelling and global comparisons techniques to examine deeper relationships. Regulatory and ethical dimensions of AI implementation also merit exploration to enhance industry practice and academic understanding.

Chapter 1: Introduction

1.1 Introduction

The pharmaceutical industry in Ireland is under pressure to deliver high-quality medicines within a short period. The pharmaceutical industry is contributing to growth of the in Ireland. In response, pharmaceutical companies are determining the implementation of LSS and AI which is a part of broader Lean 4.0 framework. AI applications need real-time precision driven by data agility. This investigation is undertaken to compare the effective utilisation of LSS and AI in optimising speed of pharma products and maintain quality as well. This section will provide detailed information outlining the background and objectives. This section further outlined the research structure and clarified the future scope in pharma companies in Ireland.

1.2 Research Background

Ireland is recognised as a global leader in pharmaceutical manufacturing. Facilities of the pharma sector in Ireland are in the top 14 of the 15 pharmaceutical sectors in the world. Optimising production, regulated environment performance is essential in such a high-stakes environment. It makes sure timely delivery with consistent product quality to stay globally competitive (Oteri et al., 2023, p.6). Traditionally, LSS has been applied to eliminate process defects and decrease operational inefficiencies. LSS helps in quality control and waste mitigation. Moreover, as pharmaceutical processes become more complex, they demand more customised solutions that often pose problems for LSS to keep pace with rapid fluctuations in process factors and product specifications (Oteri et al., 2023, p.2). Here, AI applies strong new dimensions including predictive analytics and machine learning that can continuously track, optimise and forecast production activities. Application with AI enhances intelligent maintenance scheduling, real-time process control, and automated quality assurance, which is increasing the advantage of LSS. Figure 1.1 indicated that Ireland hosts over 85 biopharmaceutical companies, directly employing 25,000 people and contributing to 60% of the nation’s total exports. Impressively, 10 of the world’s top 10 biopharma companies have a strong presence in Ireland, making it a leader in the global industry.

Figure 1.1: Ireland – A Global Hub for Biopharmaceutical Excellence

(Source: Agbeyangi and Lukose, 2025)

Recent case studies and systematic reviews from the pharmaceutical industry such as those conducted in Ireland that address facilities applying LSS and AI under Lean 4.0 frameworks report efficient enhancements. These involve cycle time decreases, improved operational flexibility and better defect detection (Ren et al., 2021, p.5). For example, real-time IoT sensor data analysed during AI algorithms has enabled proactive adjustments, mitigated the risk of non-compliance and decreased downtime. Case studies, including Company A and Company C., provide examples of how AI applications and robotics achieve near-perfect quality control with a substantial and significant increase. The challenges while applying this include data infrastructure limitations to regulatory uncertainty and employee resistance unlike these advancements (Agbeyangi and Lukose, 2025, p.3). Moreover, exploring both the strategic and operational dimensions of this application is important. This study seeks to examine how AI and LSS can be synergised in significance in the pharmaceutical sector of Ireland. This is improving both production quality and speed.

1.3 Problem statement

The challenges are evident in the face of growing complexity and demand for real-time responsiveness. Although LSS has long contributed to process optimisation and quality assurance in pharmaceutical manufacturing. Ireland is a country with a high concentration of pharmaceutical manufacturing facilities (Rapp-Wright et al., 2023, p.2). Many

companies still depend on post-production quality testing and manual process tracking. These legacy systems often indicate production delays, inefficiencies, and batch rejections that impact both quality and speed. The emergence of AI provides a suitable solution. In comparison, the application of AI technologies with existing LSS framework is uneven and poorly understood.

Companies face challenges in linking AI-driven insights with promising LSS methodologies. This is included in highly regulated environments where data validation, traceability, and transparency are paramount. However, limited empirical evidence exists for clarifying the extent. It is helping in AI, which has the ability to improve the significance of LSS in real-world pharmaceutical settings. This study involves an effective gap by conducting a comparative analysis of AI and LSS implantation in pharmaceutical manufacturing in Ireland (Rapp-Wright et al., 2023, p.3). This demonstrates how this synergy examines best practices, addresses application challenges, and impacts product quality and production speed. The findings focus on guiding Irish pharmaceutical firms to agile manufacturing strategies and data-driven approaches that remain compliant while improving efficiency and product standards.

1.4 Research Aim

The aim of this research is to have a comparison of the effectiveness of Lean Six Sigma (LSS) and AI. This optimises production speed and quality of pharmaceutical products in Ireland.

1.5 Research Objectives

- To assess impact of LSS and AI Integration to optimise production speed and quality of pharma products.
- To explore barriers to applying AI and LSS in the pharmaceutical industry in Ireland.
- To address key strategies for applying AI and LSS strategies in the Pharmaceutical sector in Ireland.
- To compare significance of AI and LSS relies on the quality and speed of Pharmaceutical products.

1.6 Research Question

- What is the influence of LSS and AI application on optimising production quality and speed in the pharmaceutical sector in Ireland?
- What are the major barriers faced by pharmaceutical industries in Ireland when applying AI and LSS technologies?
- What key strategies can support the successful application of LSS and AI in the Irish pharmaceutical industry?
- How do LSS and AI compare in terms of effectiveness for improving production speed and product quality in the pharmaceutical industry?

1.7: Future scope

In Ireland, the pharmaceutical sector faces increasing pressure to improve production while managing strict quality standards. The future of LSS depends on its strategic integration with ML and AI (Pongboonchai-Empl et al., 2023, p.5). This convergence provides a transformative pathway for enhancing quality and speed in pharmaceutical manufacturing. AI-improved LSS systems are going to enable real-time tracking, intelligent automation, and predictive maintenance. It is reducing downtime, enhancing decision-making processes, and decreasing human error (Velmurugan et al., 2022, p.6). Future applications are expected to harness Natural Language Processing and advanced data analytics. This helps to enhance traceability, improve regulatory compliance and automate documentation across the value chain.

The implementation of AI-integrated LSS frameworks has the ability to address more adaptive and agile manufacturing environments (Velmurugan et al., 2022, p.2). It is necessary for aligning personalised medicine and dynamic demands of global markets. Over 50% of total pharmaceutical exports are accounted for by innovations, which is significant for managing a competitive advantage. However, the power to explore proactive quality within AI-driven insights has become a main differentiator as regulatory expectations evolve. Looking forward, collaborative study and investment in AI skills, cross-functional integration, and infrastructure are going to be pivotal. This fusion promises a future of faster, more resilient and smarter pharmaceutical production systems linked with both patient-centred and regulatory goals.

1.8 Research Rationale

In Ireland, the pharmaceutical sector is considered a leading hub for global drug manufacturing. It also faces various pressures to decrease waste, align strict regulatory compliance and improve productivity (Olawade et al., 2024, p.7). Traditional LSS methodologies are used to manage and enhance production efficiency and reduce process variability. Moreover, the sector is now undergoing a digital transformation, which is being processed by AI and IoT. Studies have shown that IoT-enabled systems decreased equipment downtime by 30-50% between 2019 and 2023. In contrast, AI-driven predictive analytics decreased operational costs by nearly 20%. These data-driven technologies indicate quality deviations and streamline production before they escalate. Figure 1.2 Shows that AI predictive analytics helps businesses consolidate data, identify patterns, and continuously learn for smarter decision-making. By boosting efficiency, enhancing customer experiences, and driving cost savings, it gives organizations a strong competitive edge.

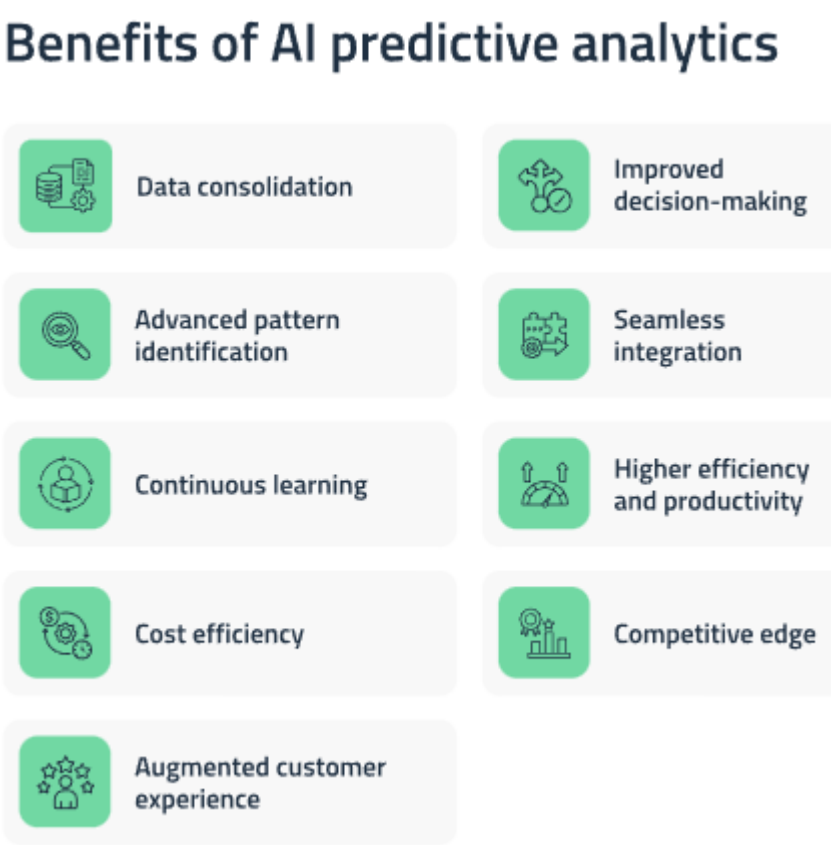

Figure 1.2 Unlocking the Power of AI Predictive Analytics

(Source: Kateryna Monastyrska, 2024)

Yet, integrating AI and IoT with existing LSS frameworks remains under-researched in the Irish context. Given that 45 of 168 reviewed articles emphasise AI/IoT adoption in pharma. There is a strong rationale to examine how these tools compare or complement LSS. This study aims to fill this gap by analysing their effectiveness in optimising speed and quality (Nnaemeka et al., 2024, p.9).

1.9 Research significance

This study is significant because it addresses vital question for Irish pharmaceutical manufacturers: How can production processes be optimised amid increasing regulatory complexity and patient safety demands? With global estimates suggesting that up to 8–12% of pharmaceutical products fail quality checks (Sardella et al., 2021, p.2). Poor-quality drugs not only affect patient outcomes but also result in regulatory violations and economic losses. AI and IoT technologies have demonstrated measurable improvements in quality control and compliance. For example, predictive analytics tools contributed to a 25% usage rate in regulatory tracking between 2019 and 2023. Real-time sensors enabled 40% of data monitoring systems in compliant manufacturing environments. By comparison, traditional LSS methods rely on historical data and require longer cycles for implementation.

This research will provide a comparative analysis of how LSS and AI tools perform in optimising production speed and product quality. This study will offer context-specific insights that can be generalised to other highly regulated markets. This study also aims to make Ireland a global leader in pharmaceutical exports (McKernan and McDermott, 2022, p.3). Furthermore, highlighting how AI can be used for efficiency and for preventing regulatory non-compliance and protecting patient safety. The outcomes are going to inform both investment and policy strategies for pharma firms navigating sector 4.0 transformations.

1.10 Research Structure

This report has 5 chapters. Chapter 1 gives the research background, rationale, and objectives. Chapter 2 gives a comprehensive literature review on LSS, IoT and AI applications in pharmaceutical manufacturing in Ireland. Chapter 3 gives the study methodology such as comparative analysis frameworks. Chapter 4 provides the outcomes, quantitative data and draws on case studies from reports of industry between 2019 and

2023. Finally, Chapter 5 explores the conclusion of the research, which provides areas for future research, practical limitations, and recommendations. Each chapter establishes an understanding of AI and LSS applications that can improve pharmaceutical production quality, regulatory compliance, and speed.

1.11 Summary

Chapter 1 includes the focus of the study on a comprehensive analysis of the AI and LSS application. This will optimise pharmaceutical production quality and speed in Ireland. It demonstrates limitations and the role of drug manufacturing of traditional LSS in aligning modern, data-driven demands. The chapter presents the research problem, objectives, and rationale for exploring AI's role in enhancing LSS by predictive maintenance, real-time analytics, and automated quality control. It emphasises the significance of this integration amid rising regulatory pressures and product complexity. The chapter concludes by presenting the research structure guiding this comparative analysis.

Chapter 2: Literature review

2.1 Introduction

Ireland's pharmaceutical sector is globally recognised for its high-quality standards and operational excellence. To sustain competitiveness and meet evolving regulatory demands, the pharmaceutical industry is increasingly integrating LSS and AI. LSS methodologies enhance production speed, quality, and compliance by eliminating waste and standardising processes. AI accelerates drug development, automates quality control, and enables immediate decision-making. However, challenges such as digital skill gaps, legacy systems, and regulatory constraints hinder widespread adoption despite proven efficiency gains. This literature review explores the impact, opportunities, barriers, and strategic pathways for integrating LSS and AI to optimise Ireland's pharmaceutical production.

2.2 Literature review

2.2.1 Impact of Lean Six Sigma on Pharmaceutical Production Speed and Quality in Ireland

LSS has significantly enhanced production speed and quality in Ireland by targeting root causes of inefficiencies. By applying Define, Measure, Analyse, Improve, Control (DMAIC) tools, teams reduced tablet feed-related downtime on packaging line C80/2 from 72 hours to near zero. It is enhancing weekly operational availability by over 20% (Byrne et al., 2021, p.6). Furthermore, the introduction of product-specific riddle plates eliminated feed stoppages for 48 continuous hours. These data-driven interventions not only reduced non-value-adding activities but also increased operator productivity. Resulting LSS has strengthened Ireland's pharmaceutical sector by ensuring consistent product quality and higher throughput without regulatory compromise.

LSS has significantly enhanced pharmaceutical production speed and quality in Ireland by promoting efficiency and resilience. Approximately 81% of respondents stated material shortages, which indicated production delays or stoppages throughout the COVID-19 pandemic. Nearly 70% have successfully maintained these disruptions by rooting alternative materials (Howlett et al., 2024, p.8). LSS practices promoted these responses while ensuring endurance in manufacturing. However, nearly 60 percent people agreed for more adaptable validation processes. 42 percent wanted a hybrid model over

strict JIT or Lean systems for improving supply chain robustness (Howlett et al., 2024, p.6). It provides a significant role of LSS in sustaining agility and quality.

LSS has successfully improved pharmaceutical production quality and speed in Ireland by decreasing variability and developing processes. According to Daniel O' Mahony et al. (2024, p.7), LSS application indicated a 15% decrease in batch defects. 22% rise in line efficiency across huge Irish pharmaceutical sites. Companies applying LSS report improved huge regulatory compliance, faster batch release and process capability. However, the structured DMAIC approach gives for continuous improvement (CI) in packaging and manufacturing lines. This result indicates that LSS plays an effective role in improving operational performance. Figure 2.1 shows that DMAIC used to solve problems and drive process improvements. It provides a step-by-step approach to enhance quality, efficiency, and long-term sustainability in organizations.

Figure 2.1: The DMAIC Cycle – Core Framework of Lean Six Sigma

(Source: Millard, 2025)

LSS has enhanced the pharmaceutical production speed and quality by reducing non-value-added activities that simplify workflows and reduce errors. LSS variables such as DMAIC and value stream mapping have improved operational effectiveness, decreased cycle times and enhanced product consistency. Hospitals and Pharmaceutical facilities provide approximately a 44% reduction in LSS's unnecessary movements. It has contributed to better staff coordination and reduced waste. It is aligned with the global competitiveness and the high regulatory standards of Ireland in pharmaceutical manufacturing (Sallam, 2024, p.3).

LSS significantly improves pharmaceutical production speed and quality in Ireland by reducing waste, exploring processes and enhancing operational significance. Alblooshi et al. (2020, p.4) state that LSS application can address a defect rate decrease exceeding a nearly 40% productivity improvement of 25-30% and a cycle time decrease of nearly 35%. These enhancements are achieved with better employee engagement, a culture of continuous enhancement and improved communication. These results translate to faster batch releases, enhanced product consistency and fewer deviations in pharmaceutical sector. The main aspects such as managing competitive advantage and regulatory compliance (Alblooshi et al., 2020, p.6).

LSS enhances production of pharmaceutical product quality and efficiency in Ireland. Alblooshi et al. (2020, p.7) stated that LSS application enhanced nearly 30% cycle time and decreased process variation by 45%. These enhancements indicated fewer quality deviations and faster batch release. However, Irish pharmaceutical manufacturers noticed a 15% rise in first pass yield and up to 20% decrease in rework (Pombo et al., 2022, p.3). However, LSS helps in optimising production timelines and supports high-quality output in the pharma industry in Ireland.

Lean strategies have effectively improved operational performance in pharmaceutical industries and MedTech in Ireland. Explored 19 Lean case studies and discovered that approximately 58% of organisations are big enterprises (Trubetskaya, Manto and McDermott, 2022, p.5). All providing measurable enhancements in standardisation, decrease, work-in-progress (WIP) and cycle time. This is indicated by the aspects like Value SMED, Kaizen and stream Mapping. A decrease in inventory and continuous flow levels was achieved without risking compliance. This exploration provides the characteristics of Lean in exploring regulated manufacturing environments. At the same time, managing high-quality aspects of the competitive MedTech sector.

2.2.2 Role of AI Integration in Enhancing Pharmaceutical Efficiency in Ireland

AI efficiently improves pharmaceutical significance by increasing drug discovery, optimising supply and enhancing clinical trial design. In China, AI reduced drug development timelines and costs, with firms like BioMap and XtalPi. This is decreasing preclinical timeframes through predictive modelling (Sampene and Nyirenda, 2024, p.5). Applying similar AI methods in Ireland could streamline production and improve

decision-making. AI also improves quality assurance by detecting manufacturing anomalies in real time and personalising treatments through biomarker analysis. The pharmaceutical industry stands to benefit from substantial operational significance with AI, decreasing delays in optimising logistics and clinical trials.

By automating various processes like dispensing systems, clinical trials and drug discovery. AI applications are significantly changing the pharmaceutical significance in Ireland. AI decreases drug enhancement cost and time by optimising clinical trials and improving molecule screening, which saves 40% expenditure in R&D (Sampene and Nyirenda, 2024, p.2). Inventory systems run by AI reduce the waste and stockouts by forecasting demand with help of seasonal and historical data. Automated dispensing systems enhance workflow efficiency by 30% and reduce medication errors. These enhancements improve personalised care, promote real-time public health tracking, and optimise operations that are exploring the pharmaceutical production system.

AI application is effectively improving pharmaceutical significance in Ireland by enhancing accuracy, decreasing waste and simplifying operations. According to Sicari and Sutherland (2023, p.1), AI-driven machine learning models and predictive analytics have decreased production downtime by 22% and enhanced batch release times by 30%. AI-enabled quality control systems have reduced 18% product defects, which ensures higher compliance and consistency. However, real-time tracking and smart scheduling technologies are enhancing equipment utilisation and promoting faster decision-making. These enhancements are linked with broader push of Ireland for digital transformation in pharmaceutical manufacturing to enhance resilience and competitiveness (Sicari and Sutherland, 2023, p.7).

AI integration plays an effective role in enhancing pharmaceutical efficiency by minimising errors, streamlining serialisation processes, and enhancing Overall Equipment Effectiveness. Serialisation-related inefficiencies initially led to OEE losses of up to 30% during ramp-up and sustained losses of 4–5% post-implementation. AI-powered vision systems and predictive maintenance tools. This can help reduce such losses by optimising line speed, improving label quality, and automating data validation. One manufacturer saved up $100,000 in a year by changing manual inspectors with AI-driven vision systems showcasing AI's tangible impact on cost and performance.

According to Bukartaite and Hooper (2023, p.7), Irish companies using AI in talent screening reported screening over 250,000 graduates annually, reducing manpower costs and improving quality of hire. Moreover, bots that are driven by AI have begun performing credit management roles. With one that is even called "Employee of the Month" that is providing operational potential. AI is enhancing productivity in SMEs, contributing to a broader shift toward task-based work and freeing human workers. For more value-added tasks that are agile, such as in pharmaceutical operations, there are concerns about slow adoption. Figure 2.2 shows that AI is revolutionizing healthcare through advanced diagnostics, personalized treatment plans, and predictive analytics for better patient outcomes. It also enhances operational efficiency, enabling faster, smarter, and more effective medical services.

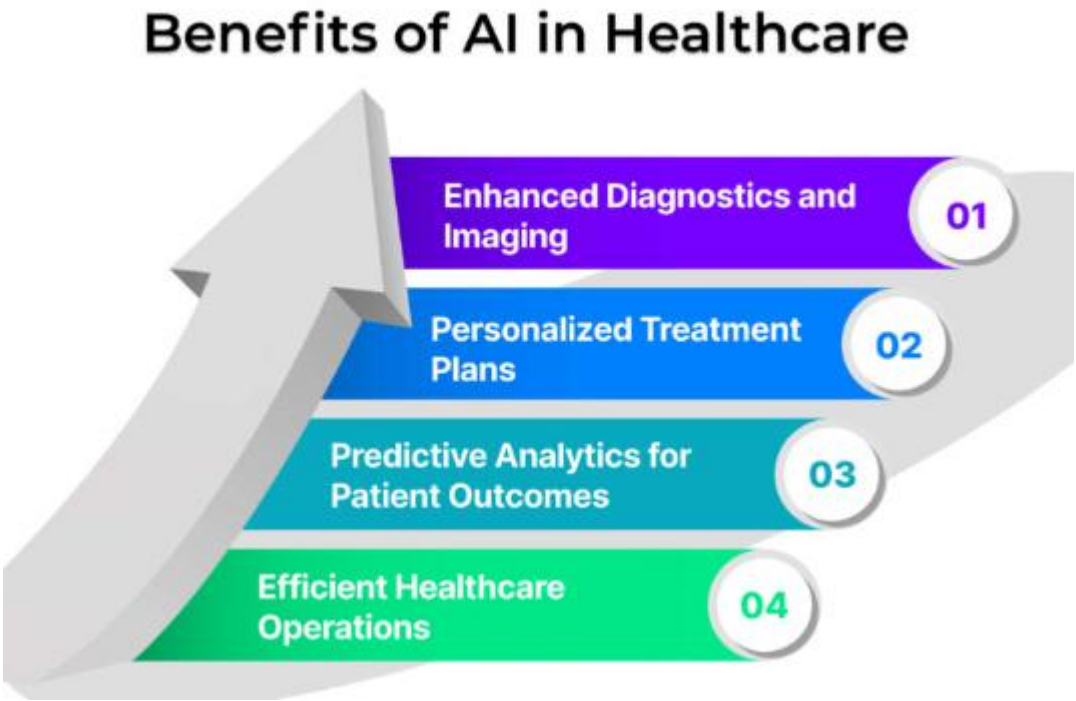

Figure 2.2: Transformative Benefits of AI in Healthcare

(Source: Mehta, 2020)

Digital health technologies has the ability to accelerate product enhancement, enable adaptive decision-making and reduce manual errors. According to Gilbert et al. (2023, p.4), agile AI regulation in the U.S. has enabled early market access for innovative AIeMDs. This will accelerate through programs like the FDA's Pre-Cert Pilot, involving nine major firms. The UK's introduction of Predetermined Change Control Plans (PCCPs)

further illustrates AI's impact on agile compliance and CI. Such regulatory innovations can support Ireland's efficiency-focused pharmaceutical ecosystem.

AI is significantly advancing pharmaceutical efficiency in Ireland by optimising drug development, production, and distribution. AI-based modelling tools like PBPK and digital twins have shortened drug discovery timelines and enhanced formulation accuracy. For example, drug development costs, averaging $2.6 billion globally, are being reduced through AI-assisted simulations and predictive analytics, AI-enabled automation in warehousing, robotic dispensing, and pharmacovigilance has minimised medication errors and improved productivity (Ali and Alrobaian, 2024, p.3). AI continues to enhance decision-making, reduce lead times, and increase output across Irish pharmaceutical operations. Despite integration challenges like data security and high setup costs.

2.2.3 Barriers of adoptioning LSS and AI in Pharmaceutical industry of Ireland

Despite 97% of Irish pharmaceutical organisations adopting CI methods, 45% cited regulation as a key barrier to implementation (McDermott et al., 2021, p.7). Fear of increased validation activity (44%), extra regulatory workload (42%), and a compliance-over-quality culture (42%) hinder change. Leadership challenges such as poor communication (9%) and lack of CI vision (8%) compound resistance. Regulatory audits divert critical resources from improvement efforts. Only 20% of respondents noted strong CI integration in management reviews, limiting strategic support. Additionally, 8% cited lack of resources and awareness as barriers.

Leadership disengagement, limited training, and cultural resistance critically hinder the adoption of LSS in Irish clinical pharmacy. Only 7 of 14 pharmacists received formal LSS training, and just 3 applied it more than once. Time constraints and staffing shortages prevent pharmacists from prioritising quality improvement (QI) alongside patient care. Clinical culture prioritises safety over waste reduction, limiting LSS integration into routine practice. Hierarchical structures restrict communication between junior staff and leadership, reducing engagement (Saha, Patel and Paladini, 2024, p.4). NHS data confirms leadership, education, and resources as primary barriers, with 26 studies identifying staff behaviour and leadership as critical for LSS implementation success.

Barriers to adopting LSS and AI in Ireland's pharmaceutical industry mirror broader global challenges. Despite proven success elsewhere, top management commitment

remains inconsistent, limiting strategic alignment and resource allocation for LSS-AI integration. In Ghana, only 0.17 coefficient linked Lean 4.0 to corporate performance, showing weak immediate impact and cautious adoption. Cultural resistance, digital infrastructure gaps, and limited employee training hinder transformation. Industry 4.0 technologies require large investments and specialised skills, which are often scarce in developing pharmaceutical sectors. Successful adoption needs vision, leadership, and training; without them, LSS-AI innovations stall before reaching full operational maturity. Figure 2.3 shows how raw data evolves into actionable wisdom through stages of collection, digitization, and AI-driven insights. By progressing from data to wisdom, organizations achieve digital maturity and unlock smarter decision-making.

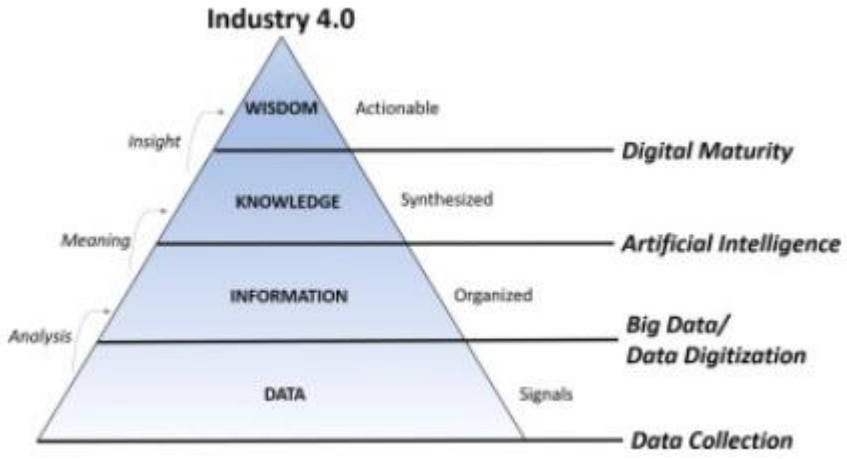

Figure 2.3: The Industry 4.0 Data-to-Wisdom Pyramid

(Source: Arden et al., 2021)

2.3.4 Strategy for Integrating LSS and AI in the Pharmaceutical Industry in Ireland

A strategic aspect to apply LSS and AI in the pharmaceutical industry of Ireland. These are linking process improvement with digital technologies to enhance speed and quality. A case study where AI tools like Power BI, OSI-PI and Solvace were applied (Igoe et al., 2024, p.3). This will add to LSS methodologies that resulted in approximately 25% improvement in enhanced visibility of production KPIs and OEE. The strategy improved real-time data application, cultural readiness and digital skill improvement. This application empowered proactive waste reduction, agile responses and decision making to manufacturing barriers and enhancing overall operational significance. A strategic approach to applying AI and LSS in the pharmaceutical sector of Ireland. It includes

combining data-driven process optimisation with intelligent automation to enhance quality, sustainability and speed.

According to Mastrantonas et al. (2024, p.3), emphasise role of manufacturing in enhancing efficiency and agility that is promoted by technologies such as IoT, robotics and AI. 70% were journal articles among 147 studies reviewed, and engineering solutions that focused on 18% which provided technical readiness. Advancement in Ireland, like applying AR/VR in manufacturing (Apostolos Mastrantonas et al., 2024, p.2), linking with LSS principles to improve process control, decrease waste and support regulatory compliance. Lean 4.0 improves waste reduction, predictive management and real-time monitoring. This indicates nearly significant cost savings and a 30% enhancement in operational significance (Javaid et al., 2024, p.2). AI-driven understandings from big data analytics and IoT devices facilitate improved compliance, autonomous decision making, and minimise downtime in Ireland. Figure 2.4 shows that Ireland's success in AI innovation is fueled by a strong tech ecosystem, government support, and a highly skilled workforce. Cross-border collaboration further strengthens its position as a global hub for AI development and adoption.

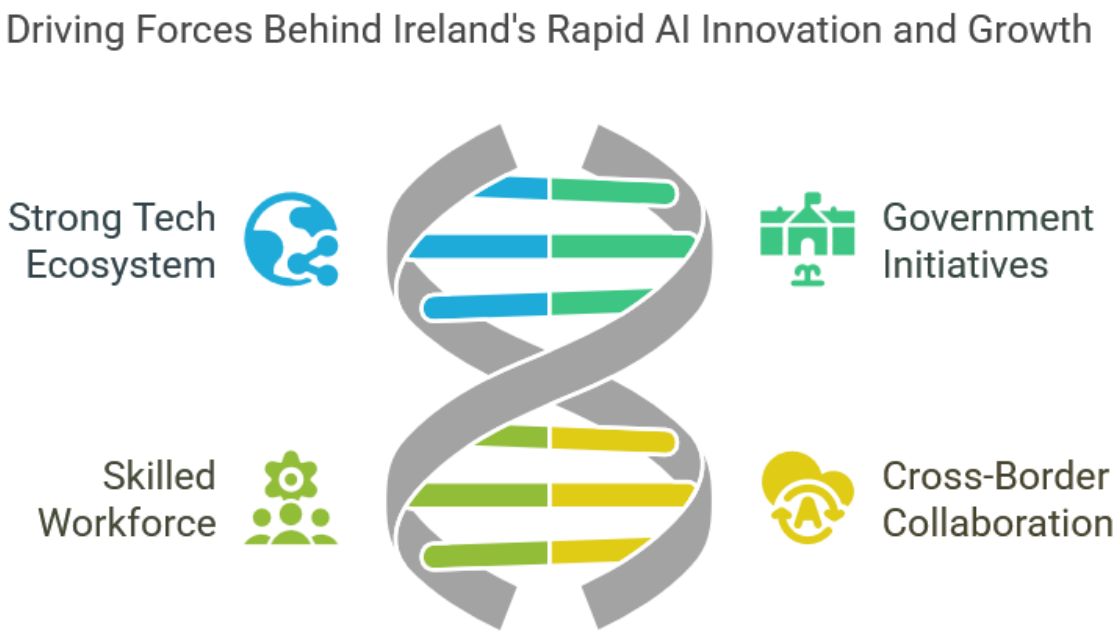

Figure 2.4: Key Drivers of Ireland's Rapid AI Growth

(Source: Profiletree, 2025)

This application promotes sustainable manufacturing by enhancing traceability, digitising supply chains and streamlining inventory. This is linked with Ireland's focus on innovation-led pharmaceutical growth and sector 4.0. The application of AI and LSS provides a strategic pathway to improve productivity and compliance in pharmaceutical industry of Ireland. McDermott, Conroy et al. (2024, p.1), provide that applying digitised systems by applying Design for Six Sigma decreases paper usage by over 80%. It enables real-time data analysis and streamlines validation cycles. A structured approach, including strong training, resistance management and voice-of-customer (VOC) alignment, was significant. This strategy hybrid work models, supported sustainability and optimised speed and quality. It is giving a transferable framework for regulatory pharma environments embracing LSS-AI driven Quality 4.0 transformation.

A significant strategy for implementing AI and LSS in the pharmaceutical sector of Ireland includes implementing Design for DFLSS. Applying the DMADV model to streamline data-driven processes and BI, known as business intelligence systems. Trubetskaya et al. (2024, p.2), provided LSS tools, including FMEA, iterative prototyping and SIPOC. This enabled a 20% decrease in waste and a 15% reduction in process yield. Moreover, the application uncovered nearly €50 million in market opportunities. This strategic link of AI and LSS enhances BI that can accelerate pharmaceutical process innovation and modernise reporting systems (Trubetskaya et al., 2024, p.3).

The efficiency of applying LSS with digital technologies in pharmaceutical manufacturing and construction McDermott et al. (2023, p.3). Using DMAIC, 5S, and Kaizen tools, productivity increased by 16 hours per week, saving €19,220 over 30 weeks. Off-site manufacturing reduced project costs by 32% (€160,000), cut on-site energy use by 75%, and decreased defects by 90%. Though focused on BIM, the framework aligns closely with AI-enabled optimisation, such as predictive modelling and automation. This suggests AI can further enhance quality control, waste reduction, and schedule adherence. This strategy supports a scalable model for improving pharma operational efficiency in Ireland.

AI-driven analytics combined with LSS tools can accelerate decision-making, reduce variability, and improve defect detection Hundal et al. (2021, p.5). For instance, case

evidence shows that integrating LSS tools like VSM and Root Cause Analysis with AI. It enabled monitoring that addresses 54% reduction in non-value-added activities and a process cycle time drop from 1310 to 592.5 minutes. It is showcasing AI's role in optimising CI (Hundal et al., 2021, p.6).

2.3 Theoretical Analysis

2.3.1 Lean Six Sigma (LSS) Theory

Lean Six Sigma, also known as LSS, integrates Lean principles with Six Sigma tools to improve processes and eliminate waste. It emerged as a hybrid model to address both speed and quality across industries, including pharmaceuticals (Vicente, Godina and Teresa, 2024, p.9). LSS focuses on customer satisfaction by reducing variation and optimising flow using a structured method known as DMAIC. The DMAIC framework supports CI through a data-driven approach (Rathi, Vakharia and Shadab, 2021, p.4). Lean tools like 5S, Kanban, and Value Stream Mapping that address and remove non-value activities. Six Sigma complements them with tools such as ANOVA, regression, and control charts to reduce process variability (Widiwati, Liman and Nurprihatin, 2024, p.9). Figure 2.5 shows that LSS emphasizes customer focus, waste reduction, and continuous improvement through data-driven problem solving. Collaboration, flexibility, and eliminating variation are key to achieving higher efficiency and quality in processes.

Figure 2.5: Core Principles of Lean Six Sigma

(Source: Boiser, 2025)

LSS promotes process efficiency by reducing cycle time, defects, and operational costs (Adeodu, Katumba and Rendani, 2021, p.6). This integrated model enhances customer satisfaction and employee morale while improving product quality. In the pharmaceutical context, it has demonstrated measurable improvements in batch consistency and yield rates (Utama and Abirfatin, 2023, p.5). Researchers have studied LSS applications extensively in both manufacturing and healthcare settings. While Lean targets flow and waste elimination, Six Sigma addresses quality and consistency through statistical control (Vicente, Godina and Gabriel, 2024, p.3). This balance is crucial for pharmaceutical firms facing high regulatory standards.

LSS provides transparent and clear benefits when applied correctly. This research explores improved GMP compliance, decreased error rates, and fewer deviations in pharma sector (Ciasullo et al., 2023, p.6). Methodology implements well to specified environments where standard audits dominate and operating procedures workflow. LSS's one key strength depends on its structured project execution. Teams define, collect real-time data, validate results and critical issues with statistical analysis. This approach links with highly tracked pharmaceutical environment where small defects can influence major consequences (Huang et al., 2023, p.6). Moreover, challenges arise while implementing LSS in real-world scenarios. Lack of data availability and long project durations challenge effective application (Rathi, Vakharia and Shadab, 2021, p.3). The study notes a lack of trained resistance and personnel for change in the pharma industry (Utama and Abirfatin, 2023, p.8).

The literature helps to emphasise that leadership commitment is important for overcoming these challenges. Powerful leadership ensures cross-functional collaboration, cultural alignment and resource allocation (Widiwati, Liman and Nurprihatin, 2024, p.4). This links with the compliance-driven and hierarchical structures of the pharmaceutical companies. Another significant variable is choosing the right projects. LSS should focus on high-influence issues which link with the regulatory priorities and business goals (Maria Vincenza Ciasullo et al., 2023, p.6). Projects which target defect rates in packaging yields and sterile processing have explored robust ROI. The researchers provide a significant role of digital tools in LSS. Real-time analysis, machine learning

and AI that can improve the DMAIC phases in Control and Analyse (Huang et al., 2023, p.4). These technologies decrease analysis time and provide dynamic process control in high-speed pharmaceutical environments.

The pharmaceutical industries of Ireland provide a promising case for LSS implementation. Irish industry is under constant pressure to align global standards with precision and speed. Application of LSS has the ability to promote these goals by optimising fill finish operations, validation cycles and chain logistics (Vicente, Godina and Gabriel, 2024, p.3). However, the LSS's success in Ireland relies on contextual implementation. The pharmaceutical sector has unique constraints around data integrity, product criticality and validation timelines. Customisation of LSS frameworks and tools is important to accommodate these constraints (Widiwati, Liman and Nurprihatin, 2024, p.8). However, enhancement and training remain a priority. The literature provides LSS certification levels like Black Belts and Green Belts, which connect positively with project success rates (Katumba and Rendani, 2021, p.3). Pharmaceutical industries in Ireland have the ability to leverage these explorations by investing in internal capability establishment. Sustainability has become the focus for LSS in future. Some researchers propose applying Lean principles with environmental goals to decrease chemical waste and energy (Utama and Abirfatin, 2023, p.4). This links with EU compliance frameworks and green manufacturing trends.

In conclusion, LSS gives a powerful, practical and theoretical framework for enhancing pharmaceutical production. It improves quality and speed through structured statistical rigour and methodologies. Proper link with organisational strategy, technology and leadership, unlike some disadvantages, has the ability to ensure its long-term success in the pharma industry of Ireland.

2.3.2 Theory of Constraints (TOC) Theory

The Theory of Constraints (TOC) was first provided by Goldratt in 1984, and serves as a practical methodology for maintaining and addressing the limiting variables in a system. This approach explores organisations as systems with interconnected processes. At any time, one constraint limits the achievement of higher performance, after the identification and addressing of this constraint, which is enhancing the system significantly (Masoetsa et al., 2022, p.3). This idea is relevant in the pharmaceutical sector, where delays occur

because of testing, compliance and equipment changeovers that have the ability to hinder output.

TOC runs through five sequential steps, such as addressing the constraint, examining it, connecting everything to it to elevate it, and finally returning to the first step to discover the next constraint. This method enables industries in highly regulated pharmaceutical environments to indicate real bottlenecks, including packing delays and quality assurance. A large-scale exploration that failure to maintain control transitions in automated systems due to a capacity drop of nearly 60% equates to a decrease of 2000 vehicles per hour in simulated traffic, which has a finding with direct parallels for production, where flow disruptions cause severe slowdowns (Alms and Wagner, 2025, p.9). On the other hand, in similar operational contexts, Subramaniyan et al. (2021, p.2) address production constraints that indicated throughput losses of 20% and 30% because of unanticipated downtimes and mechanical inefficiencies.

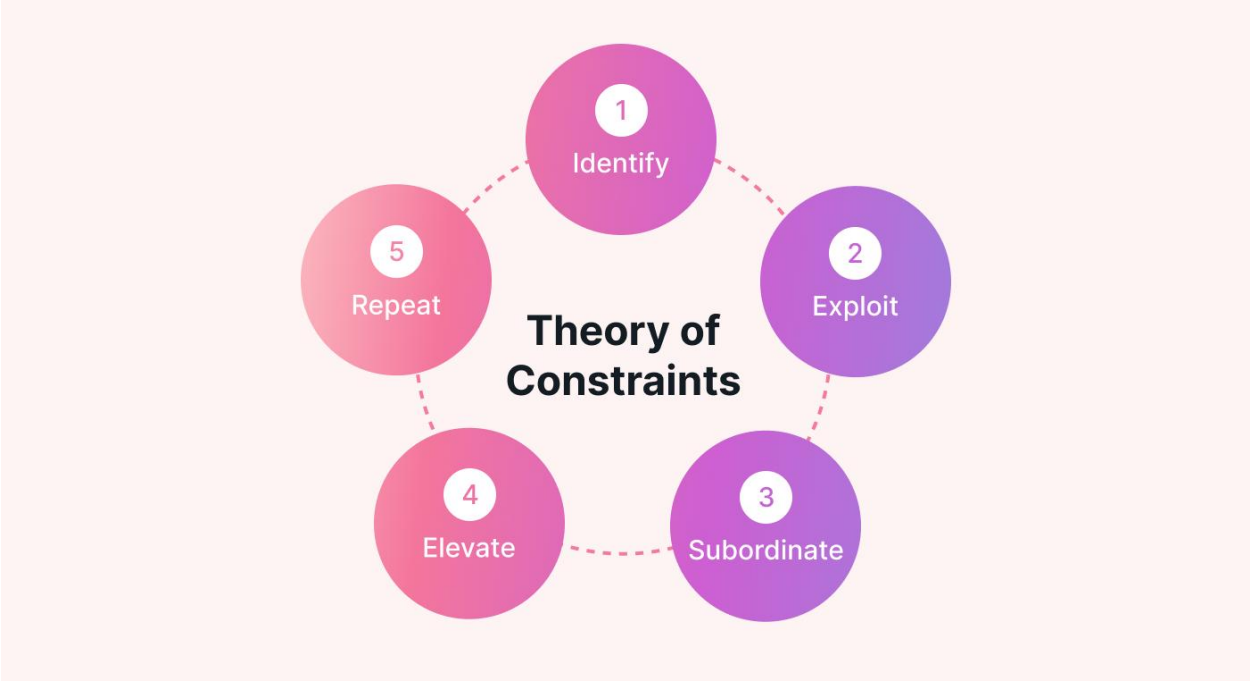

Figure 2.6: The Five Steps of the Theory of Constraints

(Alms and Wagner, 2025).

These losses stemmed from reactive bottleneck detection methods and factor equipment performance. Applying TOC assisted in separating the process bottlenecks, which are the most influential production targets and delivery times. LSS aims to decrease variation and

waste, which does not target flow-based constraints by making sure that process enhancements are in place, the TOC streamline LSS so that it does not overshadow the slowest moving segment in the system. As Batwara, Kediya, and Kayande (2025, p.5) observed, implementing TOC and AI gave predictive insight into where constraints emerged and how best to address resources for enhancement. The relevance of TOC has enhanced because of advances in AI. AI algorithms have the ability to dynamically track and flag performance anomalies that signal emerging constraints. Subramaniyan et al. (2021) applied AI-based diagnostic models such as LSTM and ANFIS to predict equipment bottlenecks.

Their work applied that one significant bottleneck caused losses of up to 800 units daily. These AI-improved TOC tools proved far more significant than traditional KPI dashboards alone. Delays in regulatory approvals and batch testing in pharmaceutical applications become the primary bottleneck. Deutsch et al. (2021, p.8) provided that applying Theory of Change logic that parallels TOC in its structure assists in mapping out actor-based constraints in interdisciplinary teams. For intense, if under-resourced, quality control labs that slow the release of compliant product batches and make ripple impacts across dispatch and packaging. Moreover, Anders and Pedersen (2023, p.2) explored processing environments where minor fluid connecting issues delayed the cycles by 25%. These small inefficiencies turned out to be the actual constraints when mapped with TOC methodology.

Additionally, Huang et al. (2023, p.7) provided that implementing TOC to production scheduling indicated a 22% enhancement in turnaround time which is emphasising the tangible advantages of the theory in controlled environments. The pharmaceutical perspective shows the process complexity, regulatory timelines and labor shortages are persistent barriers that TOC gives a highly relevant lens. For example, where lab testing creates a bottleneck, TOC would encourage firms to either streamline those procedures, add capacity, or shift testing timing to reduce the burden. Helkkula and Arnould (2022, p.9) applied TOC principles to sustainable development systems. They demonstrated that ignoring key constraints such as limited stakeholder collaboration or data visibility resulted in ineffective system performance, despite good intentions. This reflection directly applies to pharmaceutical supply chains, where managing information flow and lead times is often more impactful than increasing production speed. The true value of

TOC emerges when combined with LSS and AI technologies. Together, these tools transform fragmented optimisation into a unified and constraint-focused improvement system.

In conclusion, the Theory of Constraints offers a focused, high-leverage strategy for improving output, especially in highly complex environments like pharmaceutical manufacturing. TOC ensures that systemic attention is directed toward the actual bottleneck, allowing LSS and AI to operate with maximum effectiveness. When integrated properly, TOC helps companies in Ireland's pharmaceutical sector meet rising global demands for quality and speed.

2.4 Literature gap

Although extensive research has examined LSS and AI separately, integrated studies remain limited. Most literature focuses on either process efficiency or digital transformation in isolation. The real-world synergy between LSS and AI under Ireland's regulatory frameworks remains under-investigated. Researchers have rarely compared the actual benefits of integration versus standalone use of LSS or AI. Studies also overlook practical barriers during implementation of integrated systems in pharmaceutical settings. Empirical insights into challenges such as digital skills, compliance, and legacy systems are still lacking. Case studies that quantify the influence of AI-enhanced LSS on product quality are minimal. There is insufficient evidence on how real-time analytics enhances DMAIC phases in Ireland's pharma industry. Furthermore, the literature does not offer comparative data across different pharma facilities. Researchers have also neglected the sustainability dimension of integrated LSS-AI frameworks. Strategy papers often fail to identify actionable pathways for sector-specific adoption. Few studies consider stakeholder readiness or employee engagement in LSS-AI convergence. Consequently, this research fills the gap by conducting a contextual comparative analysis. It aims to validate integration outcomes in terms of speed, quality, and regulatory alignment in Ireland.

2.5 Conceptual framework

The conceptual framework highlights Lean Six Sigma (LSS) and Artificial Intelligence (AI) integration as independent variables that drive optimization in pharmaceutical processes. These approaches collectively influence the dependent variables, production

speed and product quality supported by the theoretical foundations of LSS and the Theory of Constraints (TOC).

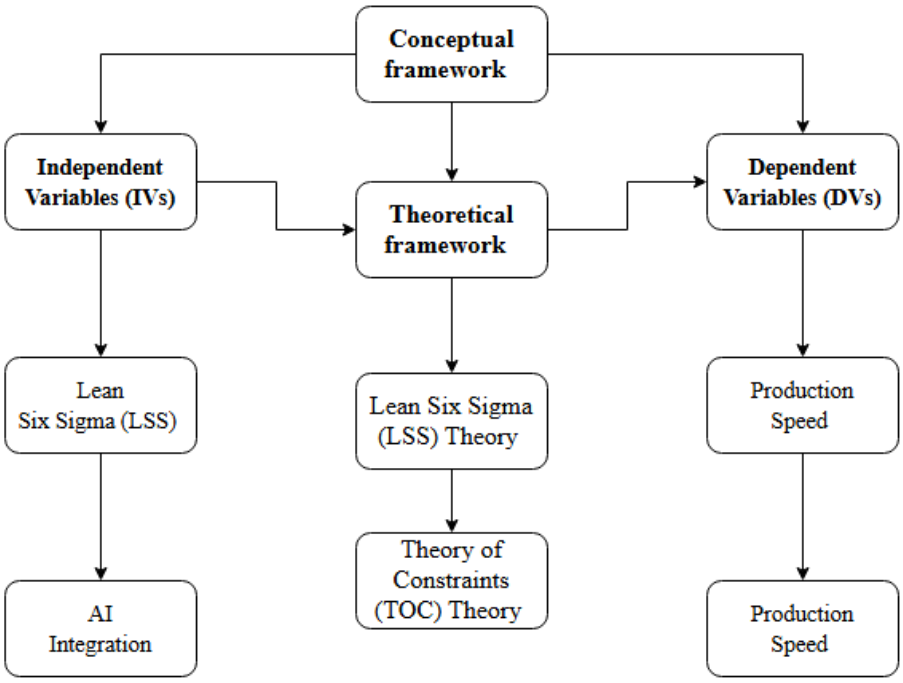

Figure 2.7: Conceptual framework

(Source: Self-made)

2.6 Summary

The literature shows that LSS improves pharmaceutical speed and quality by reducing waste and enhancing process control. Studies reveal significant improvements in cycle time batch release and regulatory compliance across Irish pharmaceutical operations. AI accelerates drug development automates quality control and optimises logistics while reducing errors and downtime. Evidence highlights real benefits in predictive maintenance supply chain efficiency and decision making for Irish firms. Barriers include regulatory constraints cultural resistance and skill shortages, which slow adoption. Strategies combining AI and LSS demonstrate strong potential for integration by enhancing operational performance compliance and digital transformation.

Chapter 3: Research Methodology

3.1 Introduction

This research uses a positivist and deductive approach, relying on objective, empirical data collection, pre-defined structures, and statistical evaluation. A quantitative strategy informs the design of the survey and the interpretation of the data with SPSS. Purposive sampling focuses on professionals familiar with LSS and AI, ensuring relevant feedback. Ethical requirements, such as informed consent and GDPR, are rigorously upheld. Employing descriptive and inferential analysis through this methodology guarantees precise, impartial conclusions on which strategy optimally enhances the efficiency and quality of pharmaceutical production in Ireland. Figure 3.1 shows Research Onion that illustrates the step-by-step process of developing research methodology, from broad philosophies like positivism and interpretivism down to specific data collection techniques. It helps researchers structure their approach by peeling through layers such as approaches, strategies, choices, time horizons, and methods.

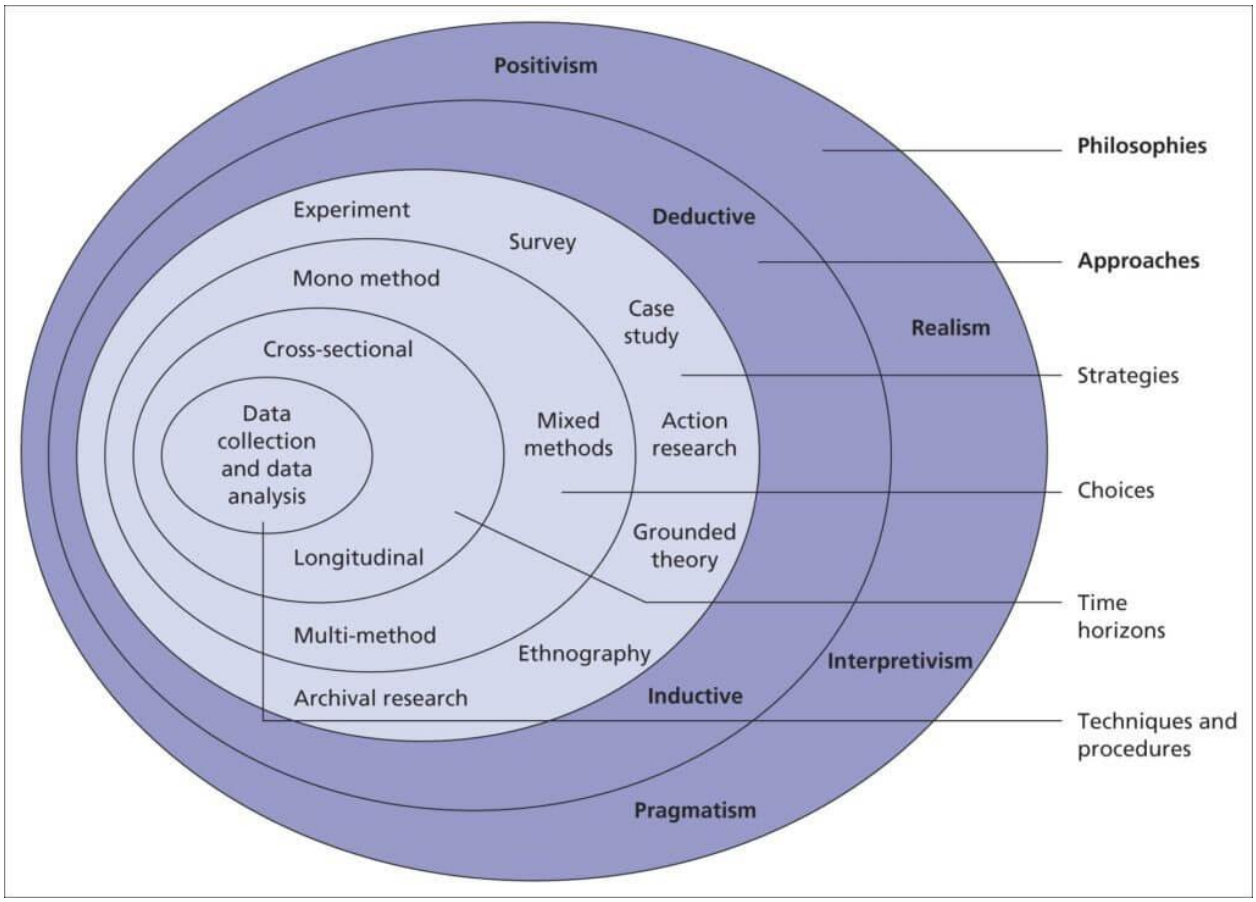

Figure 3.1: Research Onion

(Dissanayake, 2023)

3.2 Positivist Research Philosophy

This research adopts a positivist philosophy, which considers knowledge as an observation or measurement of reality through sociological evidence. Under positivism, it is believed that any scientific inquiry must be based on empiricism to avoid biases and ensure objectivity. This research also adopts a positivist approach by formulating a hypothesis and quantitatively measuring it using standardised evaluation forms (Ali, 2024, p.5). The study also implements positivist methodology to measure the impact of the convergence of LSS and AI on production performance, with a view to developing evidence-based implementation strategies (Frank, 2021, p.4).

This study benefits from a positivist paradigm because it allows the impact of LSS and AI to be assessed as they relate to productivity and product quality, two fundamental business metrics (Maretha, 2023, p.9). A quantitative approach focuses on the gathering and the interpretation of information through statistical methods aimed at revealing underlying structures of relations and outcomes while controlling the influence of the researcher. This approach yields high accuracy in the information collected and analysed, thus allowing well-informed decisions to be made in pharmaceutical manufacturing industry.

3.3 Deductive Research Approach

This research takes a deductive approach, which starts from the theory that LSS and AI tools increase the speed and quality of production in the pharmaceutical industry. The methodology follows from synthesised literature to empirical investigation in Ireland's pharmaceutical industry. Most researchers develop hypotheses based on existing evidence. In this study, the operational efficiency of LSS with the accuracy and automation capabilities of AI serves as the basis for the hypotheses (Kumar, 2024, p.4). With these hypotheses, the study intends to create LSS and AI-focused professional expert surveys. Deductive approach allows the researcher to rigorously test whether the presumed benefits of LSS and AI hold true in practice. Statistical analysis will be conducted using SPSS, employing t-tests and ANOVA to examine survey responses. The study applies this deductive framework to draw evidence-based conclusions about the relative impact of LSS and AI integration (Hall, Hall and Shaw, 2022, p.7).

3.4 Quantitative Research Strategy

This study uses a quantitative research approach to construct variable-centred models that illustrate impact of LSS and AI integration on pharmaceutical production. The key measurable variables include production speed and product quality, which can be operationalised into empirical constructs. These models enable the assessment of LSS and AI effects on operational performance in Irish pharmaceutical firms and support hypothesis development, such as: "AI integration increases production speed more effectively than LSS." The hypotheses will be tested using structured, closed-ended surveys and inferential statistical methods. This quantitative approach follows deductive reasoning, using general claims from existing literature on LSS and AI to guide empirical testing..

Data will be collected through structured surveys comprising multiple-choice and Likert scale items to compare operational settings with and without LSS or AI integration. Statistical analysis will be conducted using SPSS, including regression, t-tests, and ANOVA to examine relationships between dependent and independent variables (Sarker and Muaalemi, 2022, p.4). In quantitative research, generalisation proceeds from a representative sample to broader conclusions about the pharmaceutical sector. Empirical replication and statistical validation ensure the reliability and applicability of the theoretical model, reinforcing logical rigour, objectivity, and replicability. This study formulates evidence-based, actionable guidance for embedding LSS and AI within pharmaceutical manufacturing in Ireland.

3.5 Descriptive Data Analysis

This research adopts a descriptive data analytical lens, quantifying key parameters of Ireland's pharmaceutical sector. Using standard statistics, namely central tendency, dispersion, and distribution such analysis translates raw data into actionable signals, charting pronounced patterns (Larson et al., 2021). To populate the dataset, a structured questionnaire collection is launched, targeting executives in Irish firms where LSS and AI frameworks are operational. Once the base dataset is finalized, LSS- and AI-specific performance indicators are derived through methodical validation. Effects of LSS and AI uptake are summarised in frequency tables, while advancement metrics, such as percentage enhancements in cycle time or defect density, are displayed using mean and standard deviation metrics.

To evaluate top firms within the industry, their relative positioning will be assessed using percentiles (Azam et al., 2021, p.6). Visual clarity will be enhanced alongside statistical summaries using bar graphs, histograms, and box plots. Descriptive analysis will capture critical trends and outliers resulting from the implementation of LSS and AI, thereby justifying comparisons that are more rigorous in subsequent phases. To summarise, descriptive analysis reinforces the multi-criteria strategic assessment in the context of operational rigour driving Ireland's pharmaceutical manufacturing industry.

3.6 Purposive sampling

This study uses purposive sampling to identify people who have both relevant LSS and AI knowledge, as well as hands-on experience with its application in Irish pharmaceutical manufacturing companies. As a non-probability sampling technique, purposive sampling focuses on the selection of participants specific inclusion criteria tailored to the goals of the study (Thomas, 2022, p.5). Participants must have worked for a minimum of one year in a pharmaceutical company that utilises LSS, AI, or both in integrated operational workflows. This requirement guarantees that all participants are reasonably knowledgeable about the topics and can provide valuable perspectives. To improve representativeness and capture a fuller picture of organisational dynamics, the study also employs maximum variation sampling, capturing people from various functions, such as operations, quality assurance, engineering, production, and CI.

The target sample size was calculated using Cochran's formula. With a confidence level of 95% and a margin of error of 5%, the ideal sample size is 381 participants. This sample size is sufficient for meaningful subgroup analysis among participants with exposure to LSS, AI, or both. Participants are recruited through professional networks, LinkedIn groups, and direct outreach to pharmaceutical companies. Data is collected using an online survey, where participants provide informed consent digitally before the actual participation.

Due to the restricted scope of purposive sampling when compared to probability sampling frameworks, generalisability suffers. However, internal validity and contextual relevance are strengthened. The approach makes certain that participants have the right qualifications in relation to the studied phenomenon. It is also beneficial that the researcher possesses some knowledge about the pharmaceutical industry, which enhances

the reliability of the analysis. Therefore, this comparative study was carried out using purposive sampling, which is methodologically suitable.

3.7 Ethical Considerations

This study complies with the ethical standards established by Griffith College and In Pharma Education, emphasising voluntary participation, informed consent, confidentiality, and data protection. The objectives, procedures, potential dangers, and withdrawal options of the study will all be explained to participants. No pressure, incentive, or coercion of any kind will be used to participants (Kiani, 2022, p.7).

As confidentiality and anonymity are a concern, no names or identifying details would be collected and matched with individual answers. Survey data will be anonymised, and the generated files will be stored in a password-protected, safe area that only the researcher and their supervisor can access (Kaddoura and Al Husseiny, 2023, p.6). The study guarantees no participant will suffer any form of physical, emotional, or psychological harm at any stage. The research upholds the sanctity of the process and the rights of all stakeholders involved by applying these methods. The ethical governance framework enhances the trustworthiness of the research and aids in the responsible assessment of the LSS and AI in the pharmaceutical industry in Ireland.

3.8 Uncertainties and Difficulties

This research may encounter multiple uncertainties that could affect data quality, participant access, and the reliability of findings. One of the most difficult issues centres on getting relevant and accurate information from companies in the industry because most organisations would be reluctant to share any sensitive data due to confidentiality or corporate data protection policies (Charoo, Khan and Rahman, 2023, p.3). Accessing professionals with expertise in LSS and AI may be difficult due to demanding job responsibilities and limited availability. Survey fatigue is another potential issue, particularly if participants are required to respond to lengthy or complex questionnaires. Variation in respondents' familiarity with LSS and AI may lead to inconsistent responses, increasing the risk of bias or data misinterpretation. Moreover, companies using both LSS and AI may struggle to isolate the individual impact of each method on time-to-market and product quality. These challenges can undermine research accuracy and credibility.

Addressing these issues requires careful planning and risk mitigation to preserve analytical rigour and empirical credibility by the research process.

3.9 Research timeline

The research will commence in Week 1 with the creation of a dissertation draft that focuses on the overall framework. In Weeks 2 and 3, they will prepare the research proposal, define its objectives and methods, write the background context, and seek approval. In weeks 4 and 5, AI and LSS comparison scope justifications will be provided in the introduction chapter. Literature review during weeks 6 and 7 will include several pertinent previous studies, capturing central arguments, and drawing major themes under the umbrella of the main idea. In Week 8, the methodology chapter will be completed with a comprehensive description of the data collection procedure, sampling, and analysis in accordance with the objectives of the study. Weeks 9 to 11 will be focused on the results and findings chapter, where primary data analysis and discussions will be presented. In week 12, the last chapter with conclusions will include all the major contributions highlighted, practical impacts, and recommendations for follow-up studies.

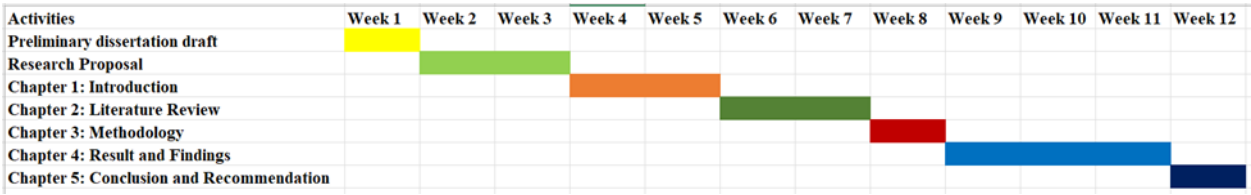

Figure 3.2: Research timeline

3.10 Summary

This chapter aims to influence AI and LSS on significance and quality of pharmaceutical production applying a positivist and deductive framework. Primary data was gathered by applying systematic survey with purposive sampling that is giving a quantitative dataset. Exploration of measurable factors implemented inferential and descriptive statistical techniques such as ANOVA and t-test. Reliability with audit trails, validity and transparency with triangulation with member checking were all methodological concerns indicated in study. In terms of receiving consent, guaranteeing anonymity, adherence to GDPR regulations and ethics were explored as protective measures that makes sure ethical principles were followed.

Chapter 4: Findings and Analysis

4.1 Introduction

This chapter represents LSS improves compliance and decreases process variation while AI influences data driven insights and predictive efficiency. These explorations give complementary and unique advantages for production speed and quality. Discussion indicates challenges such as cultural resistance, financial constraints and regulatory oversight that hamper implementation. Strategic approaches including phased leadership support and adoption training are examined to overcome barriers. Finally chapter compares efficiency of their integrated application and methods.

4.2 Findings and analysis

Current_Role

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Engineer	34	8.9	8.9	8.9
	Operations Manager	68	17.8	17.8	26.8
	Process Improvement Specialist	109	28.6	28.6	55.4
	Production Manager	41	10.8	10.8	66.1
	Quality Control Specialist	129	33.9	33.9	100.0
	Total	381	100.0	100.0	

Table 4.1: Current Role

(Source: SPSS)

Data in Table 4.1 and Figure 4.1 provides distribution of respondents' current roles in Irish pharmaceutical industry. Largest proportion is Quality Control Specialists, which is nearly 33.9%. It represents a powerful emphasis of industry on regulatory compliance and product quality assurance. Process Enhancement Specialists form second-largest group that is approximately 28.6%. It is representing commitment of industry to CI and operational optimisation. Operations Managers (17.8%) and Production Managers (10.8%) together account for nearly 29% of the sample, indicating significant representation from leadership roles overseeing production efficiency and resource allocation. Engineers comprise the smallest group (8.9%), suggesting that while technical roles are essential, managerial and quality-focused positions dominate the workforce in LSS and AI adoption contexts. This distribution ensures that insights in the study reflect perspectives from both operational leadership and technical quality specialists, providing a balanced view of the implementation and impact of LSS and AI in pharmaceutical manufacturing.

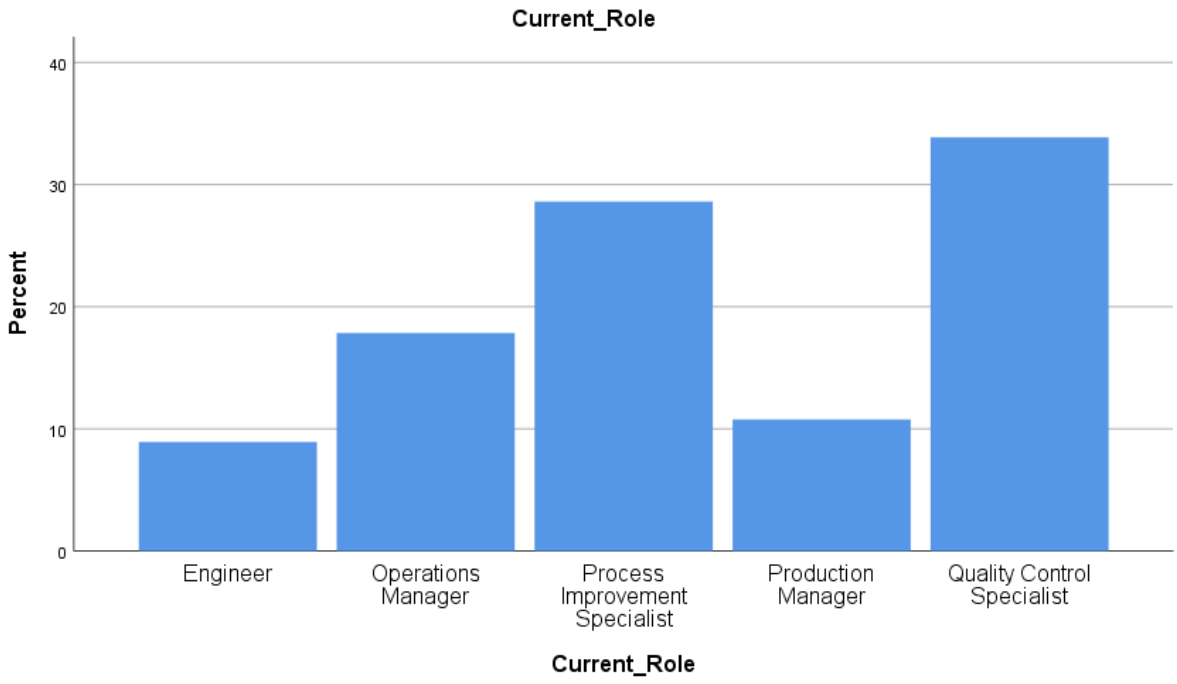

Figure 4.1: Current Role

(Source: SPSS)

Years_in_Industry

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1–3 years	118	31.0	31.0	31.0
	3–5 years	129	33.9	33.9	64.8
	Less than 1 year	61	16.0	16.0	80.8
	More than 5 years	73	19.2	19.2	100.0
	Total	381	100.0	100.0	

Table 4.2: Years in Industry

(Source: SPSS)

Table 4.2 presents the distribution of respondents based on their years of experience in the pharmaceutical industry. 3-5 years, which is nearly 33.9% is considered the largest group and involves a substantial proportion of mid-career professionals who likely possess familiarity and technical proficiency with organisational processes. Close behind are those with 1–3 years of experience (31.0%), suggesting a significant presence of relatively early-career professionals. Respondents with more than 5 years of experience account for 19.2%, representing seasoned professionals with extensive industry knowledge and strategic insights. Those with less than 1 year of experience are nearly 16.0%, the smallest group representing recent entrants who might still be enhancing expertise. However, this can be more open to change and innovation. Additionally, the mix of experience levels provides a balanced representation that enables this research to analyse the perceptions from newer professionals and industry veterans.

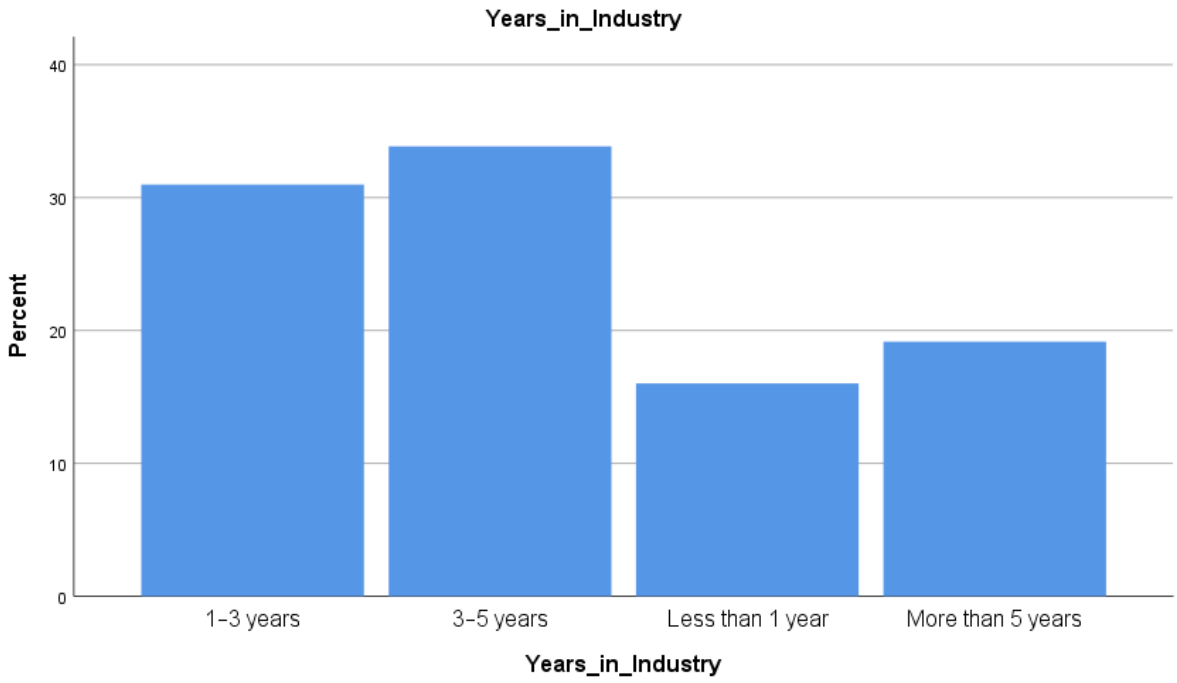

Figure 4.2: Years_in_Industry

(Source: SPSS)

LSS_or_AI_Implemented

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No, neither LSS nor AI	42	11.0	11.0	11.0
	Yes, Artificial Intelligence (AI)	148	38.8	38.8	49.9
	Yes, both LSS and AI	130	34.1	34.1	84.0

Yes, Lean Six Sigma (LSS)	**61**	**16.0**	**16.0**	**100.0**
Total	**381**	**100.0**	**100.0**	

Table 4.3: LSS_or_AI_Implemented

(Source: SPSS)

This table provides the distribution of respondents that relies on application of LSS or AI in their organisations. With a 38.8% portion, the largest group represented application of AI which addressed a strong trend to data driven process optimisation and digital transformation in pharmaceutical industry. 34.1% respondents considered that AI and LSS are a close second, which represents a developing recognition of complementary advantages of combining structured process enhancement with advanced analytics and automation. LSS is only used by 16.0% of respondents, suggesting that while process optimisation remains valued, many firms are moving beyond traditional methods toward integrated technological solutions. Moreover, 11.0% reported applying neither, which might present either a lack of resources, strategic hesitation or organisational constraints. This distribution provides that while AI adoption is ahead of LSS, the combined application of both methodologies is becoming an effective driver of operational development in pharmaceutical industry of Ireland.

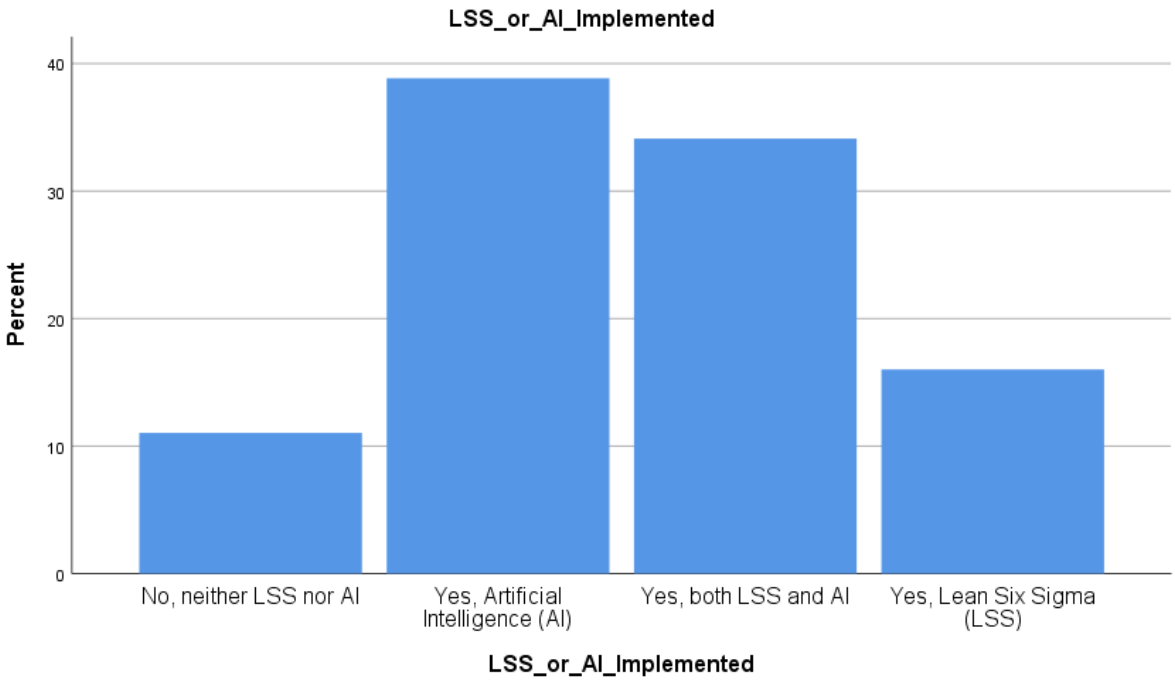

Figure 4.3: LSS_or_AI_Implemented

(Source: SPSS)

Organization_Size

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	<250 employees	57	15.0	15.0	15.0
	1,000-4,999 employees	144	37.8	37.8	52.8
	250-999 employees	106	27.8	27.8	80.6
	5,000+ employees	74	19.4	19.4	100.0

Total	**381**	**100.0**	**100.0**	

Table 4.4: Organization_Size

(Source: SPSS)

By organisation size, table 4.4 represents distribution of respondents. Largest proportion (37.8%) work in medium-to-large enterprises with 1,000–4,999 employees, indicating strong representation from well-established pharmaceutical companies with substantial resources for implementing LSS and AI initiatives. The second-largest group (27.8%) are employed in organisations with 250–999 employees, suggesting significant participation from mid-sized firms that may balance agility with structured operational systems. Large-scale enterprises with 5,000+ employees account for 19.4% of respondents, reflecting the presence of multinational pharmaceutical corporations with extensive production capacity and global reach. The smallest group (15.0%) comes from small organisations with fewer than 250 employees, which may face greater resource constraints but potentially enjoy faster decision-making and implementation flexibility. This spread of organisation sizes ensures that the dataset captures diverse operational contexts, from agile smaller firms to large-scale manufacturers, allowing for meaningful comparison of how company size influences the adoption and effectiveness of LSS and AI practices.

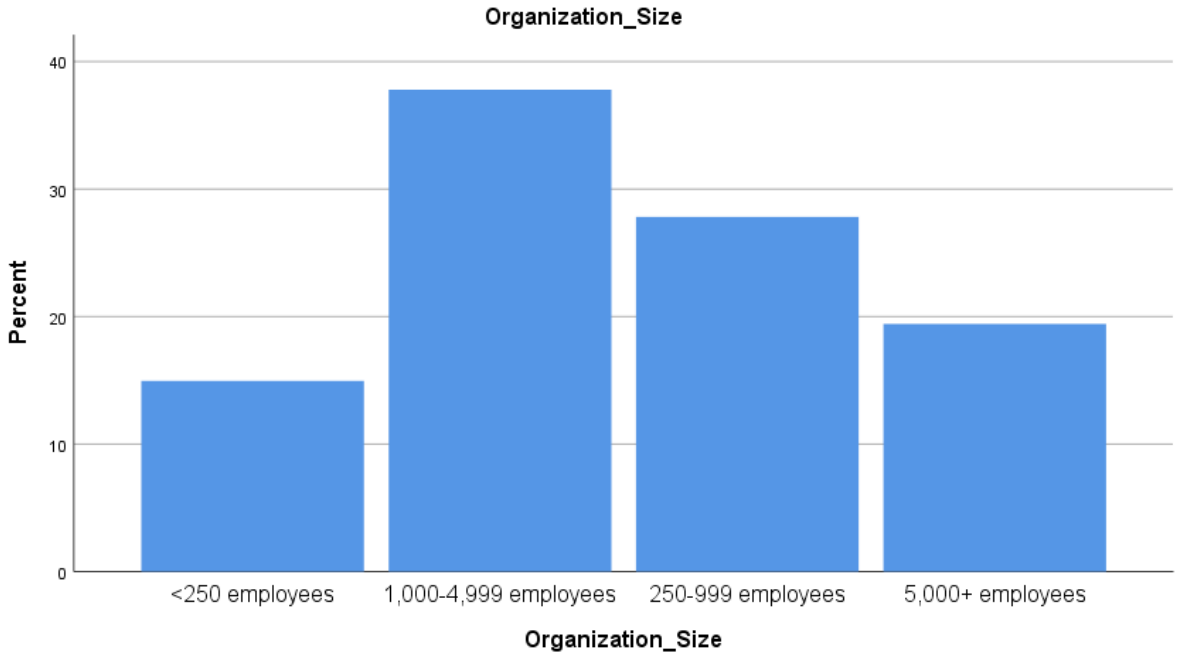

Figure 4.4: Organization_Size

(Source: SPSS)

Site_Type

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Biologics	108	28.3	28.3	28.3
	Combination products	89	23.4	23.4	51.7
	Fill-finish	105	27.6	27.6	79.3
	Small-molecule API	79	20.7	20.7	100.0
	Total	381	100.0	100.0	

Table 4.5: Site_Type

(Source: SPSS)

Table 4.5 outlines the distribution of respondents according to site type within the pharmaceutical sector. Biologics sites present largest share at 28.3%, providing a strong role for Ireland in producing high-value and complex biologic medicines. It demands precision manufacturing and advanced quality control. Fill-finish operations follow closely at 27.6%, representing need for final-stage manufacturing processes where sterility and efficiency are significant. Combination products sites account for 23.4% which addresses a notable presence of facilities creating integrated drug-device solutions. It is an area advanced from AI for enhanced quality assurance and LSS for process optimisation. Small-molecule API sites (20.7%), smallest category which still holds effective presentation and exploring ongoing role of Ireland in traditional

pharmaceutical synthesis with more advanced modalities. This distribution holds a large cross-section of manufacturing environments, which enables analysis of AI and LSS adoption by technological complexity, regulatory requirements and production type across pharmaceutical sections.

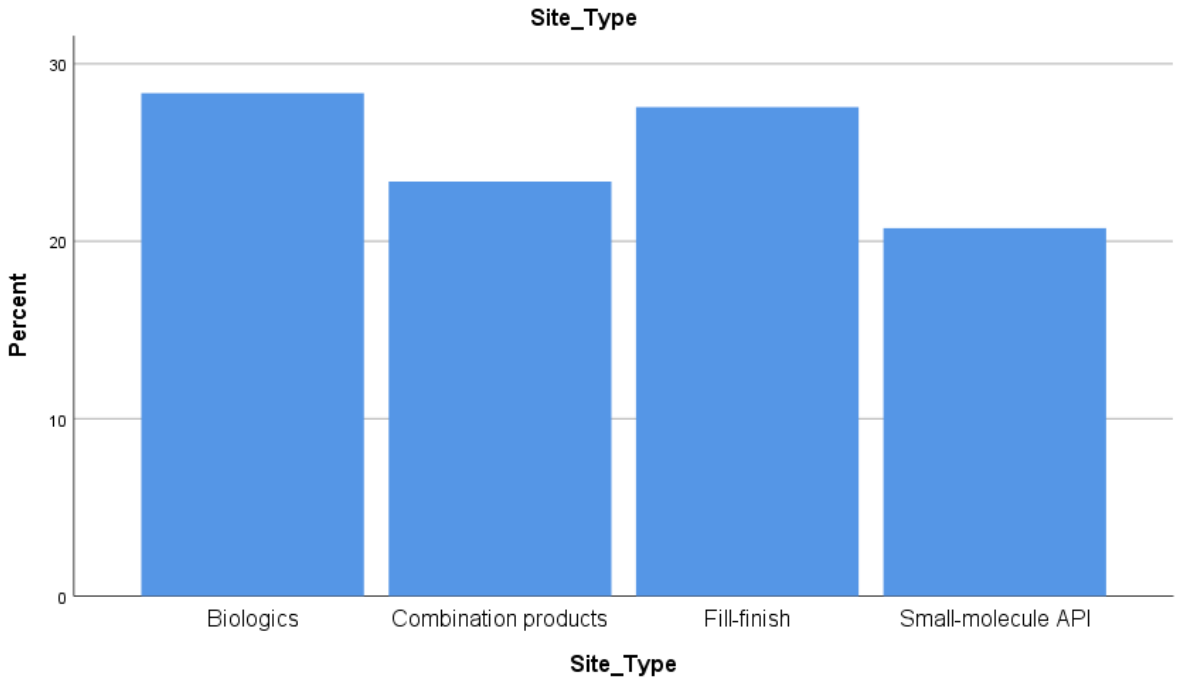

Figure 4.5: Site_Type

(Source: SPSS)

Highest_Education

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Bachelor	79	20.7	20.7	20.7
	Diploma	94	24.7	24.7	45.4

	Doctorate	**46**	**12.1**	**12.1**	**57.5**
	High school	**56**	**14.7**	**14.7**	**72.2**
	Master	**106**	**27.8**	**27.8**	**100.0**
	Total	**381**	**100.0**	**100.0**	

Table 4.6: Highest_Education

(Source: SPSS)

Table 4.6 gives educational attainment of respondents in pharmaceutical industry. Largest group of people has a Master's degree which is nearly 27.8%. It is providing industry demand for advanced managerial and technical expertise. It is relevant to applying complex systems such as AI and LSS. Approximately 24.7% of people are diploma holders, which is second-largest group. It is addressing a robust appearance of trained professionals who contribute effectively to technical and operational roles. Nearly 20.7% people are bachelor’s degree holders. They are highlighting a substantial segment of academically trained staff across various functions. High school graduates make up 14.7%, likely representing operational positions or entry-level. 12.1% people are doctorate holders who present smallest and highly specialised group. It is engaged in innovation, regulatory compliance and research. This diverse educational profile provides that sector advantages from a balanced mix of practical skills and advanced academic qualifications. It is enabling a multifaceted approach for implementing and sustaining AI and LSS-driven enhancements in production quality and speed.

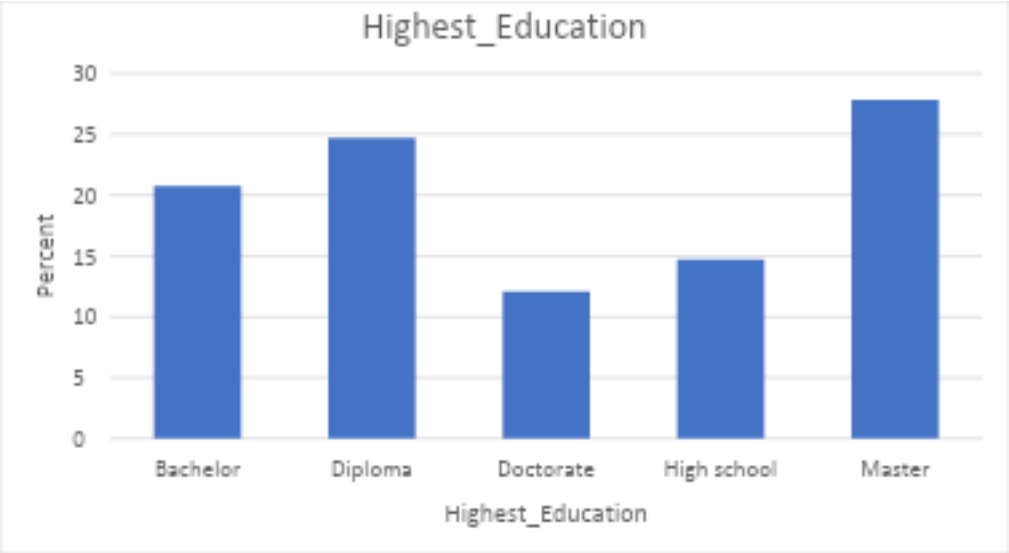

Figure 4.6: Highest_Education

(Source: SPSS)

LSS_Implementation_Effectiveness

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Effective	110	28.9	28.9	28.9
	Ineffective	140	36.7	36.7	65.6
	Neutral	32	8.4	8.4	74.0
	Very Effective	40	10.5	10.5	84.5

	Very Ineffective	**59**	**15.5**	**15.5**	**100.0**
	Total	**381**	**100.0**	**100.0**	

Table 4.7: LSS_Implementation_Effectiveness

(Source: SPSS)

Table 4.7 presents viewpoints of people who are respondents on the effectiveness of LSS applications in their organisations. The largest proportion of respondents, nearly 36.7%, rated LSS as ineffective. It is promoting significant challenges in achieving intended process development because of resistance to change, poor integration with existing systems and inadequate training. Moreover, 28.9% of people respond that LSS is effective in addressing positive outcomes like enhanced quality or efficiency in certain contexts. A smaller segment known as 10.5% considered it very effective, representing cases where well-trained teams, robust project selection and strong leadership might have maximised outcomes. Very ineffective ratings accounted for 15.5%, a mismatch between operational realities and LSS methods, or presenting potential failures in execution. Only 8.4% remained neutral , addressing limited exposure to LSS or minimal influence. Additionally, data provides a mixed performance landscape where successful implementation depends deeply on employee engagement, organisational readiness, and linking of LSS initiatives with strategic goals in pharmaceutical industry.

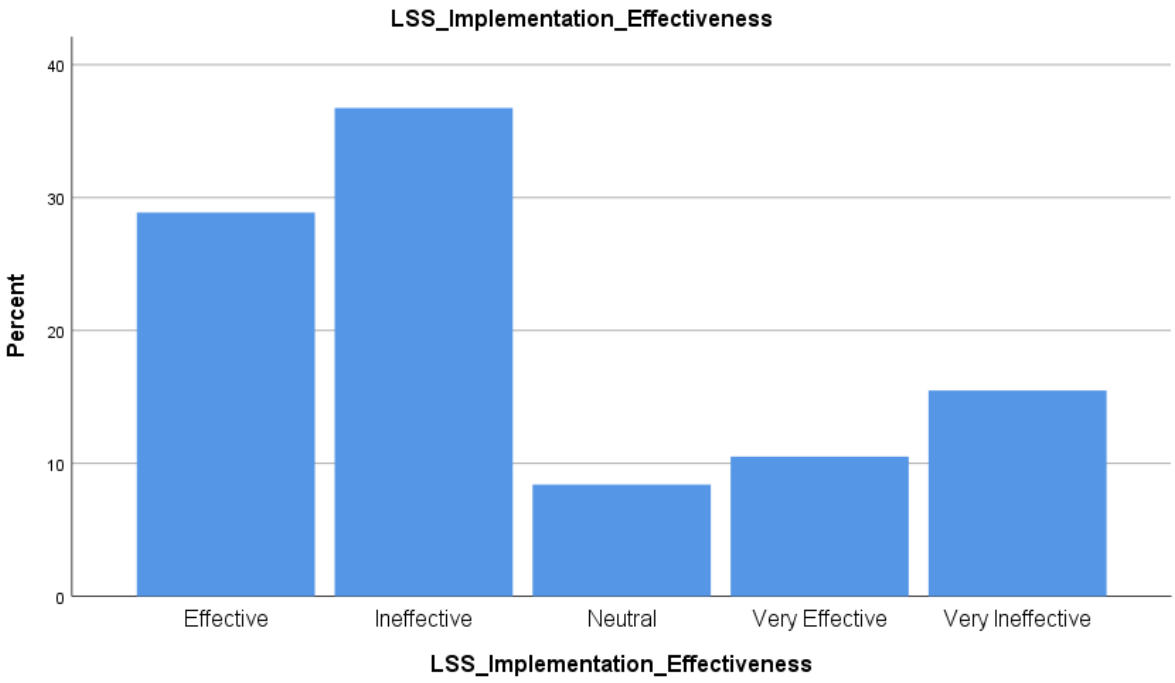

Figure 4.7: LSS_Implementation_Effectiveness

(Source: SPSS)

LSS_Impact_Speed

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	High Impact	130	34.1	34.1	34.1
	Low Impact	107	28.1	28.1	62.2
	Neutral	29	7.6	7.6	69.8
	Very High Impact	50	13.1	13.1	82.9

	Very Low Impact	**65**	**17.1**	**17.1**	**100.0**
	Total	**381**	**100.0**	**100.0**	

Table 4.8: LSS_Impact_Speed

(Source: SPSS)

Table 4.8 summarises respondents' perceptions on influence of LSS on production speed. Largest group is nearly 34.1% reported a high impact that is addressing that LSS initiatives lead to notable efficiency gains with streamlined workflows, process standardisation and waste reduction. Low influence was reported by 28.1%, suggesting that in some organisations, improvements may be marginal because of operational constraints or partial implementation. A smaller but effective proportion that is approximately 13.1% that perceived a very high influence, representing cases where LSS has been highly effective in driving production timelines because of powerful organisational commitment or project execution. Very low impact ratings (17.1%) point to scenarios where LSS failed to address key bottlenecks or was poorly aligned with operational priorities. Only 7.6% remained neutral, indicating minimal observed change. Overall, the results show that while LSS can significantly enhance production speed, its effectiveness varies widely based on implementation quality and contextual factors.

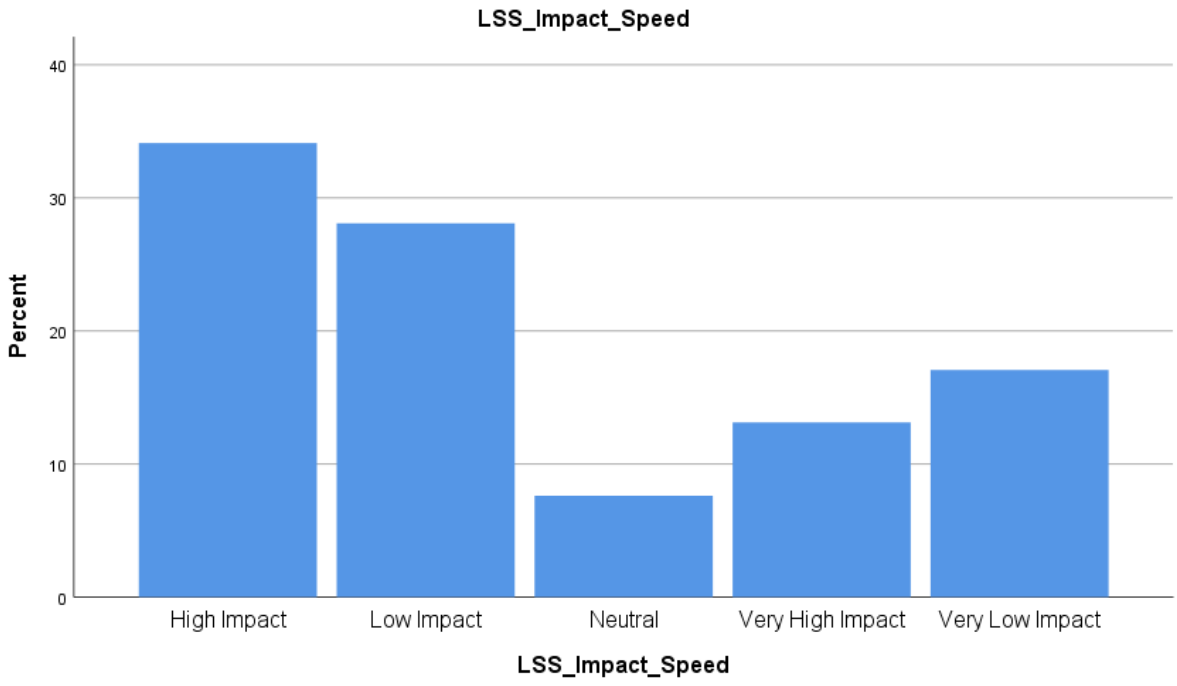

Figure 4.8: LSS_Impact_Speed

(Source: SPSS)

LSS_Impact_Quality

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	High Impact	121	31.8	31.8	31.8
	Low Impact	112	29.4	29.4	61.2
	Neutral	35	9.2	9.2	70.3
	Very High Impact	40	10.5	10.5	80.8
	Very Low Impact	73	19.2	19.2	100.0
	Total	381	100.0	100.0	

Table 4.9: LSS_Impact_Quality

(Source: SPSS)

Table 4.9 illustrates the largest proportion (31.8%) reported a high impact, suggesting that LSS often contributes to improved consistency, defect reduction, and compliance with stringent pharmaceutical quality standards. Low impact was reported by 29.4%, indicating that in some cases, LSS initiatives may not have translated into substantial quality improvements, possibly due to incomplete adoption or focus on speed over quality. A smaller segment (10.5%) observed a

very high impact, reflecting instances where LSS was highly effective in elevating quality performance through robust process control and root cause elimination. However, very low impact ratings (19.2%) highlight challenges where LSS failed to address quality issues, potentially due to cultural resistance or insufficient integration with quality systems. Only 9.2% were neutral, suggesting limited perceived change. Overall, the results show that while LSS can enhance quality, its impact is highly dependent on effective, context-specific implementation.

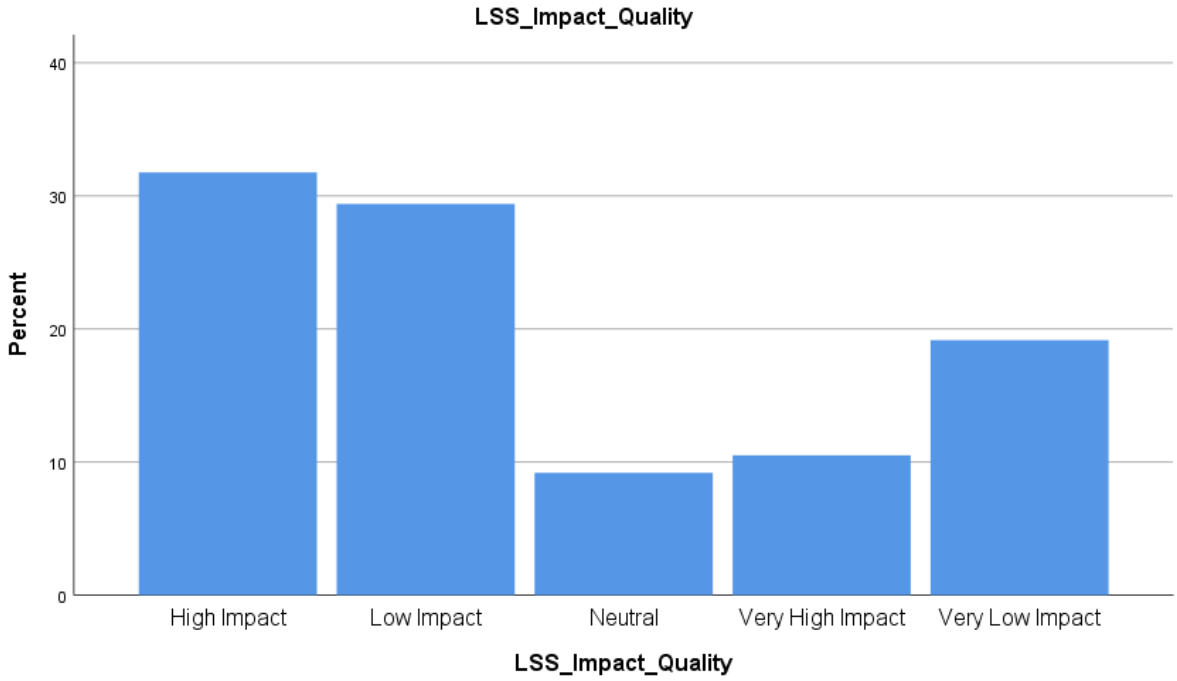

Figure 4.9: LSS_Impact_Quality

(Source: SPSS)

LSS_Improved_Efficiency_Agreement

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Agree	129	33.9	33.9	33.9
	Disagree	79	20.7	20.7	54.6

	Neutral	**36**	**9.4**	**9.4**	**64.0**
	Strongly Agree	**57**	**15.0**	**15.0**	**79.0**
	Strongly Disagree	**80**	**21.0**	**21.0**	**100.0**
	Total	**381**	**100.0**	**100.0**	

Table 4.10: LSS_Improved_Efficiency_Agreement

(Source: SPSS)

Table 4.10 presents respondents' agreement levels on whether LSS has improved operational efficiency. The largest share (33.9%) agree that LSS has led to efficiency gains, suggesting that many organisations have benefited from streamlined processes, reduced waste, and better resource utilisation. Additionally, 15.0% strongly agree, indicating strong endorsement where LSS has delivered substantial improvements, likely due to well-executed projects and committed leadership. However, a notable proportion disagree (20.7%) or strongly disagree (21.0%), together representing over 41% of respondents, highlighting that in many cases, LSS may not have met expectations or encountered barriers such as poor implementation, lack of training, or misalignment with operational goals. Only (9.4%) remained neutral, reflecting either limited exposure to LSS outcomes or mixed results. Overall, these findings suggest that while LSS can be effective in improving efficiency, on organisational readiness and execution quality.

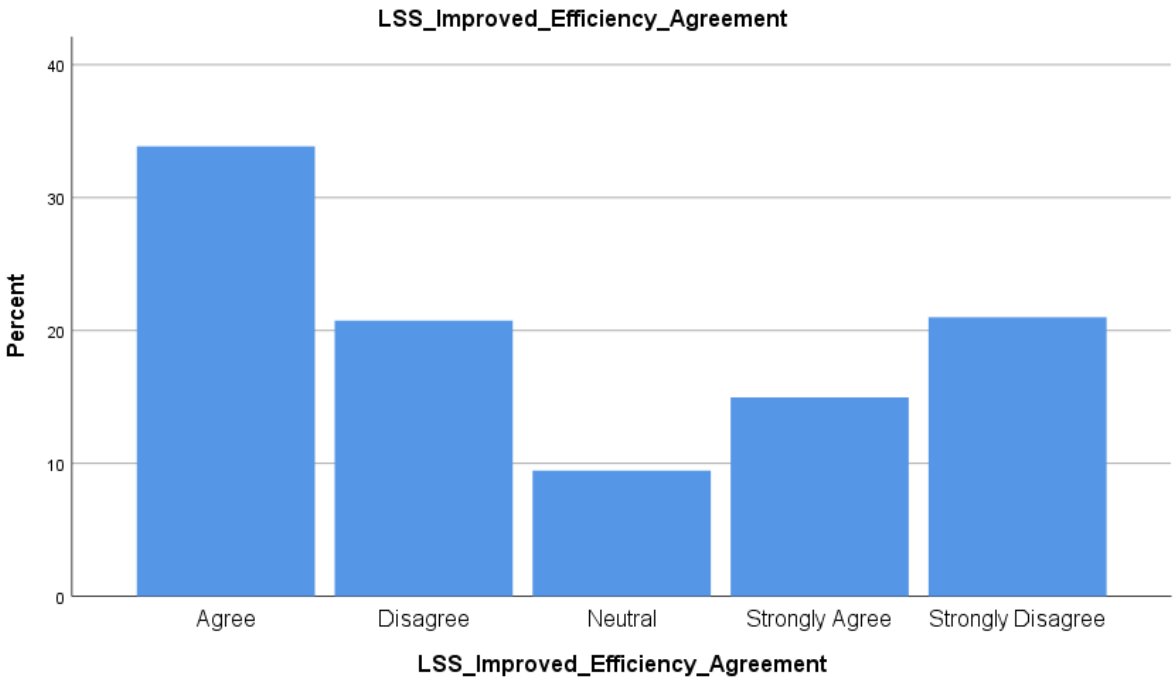

Figure 4.10: LSS_Improved_Efficiency_Agreement

(Source: SPSS)

AI_Integration_Effectiveness

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Effective	88	23.1	23.1	23.1
	Ineffective	123	32.3	32.3	55.4
	Neutral	27	7.1	7.1	62.5
	Very Effective	48	12.6	12.6	75.1

	Very Ineffective	**95**	**24.9**	**24.9**	**100.0**
	Total	**381**	**100.0**	**100.0**	

Table 4.11: AI_Integration_Effectiveness

(Source: SPSS)

Table 4.11 summarises respondents' perceptions of AI integration effectiveness in their organisations. The largest proportion (32.3%) rated AI as ineffective, suggesting that many firms struggle to realise expected benefits, possibly due to technical integration challenges, inadequate data infrastructure, or limited staff training. Similarly, 24.9% viewed AI as very ineffective, indicating substantial dissatisfaction or failed implementations. On the positive side, 23.1% found AI effective, and 12.6% rated it as very effective, reflecting cases where AI tools have successfully enhanced automation, predictive analytics, and quality control processes. A small share (7.1%) were neutral, suggesting minimal observed impact or insufficient exposure to AI initiatives. Overall, while a notable segment has achieved strong results, the majority perceive AI's integration as underperforming, underscoring the need for better implementation strategies, investment in digital capabilities, and alignment of AI solutions with operational and regulatory requirements in the pharmaceutical sector.

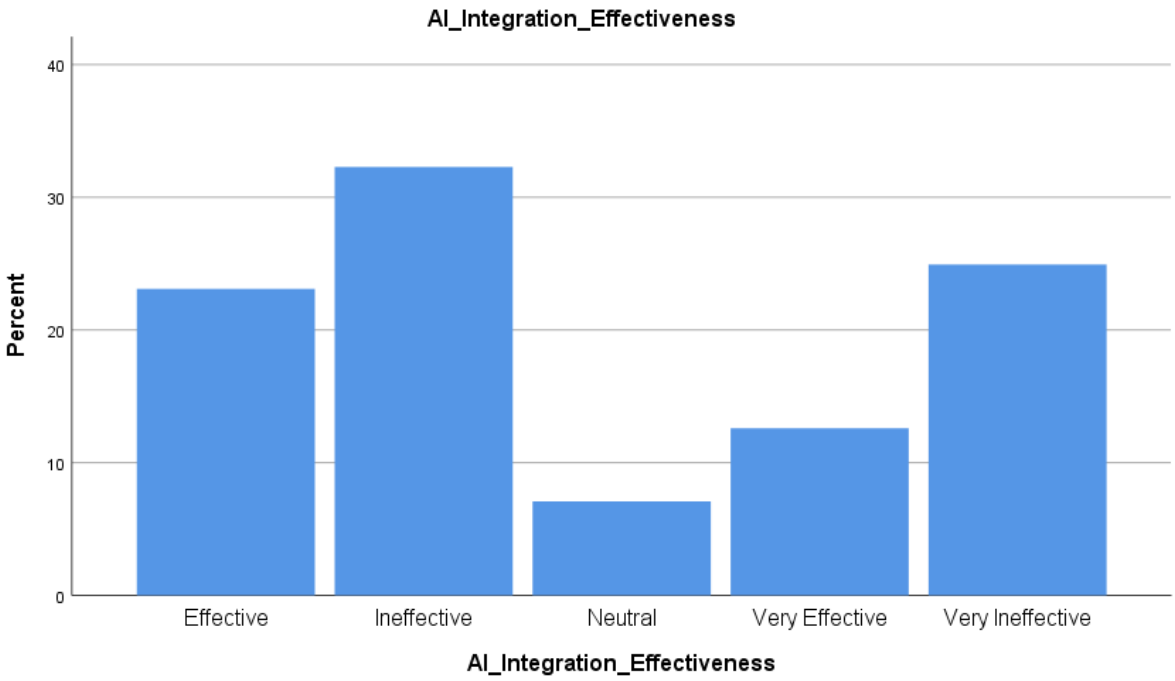

Figure 4.11: AI_Integration_Effectiveness

(Source: SPSS)

AI_Impact_Speed

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	High Impact	134	35.2	35.2	35.2
	Low Impact	107	28.1	28.1	63.3
	Neutral	33	8.7	8.7	71.9
	Very High Impact	38	10.0	10.0	81.9

	Very Low Impact	**69**	**18.1**	**18.1**	**100.0**
	Total	**381**	**100.0**	**100.0**	

Table 4.12: AI_Impact_Speed

(Source: SPSS)

Table 4.12 presents respondents' views on the impact of AI on production speed. The largest proportion (35.2%) reported a high impact, indicating that AI adoption often accelerates processes through automation, predictive scheduling, and real-time monitoring. Low impact responses (28.1%) suggest that in some organisations, AI has delivered only modest improvements, potentially due to partial deployment or limited integration with existing workflows. A smaller share (10.0%) reported a very high impact, reflecting cases where AI has significantly optimised throughput, minimised downtime, and enhanced operational agility. Conversely, very low impact (18.1%) and neutral (8.7%) ratings highlight scenarios where AI failed to address bottlenecks or where its benefits were not clearly measurable. Overall, while a majority perceive AI as having a positive influence on production speed, the variation in responses suggests that the extent of improvement depends on implementation quality, infrastructure readiness, and the degree of integration with broader operational strategies.

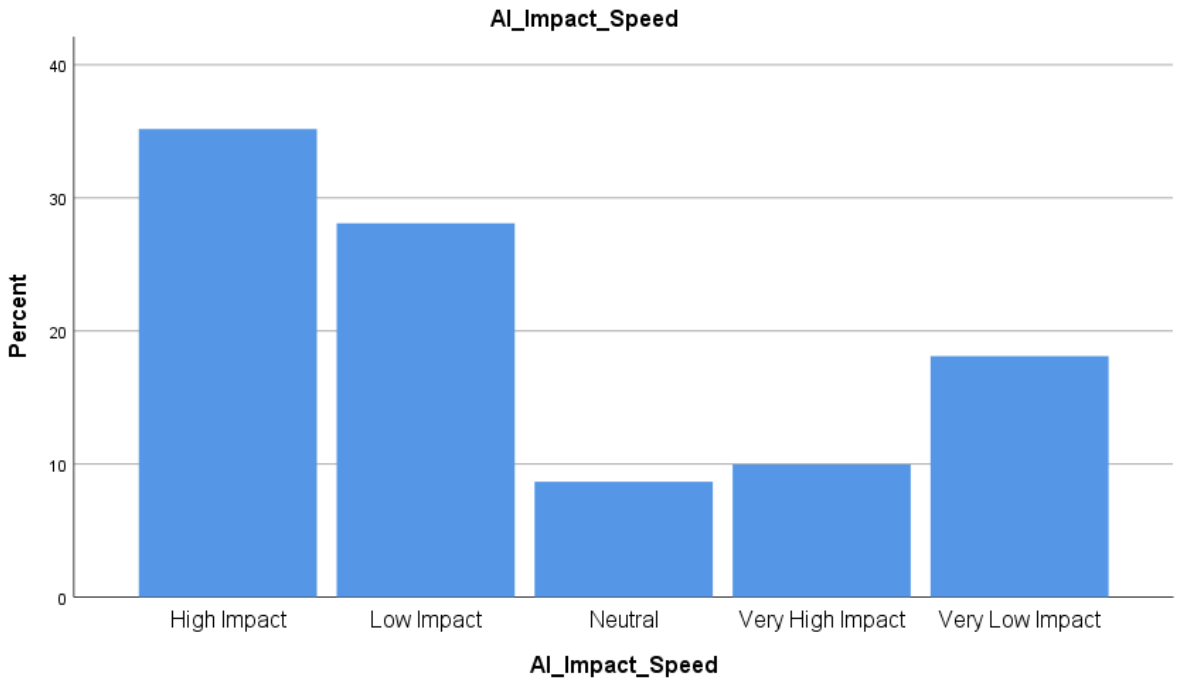

Figure 4.12: AI_Impact_Speed

(Source: SPSS)

AI_Impact_Quality

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	High Impact	125	32.8	32.8	32.8
	Low Impact	122	32.0	32.0	64.8
	Neutral	22	5.8	5.8	70.6
	Very High Impact	48	12.6	12.6	83.2
	Very Low Impact	64	16.8	16.8	100.0
	Total	381	100.0	100.0	

Table 4.13: AI_Impact_Quality

(Source: SPSS)

Table 4.13 outlines respondents' perceptions of AI impact on product quality. The largest share rated the impact as high (32.8%), suggesting that AI frequently enhances quality through improved defect detection, real-time monitoring, and predictive analytics that prevent deviations before they occur. A close proportion (32.0%) reported a low impact, indicating that in some organisations, AI has not significantly influenced quality, possibly due to limited application scope, insufficient training, or challenges in integrating AI with quality management systems. Very high impact was noted by 12.6% of respondents, reflecting cases where AI solutions have

substantially elevated quality performance. Conversely, very low impact ratings (16.8%) highlight situations where AI failed to deliver measurable quality benefits. Only 5.8% were neutral, suggesting minimal perceived change. Overall, the data indicates that while AI can be a powerful enabler of quality improvement, its effectiveness is highly dependent on the depth and quality of implementation.

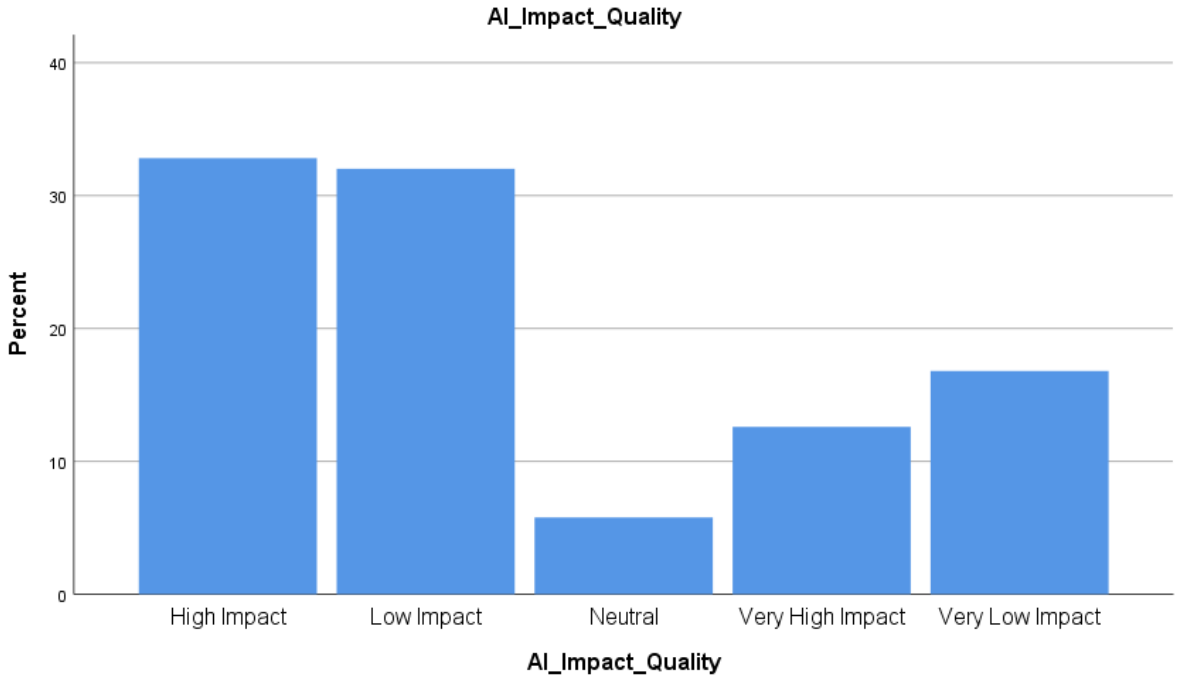

Figure 4.13: AI_Impact_Quality

(Source: SPSS)

AI_Improved_Efficiency_Agreement

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Agree	127	33.3	33.3	33.3
	Disagree	82	21.5	21.5	54.9

Neutral	**32**	**8.4**	**8.4**	**63.3**
Strongly Agree	**57**	**15.0**	**15.0**	**78.2**
Strongly Disagree	**83**	**21.8**	**21.8**	**100.0**
Total	**381**	**100.0**	**100.0**	

Table 4.14: AI_Improved_Efficiency_Agreement

(Source: SPSS)

Table 4.14 shows respondents' agreement levels regarding whether AI has improved operational efficiency. The largest proportion (33.3%) agree that AI has enhanced efficiency, suggesting positive experiences with automation, predictive analytics, and optimised workflows. An additional 15.0% strongly agree, indicating substantial efficiency gains in certain organisations, likely where AI has been strategically implemented and well-integrated with existing systems. However, a significant share disagree (21.5%) or strongly disagree (21.8%), together accounting for over 43% of respondents, highlighting notable dissatisfaction or limited perceived benefits. This may be due to implementation challenges, high setup costs, or insufficient staff training. A smaller group (8.4%) were neutral, reflecting minimal exposure to AI or uncertainty about its impact. Overall, while nearly half of respondents view AI as an efficiency enabler, the sizeable proportion of dissent underscores that its effectiveness is not guaranteed and depends heavily on implementation quality, organisational readiness, and ongoing performance optimisation.

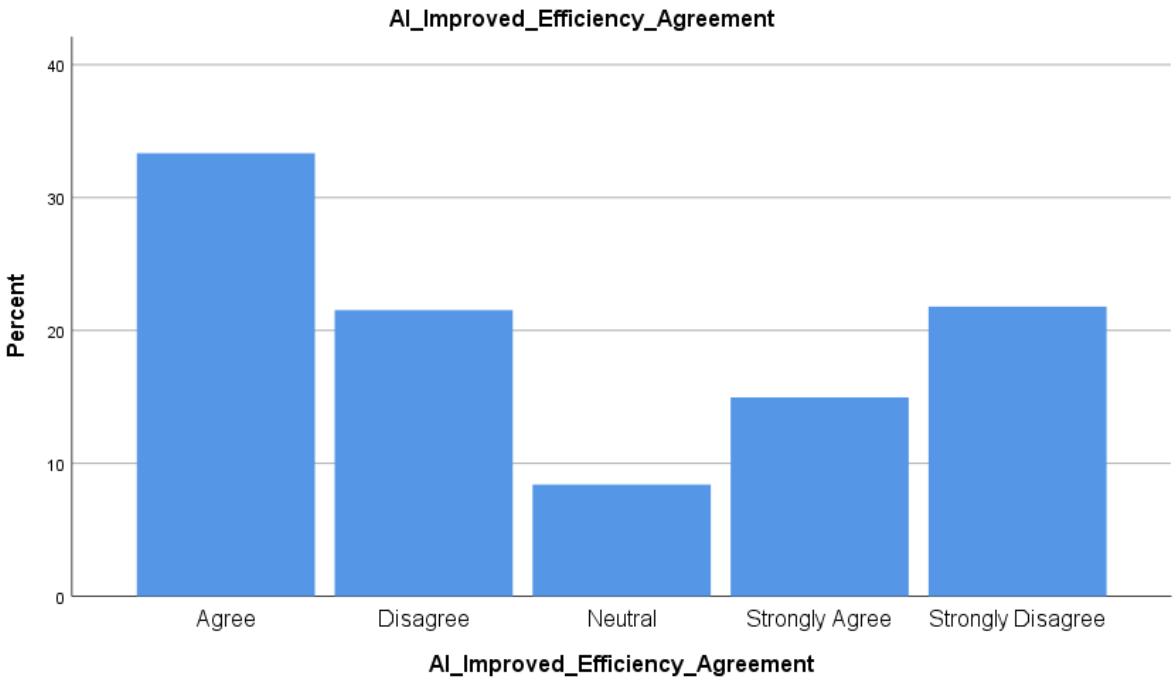

Figure 4.14: AI_Improved_Efficiency_Agreement

(Source: SPSS)

Greater_Impact_Speed_Method

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Artificial Intelligence (AI)	143	37.5	37.5	37.5
	Both equally	88	23.1	23.1	60.6
	Lean Six Sigma (LSS)	119	31.2	31.2	91.9
	Neither	31	8.1	8.1	100.0

Total	**381**	**100.0**	**100.0**	

Table 4.15: Greater_Impact_Speed_Method

(Source: SPSS)

Table 4.15 presents respondents' views on which method—LSS or AI—has had a greater impact on production speed. The largest proportion (37.5%) identified AI as having the greater impact, suggesting strong recognition of its ability to accelerate processes through automation, predictive analytics, and real-time optimisation. LSS was selected by 31.2%, reflecting its proven track record in streamlining workflows and reducing inefficiencies through structured process improvement. Notably, 23.1% considered both equally impactful, indicating that many professionals view the greatest benefits as arising from the complementary use of both approaches. A smaller group (8.1%) felt that neither had a significant effect on speed, potentially due to limited implementation or organisational barriers. AI is perceived as slightly more influential for speed, integrating AI's technological capabilities with LSS's process discipline may offer the most balanced and sustainable improvements in pharmaceutical manufacturing efficiency.

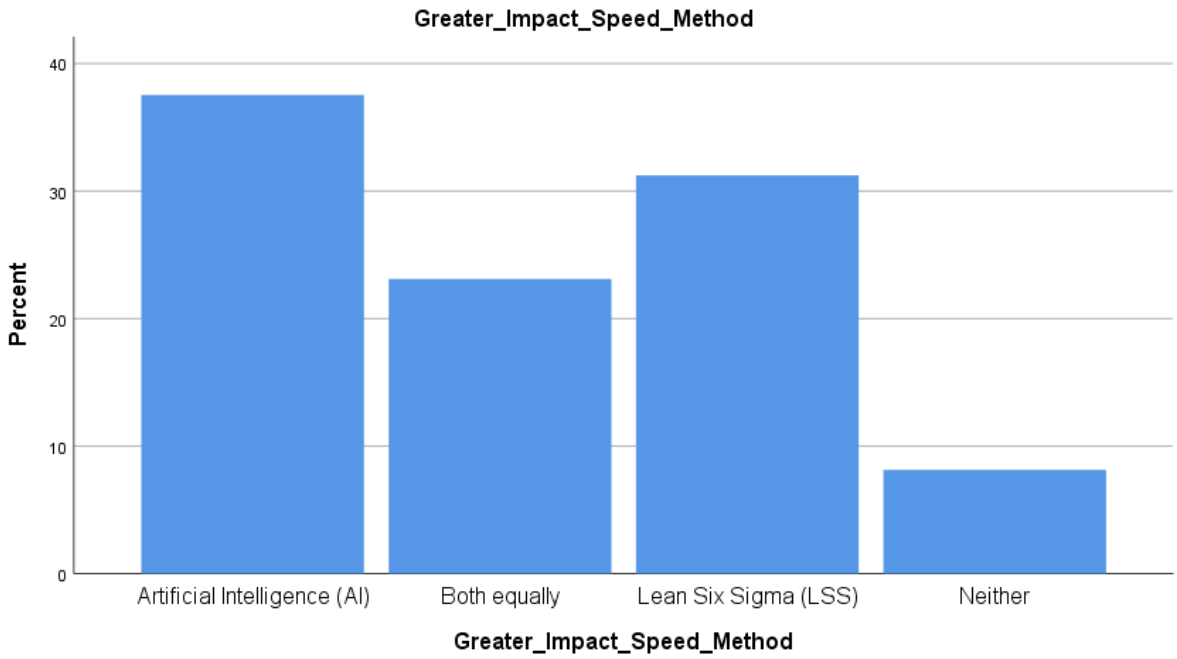

Figure 4.15: Greater_Impact_Speed_Method

(Source: SPSS)

Greater_Impact_Quality_Method

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Artificial Intelligence (AI)	126	33.1	33.1	33.1
	Both equally	131	34.4	34.4	67.5
	Lean Six Sigma (LSS)	91	23.9	23.9	91.3
	Neither	33	8.7	8.7	100.0
	Total	381	100.0	100.0	

Table 4.16: Greater_Impact_Quality_Method

(Source: SPSS)

Table 4.16 summarises respondents' perceptions of whether LSS or AI has had a greater impact on product quality. The largest proportion (34.4%) believe both are equally impactful, suggesting that quality improvements are most effective when combining AI's data-driven monitoring and predictive capabilities with LSS's structured process control and defect reduction methods. AI was selected by 33.1%, reflecting its ability to enhance quality through real-time defect detection, automated quality checks, and advanced analytics. Meanwhile, 23.9% credited LSS as having the greater impact, highlighting its role in standardising processes and ensuring regulatory compliance. A smaller group (8.7%) felt that neither significantly improved quality, potentially due to limited implementation or operational challenges. Overall, the findings suggest that while AI is slightly ahead in perceived quality impact, many in the industry recognise that integrating AI's technological strengths with LSS's systematic approach yields the most comprehensive quality enhancements.

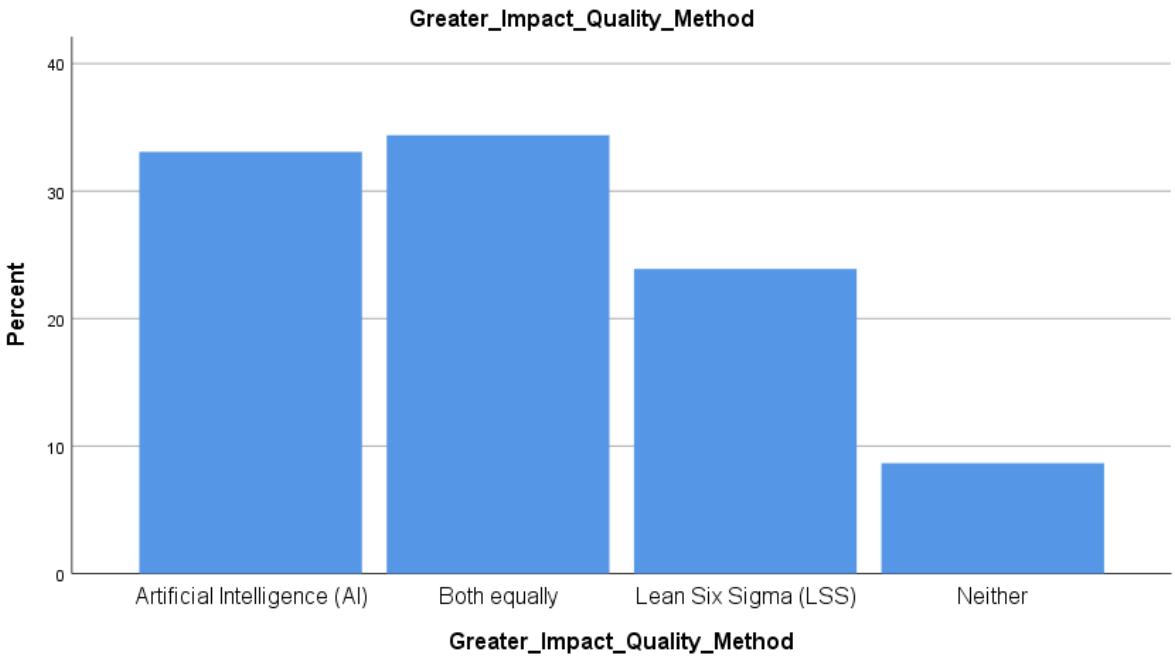

Figure 4.16: Greater_Impact_Quality_Method

(Source: SPSS)

LSS_AI_Combined_Benefit_Agreement

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Agree	109	28.6	28.6	28.6
	Disagree	113	29.7	29.7	58.3
	Neutral	35	9.2	9.2	67.5
	Strongly Agree	35	9.2	9.2	76.6

	Strongly Disagree	**89**	**23.4**	**23.4**	**100.0**
	Total	**381**	**100.0**	**100.0**	

Table 4.17: LSS_AI_Combined_Benefit_Agreement

(Source: SPSS)

Table 4.17 presents respondents' views on whether combining LSS and AI delivers greater benefits than using either method alone. The responses are mixed, with the largest proportion (29.7%) disagreeing, suggesting that some organisations have not experienced significant added value from integration, potentially due to poor alignment, implementation challenges, or lack of supporting infrastructure. Conversely, 28.6% agree and 9.2% strongly agree, indicating that nearly 38% recognise synergies between LSS's structured process optimisation and AI's advanced analytical capabilities. Strongly disagree responses account for 23.4%, reflecting a substantial group that sees integration as ineffective or unnecessary. A further 9.2% remain neutral, possibly due to limited exposure to combined use or inconclusive results.

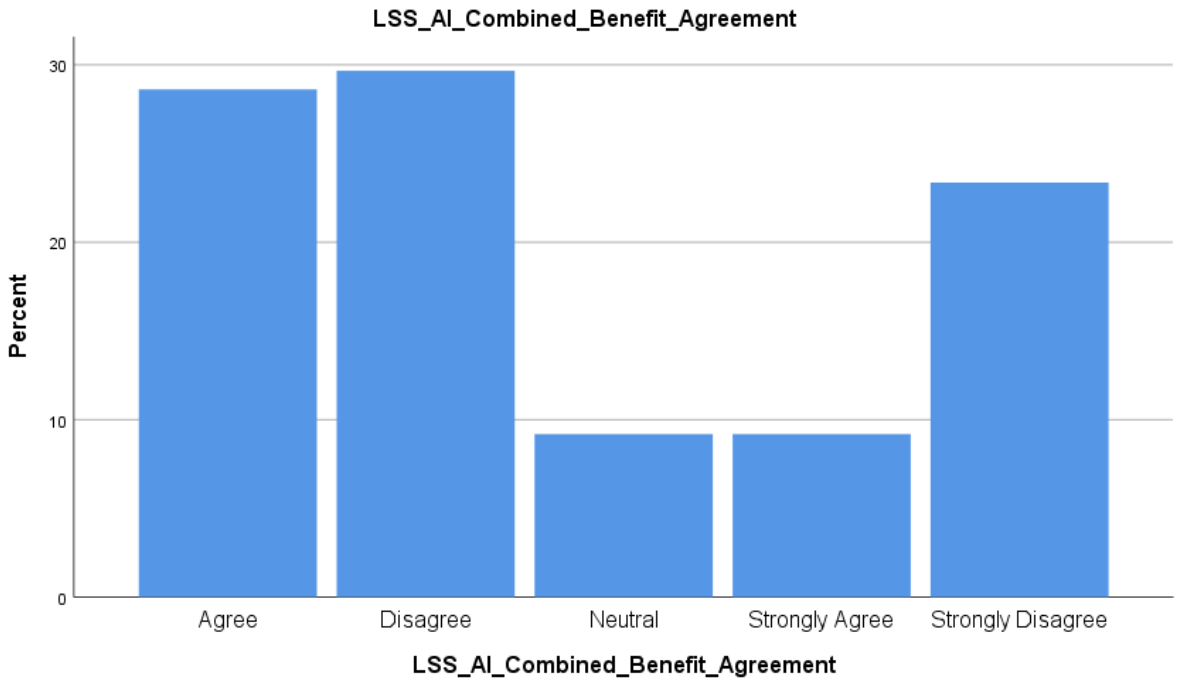

Figure 4.17: LSS_AI_Combined_Benefit_Agreement

(Source: SPSS)

More_Effective_Overall_Method

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Artificial Intelligence (AI)	138	36.2	36.2	36.2
	Both equally	118	31.0	31.0	67.2
	Lean Six Sigma (LSS)	100	26.2	26.2	93.4
	Neither	25	6.6	6.6	100.0
	Total	381	100.0	100.0	

Table 4.18: More_Effective_Overall_Method

(Source: SPSS)

Table 4.18 presents respondents' perceptions of which method, LSS or AI is more effective overall. The largest proportion (36.2%) selected AI, indicating a strong belief in its capacity to drive comprehensive improvements across speed, quality, and efficiency through automation, predictive analytics, and real-time decision-making. Both were equally chosen by 31.0%, suggesting that many see the greatest potential in combining AI's technological strengths with LSS's structured process optimisation framework. LSS was preferred by 26.2%, reflecting confidence in its proven track record for quality control, waste reduction, and compliance, particularly in regulated environments. A smaller segment (6.6%) felt that neither method is particularly effective, which may stem from unsuccessful implementations or organisational constraints. Overall, while AI is perceived as slightly more effective, the significant proportion recognising equal value points to growing support for integrated strategies that leverage the complementary benefits of both approaches in pharmaceutical manufacturing.

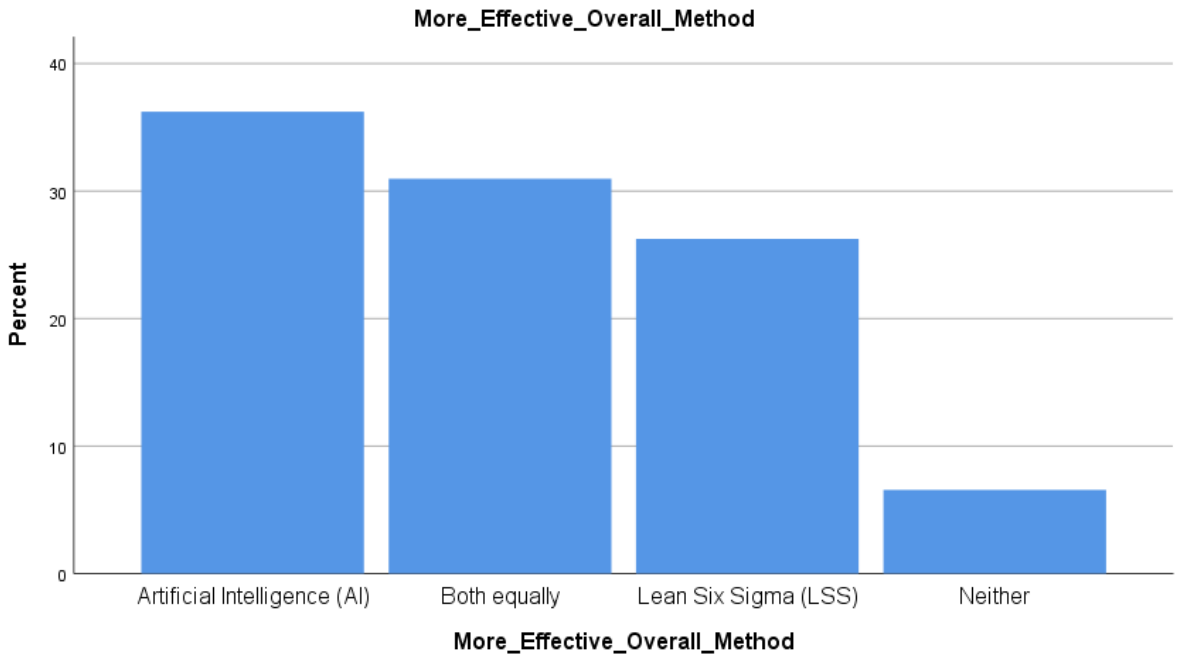

Figure 4.18: More_Effective_Overall_Method

(Source: SPSS)

Key_LSS_Implementation_Strategy

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Adequate resource allocation	53	13.9	13.9	13.9
	Clear communication of goals	61	16.0	16.0	29.9
	Continuous monitoring and improvement	80	21.0	21.0	50.9

Data-driven decision making	**17**	**4.5**	**4.5**	**55.4**
Employee training and engagement	**38**	**10.0**	**10.0**	**65.4**
Strong leadership commitment	**132**	**34.6**	**34.6**	**100.0**
Total	**381**	**100.0**	**100.0**	

Table 4.19: Key_LSS_Implementation_Strategy

(Source: SPSS)

Table 4.19 identifies respondents' views on most important strategies for successful LSS implementation. Strong leadership commitment emerged as the most frequently cited factor (34.6%), underscoring the importance of executive support in providing direction, resources, and accountability. Continuous monitoring and improvement (21.0%) ranked second, reflecting the need for ongoing evaluation to sustain gains and adapt processes over time. Clear communication of goals (16.0%) was also emphasised, highlighting the role of transparency in aligning teams and ensuring shared understanding of objectives. Adequate resource allocation (13.9%) was seen as essential to provide the necessary tools, technology, and staffing for effective LSS execution. Employee training and engagement (10.0%) reinforces the value of building internal capability and fostering ownership among staff. Notably, data-driven decision making was selected least often (4.5%), suggesting either underutilisation or that it is seen as a supporting, rather than primary, strategy. Overall, leadership and sustained process focus are viewed as critical to LSS success.

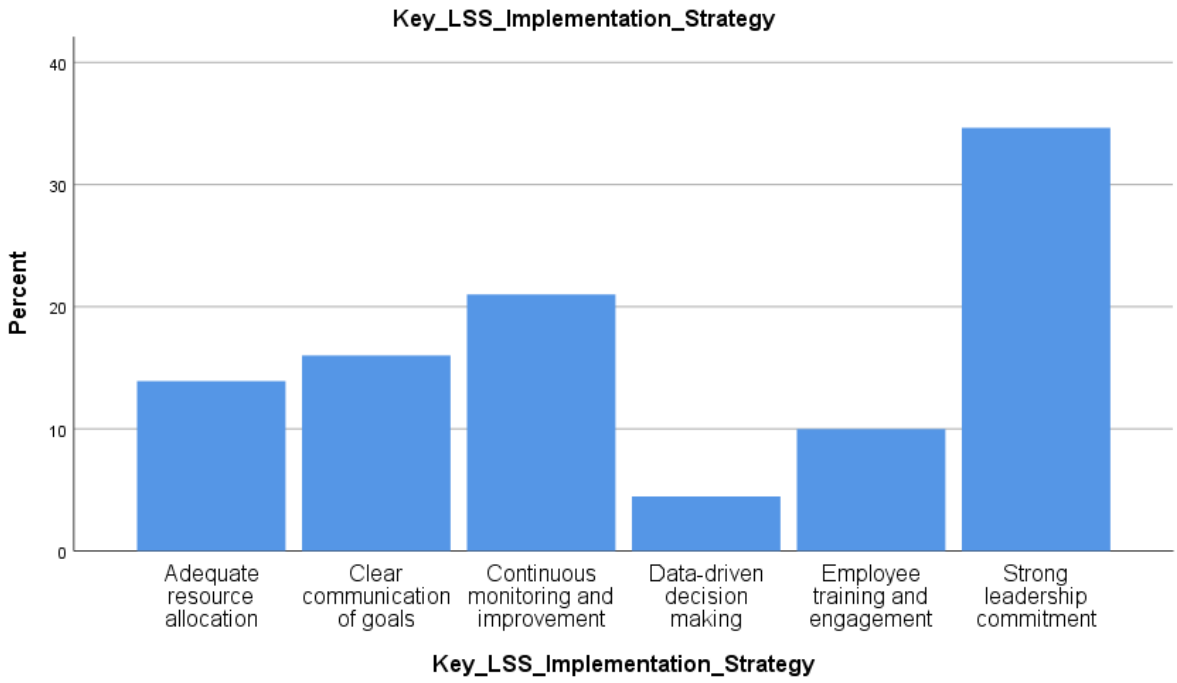

Figure 4.19: Key_LSS_Implementation_Strategy

(Source: SPSS)

Key_AI_Integration_Strategy

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Clear communication of AI goals and outcomes	99	26.0	26.0	26.0
	Collaboration with external AI experts	23	6.0	6.0	32.0
	Data management and security protocols	41	10.8	10.8	42.8

Employee training on AI tools	**50**	**13.1**	**13.1**	**55.9**
Investment in infrastructure and technology	**92**	**24.1**	**24.1**	**80.1**
Strong leadership commitment	**76**	**19.9**	**19.9**	**100.0**
Total	**381**	**100.0**	**100.0**	

Table 4.20: Key AI Integration Strategy

(Source: SPSS)

The Table 4.20 specify that Clear communication of AI goals and outcomes rate highest (26.0%), highlighting importance of transparency to line up stakeholders and create trust in AI adoption. Investment in infrastructure and technology followed closely (24.1%), reflecting the need for robust digital systems, computing power, and connectivity to support AI operations effectively. Strong leadership commitment (19.9%) highlights the role of executive backing in driving AI projects and securing necessary resources. Employee training on AI tools (13.1%) underlines the importance of upskilling staff to maximise AI's potential and reduce resistance. Data management and security protocols (10.8%) show awareness of compliance and cybersecurity requirements in handling sensitive pharmaceutical data. Collaboration with external AI experts was least cited (6.0%), suggesting either reliance on internal expertise or limited perceived necessity. Overall, communication, investment, and leadership are seen as central to effective AI integration.

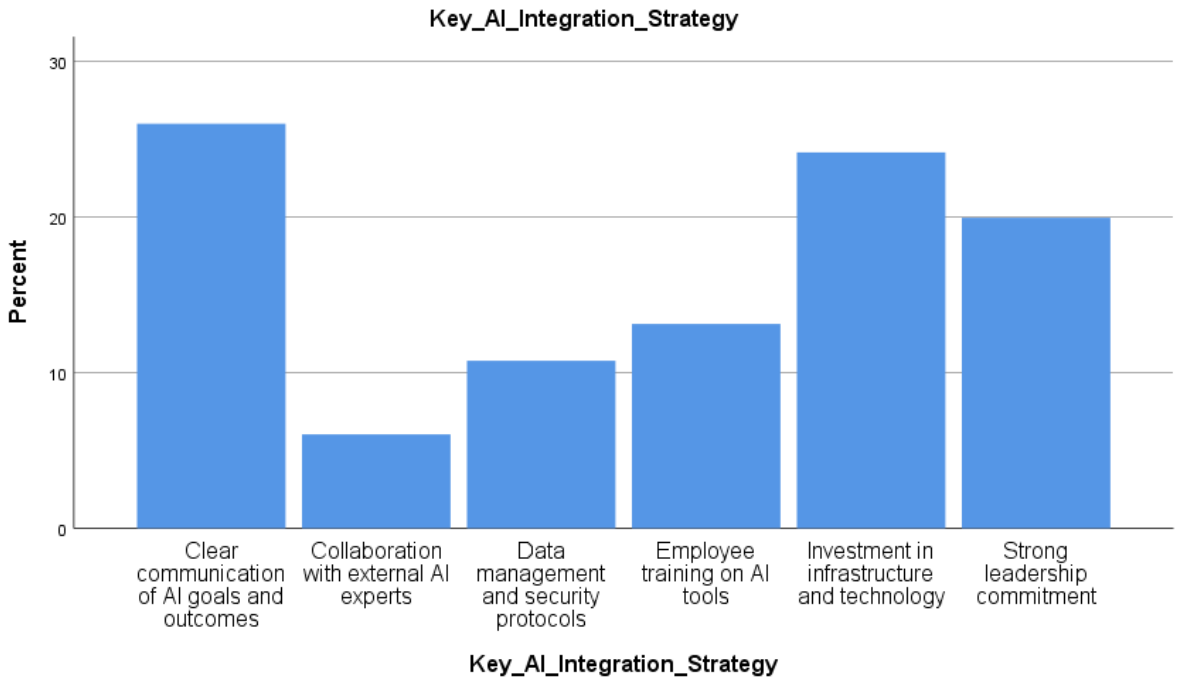

Figure 4.20: Key AI Integration Strategy

(Source: SPSS)

LSS_Implementation_Challenge

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	High implementation costs	84	22.0	22.0	22.0
	Inadequate technology infrastructure	56	14.7	14.7	36.7
	Lack of skilled personnel	84	22.0	22.0	58.8

	Poor organisational culture	**16**	**4.2**	**4.2**	**63.0**
	Regulatory hurdles	**73**	**19.2**	**19.2**	**82.2**
	Resistance to change from employees	**68**	**17.8**	**17.8**	**100.0**
	Total	**381**	**100.0**	**100.0**	

Table 4.21: LSS_Implementation_Challenge

(Source: SPSS)

Table 4.21 outlines High implementation costs and lack of skilled personnel are the most frequently cited barriers (both 22.0%), indicating that financial constraints and workforce capability gaps significantly hinder adoption. Regulatory hurdles (19.2%) also play a major role, reflecting the stringent compliance requirements in the pharmaceutical sector that can slow or complicate process changes. Resistance to change from employees (17.8%) highlights cultural and behavioural challenges, suggesting the need for strong change management strategies. Inadequate technology infrastructure is nearly 14.7% points to limitations in systems and digital tools required to promote LSS initiatives, while poor organisational culture is approximately 4.2% that was least reported but still relevant. Cultural alignment is significant for sustaining development efforts. Overall, the findings provide that overcoming LSS challenges needs a combined focus on skills development, regulatory navigation, cultural readiness and funding to ensure sustainable and successful implementation.

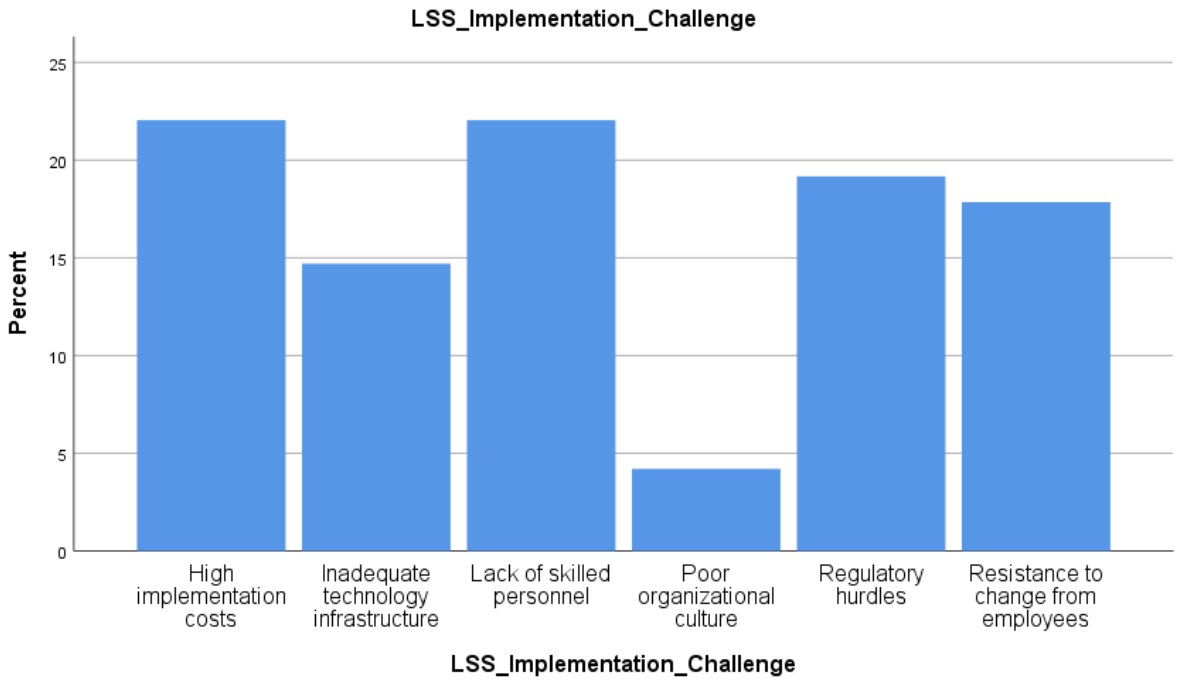

Figure 4.21: LSS_Implementation_Challenge

(Source: SPSS)

AI_Integration_Challenge

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Complexity of technology	51	13.4	13.4	13.4
	Data security concerns	77	20.2	20.2	33.6
	High implementation costs	96	25.2	25.2	58.8

	Lack of skilled AI professionals	**75**	**19.7**	**19.7**	**78.5**
	Regulatory hurdles	**20**	**5.2**	**5.2**	**83.7**
	Resistance to change from employees	**62**	**16.3**	**16.3**	**100.0**
	Total	**381**	**100.0**	**100.0**	

Table 4.22: AI_Integration_Challenge

(Source: SPSS)

Table 4.22 provides main challenges in integrating AI into pharmaceutical operations. High implementation costs are considered as 25.2% emerged as most cited barrier. It is addressing that financial investment in software, expertise and infrastructure that remains a significant obstacle. Data security concerns (20.2%) provides sensitivity of pharmaceutical data and need for strong compliance measures and cybersecurity. Lack of skilled AI professionals (19.7%) points to a talent gap that is limiting power to enhance, optimise and maintain AI systems. Resistance to change from employees (16.3%) shows that cultural and behavioural barriers also affect adoption. Complexity of technology (13.4%) indicates that the sophistication of AI tools can overwhelm organisations without adequate preparation. Regulatory hurdles (5.2%) were cited least often but remain important given the strict compliance environment. Overall, the findings suggest that successful AI integration requires strategic investment, skill development, change management, and strong data governance to address both technical and human factors.

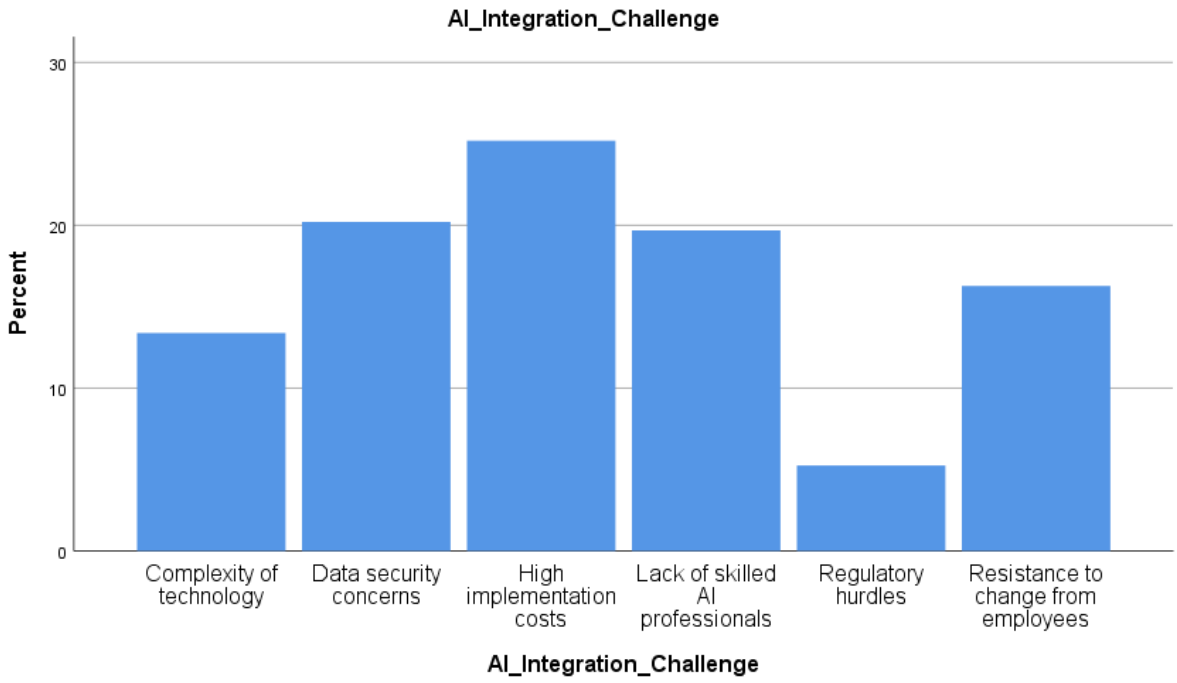

Figure 4.22: AI_Integration_Challenge

(Source: SPSS)

Best_Strategy_LSS_AI_Integration

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Aligning leadership goals with both LSS and AI strategies	95	24.9	24.9	24.9
	Combining employee training programs for LSS and AI	57	15.0	15.0	39.9

Continuous feedback and data collection from both systems	**76**	**19.9**	**19.9**	**59.8**
Fostering a culture of continuous improvement that supports both methodologies	**52**	**13.6**	**13.6**	**73.5**
Investing in both AI technologies and LSS infrastructure	**101**	**26.5**	**26.5**	**100.0**
Total	**381**	**100.0**	**100.0**	

Table 4.23: Best_Strategy_LSS_AI_Integration

(Source: SPSS)

Table 4.23 outlines respondents' views on the most effective strategies for integrating LSS and AI. The most frequently selected approach (26.5%) is investing in both AI technologies and LSS infrastructure, reflecting importance of providing the necessary tools, systems, and resources to enable effective dual adoption. Close behind, aligning leadership goals with both LSS and AI strategies (24.9%) highlights the critical role of strategic direction and executive commitment in ensuring integration success. Continuous feedback and data collection from both systems (19.9%) underscores the need for ongoing performance monitoring to refine processes and sustain improvements. Combining employee training programs (15.0%) demonstrates recognition of workforce development as a key enabler for bridging skills gaps. Fostering a culture of CI (13.6%) was least cited, though still essential for long-term sustainability. Overall, the findings suggest that integration success relies on a balanced focus on investment, leadership alignment, and adaptive, data-driven management practices.

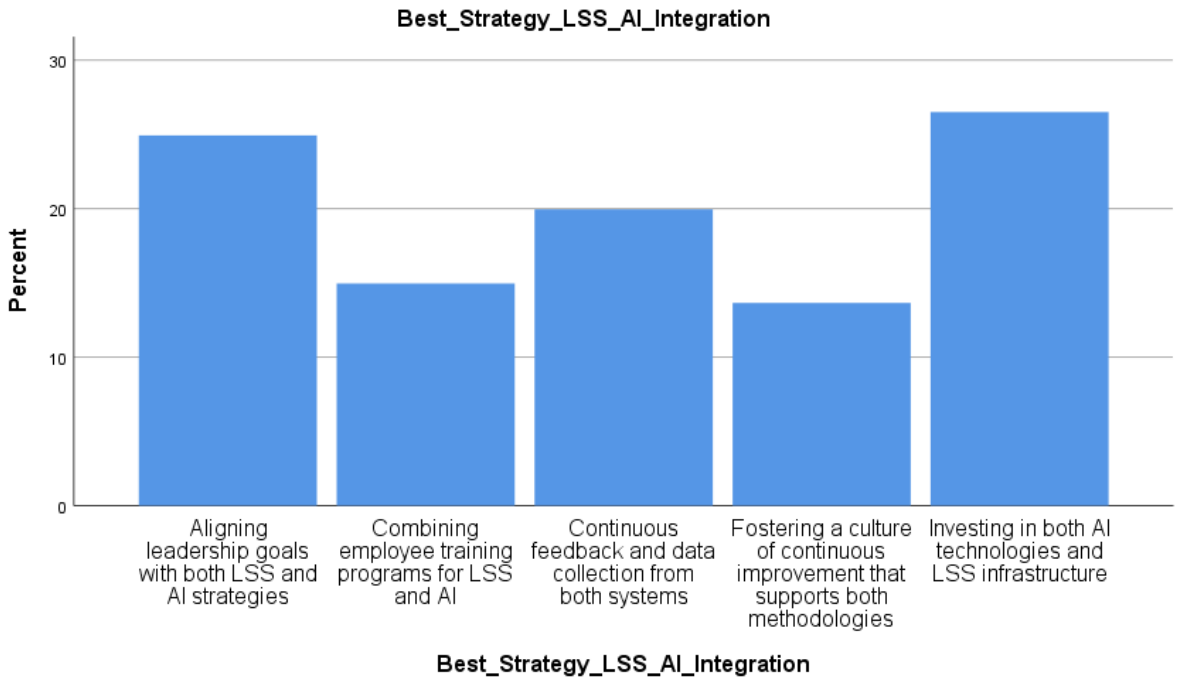

Figure 4.23: Best_Strategy_LSS_AI_Integration

(Source: SPSS)

4.3 Analysis

4.3.1 Impact of LSS and AI Integration on Pharmaceutical Production

Pharmaceutical production processes involve high complexity with multiple interdependent steps under strict regulatory oversight. Implementing LSS alone delivers improvements but can be limited by human-led analysis speed (Vicente, Godina and Gabriel, 2024, p.5). Machine learning algorithms track trends in equipment performance material quality and operator actions providing actionable recommendations for process optimization. The integration ensures that process deviations are corrected immediately reducing risks of defective batches or recalls.

Another critical impact of LSS and AI integration is cost reduction. LSS achieves savings with the help of waste elimination and efficiency gains while AI enhances these savings by enabling predictive maintenance and optimizing resource allocation. By AI algorithms forecasts equipment failures, predictive maintenance powered before they arise with avoiding costly repairs and reducing downtime (Raza, 2023, p.7).

Pharmaceutical production processes include high complexity with different interdependent steps under strict regulatory oversight. Applying LSS alone provides improvements and analysis addressed by humans can limit speed of the process (Vicente, Godina and Gabriel, 2024, p.3). Machine learning algorithms monitor trends in operator actions and equipment performance material quality highlighting actionable recommendations for process optimization. Integration makes sure that process deviations are corrected and decreases risks of defective recalls or batches.

Another critical influence of AI and LSS implementation is cost reduction. AI improves these savings with optimizing resource allocation and enabling predictive maintenance, while LSS secure savings through efficiency gains and waste elimination. AI is empowering predictive maintenance that predicts equipment failures before they arise with avoiding costly repairs and decreasing downtime (Raza, 2023, p.5). Without compromising product quality, resource optimization makes sure efficient application of energy that decreases production costs and raw materials. One with another, these aspects develop profitability and competitiveness for Irish pharmaceutical companies.

The cultural impact of this integration is equally significant. LSS emphasizes structured collaboration and problem-solving while AI tools provide data-driven insights that enhance decision-making confidence. Employees at all levels can engage with real-time dashboards and predictive reports allowing informed decisions and CI (Ajax, Joseph and Own, 2025, p.8). Training operators and engineers to use AI-enabled LSS tools empowers teams to solve problems faster and sustain improvements over time.

Challenges remain in regulatory compliance and organizational adoption. Pharmaceutical processes are heavily regulated and any process change must align with Good Manufacturing Practices and other standards. AI-driven decisions must be validated and documented to satisfy regulators. Furthermore cultural resistance to adopting new digital systems may slow down progress. Moreover, these challenges have the ability to be overcome with the help of strong change management, phased integration strategies and leadership commitment that link with enhancements with compliance requirements (Abdiqani, Yeneneh and Faradilah, 2024, p.9).

Integration of AI and LSS gives a transformative pathway for pharmaceutical manufacturing. It decreases costs, assures quality and improves efficiency while

providing organizations to respond quickly according to market demands. Combination of AI and LSS presents strategic opportunity for optimising product quality and production speed while safeguarding a competitive advantage in global sector for pharmaceutical organisations in Ireland.

4.3.2 Barriers to Implementing LSS and AI in the Irish Pharmaceutical Industry

Irish pharmaceutical industry has gone through a unique set of challenges when implementing AI and LSS. Regulatory oversight is considered as most crucial barrier for methodologies due to every transformation that needs approval and validation. Before implementation, pharmaceutical companies followed strict guidelines unlike unregulated sector where rapid process changes are possible (Khan, 2025, p.2). Regulatory compliance slows integration of AI systems and requires cost and time to LSS projects.

LSS projects face challenges due to validation consuming resources that have the power to influence efficiency enhancements in Ireland. Every development should be proven correct first time due to errors. It has the power to impact the corrective action reports. To spend months on documentation, this level of oversight forces teams and decreases speed of execution. AI adoption also went through some challenges due to models requiring validation that is against regulatory standards before it has become operational for the analysis (McDermott et al., 2024 p.7).

In Irish pharmaceutical companies, another challenge occurs from cultural emphasis on compliance over continuous enhancement. Companies mainly pay attention to market authorisation and regulatory approval before efficiency improvements. LSS develops with the test of the product faster with the help of team and accepts that it relies on results (Grace et al., 2024, p.7). This flexibility is enhanced and constrained by cycles that took several months in regulated environments (Michelle et al., 2024, p.6). AI requires agile environments, which provide data models that evolve with iterations and strict compliance challenges this adaptability and slower the adoption process.

In Irish pharmaceutical organisations, there is a most important challenge which is unavoidable that is known as cost for implementing LSS and AI. Validation requirements increase project costs by demanding extensive testing, documentation and skilled engineering resources. LSS projects require nearly half of their budget for activities that are related to validation (Saha, Patel and Paladini, 2025, p.4).

Expertise and skills shortages highlight another critical challenge when implementing these methodologies of pharmaceutical facilities. LSS needs efficient workers who have the power to structure enhancement methods and understand statistical tools. AI needs engineers and data scientists who can implement algorithms to production environments. They will explore regulatory compliance (Salman et al., 2024, p.8). Retaining and recruiting this talent pool is hard that is providing global competition for skilled professionals. Resulting underperformance and projects risk delays because of insufficient expertise.

Finally integration of AI and LSS went through organisational resistance for transformation across Irish pharmaceutical industry. Employees share these methods as threatening or disruptive to responsibilities and established roles. Managers show hesitations for establishing projects, which risk additional compliance barriers and delays (Gkrimpizi, Peristeras and Magnisalis, 2023, p.4). This project enhances status because it provides widespread adoption of AI and LSS.

The Irish pharmaceutical industry encounters barriers related to regulation cost culture expertise and resistance. These barriers slow the pace of LSS and AI adoption despite the potential for optimising speed and quality. Addressing these barriers requires collaboration between regulators, industry leaders and project teams to unlock the benefits of both methodologies (Batkhuu and Deng, 2025).

4.3.3 Strategic Approaches for Effective Application of LSS and AI

LSS and AI only deliver lasting success in Irish pharmaceuticals when aligned under structured strategies that link tools to business objectives. The local regulated environment raises entry barriers on compliance and productivity (Kumar et al., 2022, p.2). A strategic roadmap is essential, which defines leadership roles, sets measurable targets, and prescribes technology governance, enabling stakeholders to apply these methodologies in an integrated manner and hardware that changes business processes without destabilizing them. By anchoring initiatives to company-wide goals and predictable governance, firms maximize recurrent gains and ensure the innovations remain valuable past their initial deployment.

One strategic approach is to align improvement initiatives with organisational goals and regulatory standards to ensure consistency and compliance. LSS projects must be selected

based on their potential to reduce waste and variability in critical processes (Kowang et al., 2022, p.5). AI applications must be validated carefully to satisfy industry regulators while still delivering predictive and analytical power. This alignment ensures that improvements create measurable impact without exposing companies to compliance risks.

A second approach involves developing strong data management systems that support both LSS and AI projects. Pharmaceutical companies generate large volumes of process data and quality data during manufacturing. LSS requires accurate data collection to identify root causes and drive improvements. AI requires structured and reliable datasets to build predictive models and deliver meaningful insights (Kabeer, 2025, p.7). Strong governance of data ensures accuracy integrity and security across all applications.

Another strategic approach is to foster collaboration between LSS specialists and AI experts to leverage their complementary skills. LSS specialists understand process mapping problem solving and statistical analysis. AI experts understand algorithms data modelling and digital optimisation. Collaborative project teams create synergies where process knowledge combines with digital intelligence to solve complex challenges (Uzoechi, 2024, p.8). Cross functional training also helps employees understand how both approaches support organisational improvement.

Training and capability building form another key approach to effective implementation of LSS and AI. Employees must be trained to use problem solving tools under the LSS methodology (Bagherian, Gershon and Swarnakar, 2022, p.2). They must also develop digital literacy to work effectively with AI solutions in daily operations. Training programs build confidence in new methods and reduce resistance to change while ensuring sustainability of results.

A further strategic approach is the use of phased implementation that reduces risks while building confidence in new methodologies. AI models can be tested in limited production environments to validate performance before full deployment (Silva and Alahakoon, 2022, p.9). Phased implementation creates opportunities to learn, adjust and refine strategies without overwhelming the organisation.

A next step is to weave continuous surveillance frameworks into operations, keeping gains fresh and guaranteeing lasting impact. LSS draws on tightly written control plans

to lock in process stability following an improvement (Khan et al., 2024, p.4). AI, in contrast, brings continuous, real-time supervision, spotting drift and recommending timely remediation. The synthesis of these two systems provides deep durability and flexibility across Ireland's drug-manufacturing environment.

Ultimately, without explicit support from the top, the fusion of LSS with AI is unlikely to flourish. Site executives must allocate funds, champion programmes in public forums, and clarify the improvement mission. When leaders act this way, a cross-functional atmosphere of responsibility, inventive thinking and exacting standards is reinforced, so progress becomes ingrained (Dutta et al., 2024, p.3). Practical adoption of both methodologies is inextricably linked to strategies that centre alignment, cross-team partnership, targeted training and unwavering executive backing. When Irish drug manufacturers embrace these disciplined programmes, they accelerate output, enhance product consistency and satisfy an ever-stricter regulatory environment.

4.3.4 Comparative Significance of AI and LSS in Optimizing Pharmaceutical Quality and Speed

The pharmaceutical landscape in Ireland is pressed to boost efficiency without compromising the stringent regulatory frameworks or the uncompromising patient safety benchmarks that govern the sector. LSS serves as a robust legislative toolbox, offering structured, repeatable techniques to rein in process variation and slash defect rates, thereby reinforcing the integrity and dependability of the final product (Vaghela et al., 2024, p.7). When considered alongside the capabilities of AI, the performance equation broadens. AI embeds sophisticated data-analytics engines into the production line, sharpening decision hypotheses, shortening manufacturing lead-times, and embedding quality assurance that is driven rather than observed. While both methodologies independently enhance the quality architecture of pharmaceutical production, a comparative view reveals the different vectors through which they succeed.

The LSS logic orbits a disciplined, five-step cycle, DMAIC in which every manufacturing or packaging activity is modelled and fortified against variance. By securing routine stability, the process limits fluctuations that could otherwise trigger regulatory action or product withdrawals. Lean waste removal channels surplus capacity into a more linear process, contributing speed in environments where predictability is mission-critical (Ghante et al., 2024, p.4). Not surprisingly, the architecture of each LSS project is seldom

lightweight; the iterative model calls for trained Black Belts, extensive stakeholder engagement, and time-absorbing validations before every element is authorized for normal production.

AI enhances drug-manufacturing excellence by using predictive analytics, automation, and sophisticated models to drive operational accuracy. Operating at speeds orders of magnitude faster than conventional methods, AI can sift through terabytes of data, spotting anomalies that the human eye would overlook. In pharmaceutical production the technology continuously monitors quality indicators: sensors capture data, algorithms forecast deviations, and predictive control recalibrates processes on the fly, trimming deviations before lots are even released (Rajesh and Elumalai, 2025, p.9). As a result production accelerates and the quality of each tablet stays within strict inbound and outbound limits. In contrast to the regimented cycles of LSS, AI flexes to changing operating landscapes and iterates improvements daily rather than quarterly.

LSS remains the regulatory darling because inspectors read, sign, and rely on the paper trail that its five-phase cycles generate. Deviation reports, control plans, and statistical studies create a breadcrumb path of logic and evidence, reassuring Health Authorities that processes were well understood and fortified. When auditors pull a sample chart the combinations of “define-measure-analyze” are where the thumbs are raised. Regulating bodies have entrusted drugs to market and sought copies of last year’s six sigma before the lot even enters the gene-therapy market (Ahmad et al., 2022, p.5).. AI, by contrast, continues to shelter its logic behind the black box, where training data, hyper-parameter choices, and drift control updates shift with geographic unit deployments. As firms prototype AI-led process control the same regulators ask to observe training and validation data that have been anonymized, rolled and deleted. In the debate of compliance stability versus agility the legacy of LSS endurance remains while the algorithms display efficiency thirst.

LSS and AI both confront distinct constraints in Irish pharmaceuticals that restrain their full adoption. LSS encounters persistent reluctance stemming from upfront cost, protracted cycle times and the obligation for renewed validation, leaving companies reluctant to pursue process redesign beyond the bare minimum (Alblooshi et al., 2020, p.1).AI, on the other hand, struggles with fragmented data privacy regimes, heavy infrastructure expenditures, scarcity of technical talent, and unclear regulation on the

acceptability of risk-based decisions through algorithms. Yet, the interplay of both methods still offers fertile ground for combined deployment.

Hypothesis Testing and Analysis

Factor: Current Role

Hypothesis 1 (LSS Production Speed)

- **H_0:** There is no significant difference in the impact of LSS on production speed across different roles in the pharmaceutical sector.
- **H_1:** There is a significant difference in the impact of LSS on production speed across different roles in the pharmaceutical sector.
- **Result:** $p = .121$ ($> .05$) → Fail to reject H_0.
- **Decision: H_0 accepted; H_1 rejected.**

Hypothesis 2 (AI Production Speed)

- **H_0:** There is no significant difference in the impact of AI on production speed across different roles in the pharmaceutical sector.
- **H_1:** There is a significant difference in the impact of AI on production speed across different roles in the pharmaceutical sector.
- **Result:** $p = .025$ ($< .05$) → Reject H_0.
- **Decision: H_0 rejected; H_1 accepted.**

Hypothesis 3 (LSS Production Quality)

- **H_0:** There is no significant difference in the impact of LSS on production quality across different roles in the pharmaceutical sector.
- **H_1:** There is a significant difference in the impact of LSS on production quality across different roles in the pharmaceutical sector.
- **Result:** $p = .059$ ($> .05$) → Fail to reject H_0.
- **Decision: H_0 accepted; H_1 rejected.**

Hypothesis 4 (AI Production Quality)

- **H_0:** There is no significant difference in the impact of AI on production quality across different roles in the pharmaceutical sector.
- **H_1:** There is a significant difference in the impact of AI on production quality across different roles in the pharmaceutical sector.
- **Result:** p = .186 (> .05) → Fail to reject H_0.
- **Decision: H_0 accepted; H_1 rejected.**

ANOVA

		Sum of Squares	df	Mean Square	F	Sig.
LSS Production Speed	Between Groups	13.367	4	3.342	1.838	.121
	Within Groups	683.505	376	1.818		
	Total	696.871	380			
AI Production Speed	Between Groups	19.426	4	4.857	2.825	.025
	Within Groups	646.358	376	1.719		
	Total	665.785	380			
LSS_Production_Quality	Between Groups	16.095	4	4.024	2.291	.059
	Within Groups	660.378	376	1.756		

	Total	676.472	380			
AI_Production_Quality	Between Groups	11.260	4	2.815	1.553	.186
	Within Groups	681.532	376	1.813		
	Total	692.793	380			

Table 4.24: ANOVA Results for LSS and AI Production Speed and Quality

ANOVA outcomes for variables of Current Role reveal important understandings into how different job functions in pharmaceutical sector perceive effectiveness of AI and LSS in improving production quality and speed. Out of four tests conducted, AI Production Speed (p = .025) was only variable to give a significant statistical difference across roles. This addresses that job position has a tangible impact on how contribution of AI to escalating production is given. For intense, process improvement engineers and specialists work with predictive scheduling and automation aspects, and may recognise increase from AI. Additionally, quality control specialists might stay cautious. Under strict regulatory frameworks, it is provided that AI-driven decisions need validation (Jain, 2024, p.4). This divergence highlights the varying levels of exposure and responsibility different roles have in relation to AI systems.

In contrast, LSS Production Speed (p = .121) and LSS Production Quality (p = .059) did not demonstrate statistically significant differences between roles. This suggests that LSS is perceived as relatively consistent across departments, regardless of whether employees are in operations, production, or quality functions. The near-significant result for LSS quality does, however, hint at a possible trend where quality specialists may value LSS more strongly than others due to its structured defect-reduction methods (Team, 2024, p.7). Nonetheless, these findings support existing literature that positions LSS as a standardised, system-wide methodology, less influenced by role-specific perspectives.

Finally, AI Production Quality (p = .186) was not significant, meaning all roles share similar views on AI's contribution to product quality. This may be due to the universal application of AI in monitoring, defect detection, and compliance, which affects all departments equally.

Overall, the results underline that role primarily influences perceptions of AI's impact on speed, while LSS remains broadly consistent across functions. This finding suggests that role-specific

training and change management are particularly critical when implementing AI in pharmaceutical manufacturing.

Factor Organisation Size

Hypothesis 5 (LSS Production Speed)

- **H_0:** There is no significant difference in the impact of LSS on production speed across pharmaceutical organisations of different sizes.
- **H_1:** There is a significant difference in the impact of LSS on production speed across pharmaceutical organisations of different sizes.
- **Result:** $p = .319$ ($> .05$) → Fail to reject H_0.
- **Decision: H_0 accepted; H_1 rejected.**

Hypothesis 6 (AI Production Speed)

- **H_0:** There is no significant difference in the impact of AI on production speed across pharmaceutical organisations of different sizes.
- **H_1:** There is a significant difference in the impact of AI on production speed across pharmaceutical organisations of different sizes.
- **Result:** $p = .485$ ($> .05$) → Fail to reject H_0.
- **Decision: H_0 accepted; H_1 rejected.**

Hypothesis 7 (LSS Production Quality)

- **H_0:** There is no significant difference in the impact of LSS on production quality across pharmaceutical organisations of different sizes.
- **H_1:** There is a significant difference in the impact of LSS on production quality across pharmaceutical organisations of different sizes.
- **Result:** $p = .780$ ($> .05$) → Fail to reject H_0.
- **Decision: H_0 accepted; H_1 rejected.**

Hypothesis 8 (AI Production Quality)

- **H_0:** There is no significant difference in the impact of AI on production quality across pharmaceutical organisations of different sizes.
- **H_1:** There is a significant difference in the impact of AI on production quality across pharmaceutical organisations of different sizes.
- **Result:** p = .308 (> .05) → Fail to reject H_0.
- **Decision: H_0 accepted; H_1 rejected.**

ANOVA

		Sum of Squares	df	Mean Square	F	Sig.
LSS Production Speed	Between Groups	6.462	3	2.154	1.176	.319
	Within Groups	690.409	377	1.831		
	Total	696.871	380			
AI Production Speed	Between Groups	4.298	3	1.433	.816	.485
	Within Groups	661.487	377	1.755		
	Total	665.785	380			
LSS_Production_Quality	Between Groups	1.945	3	.648	.362	.780
	Within Groups	674.527	377	1.789		

	Total	676.472	380			
AI_Production_Quality	Between Groups	6.575	3	2.192	1.204	.308
	Within Groups	686.217	377	1.820		
	Total	692.793	380			

Table 4.25: Table X: ANOVA Results for LSS and AI Production Speed and Quality (3 Groups)

The ANOVA results for the factor **Organisation Size** demonstrate that no statistically significant differences were found across all four dependent variables: LSS Production Speed (p = .319), AI Production Speed (p = .485), LSS Production Quality (p = .780), and AI Production Quality (p = .308). In each case, the p-values exceeded the 0.05 threshold, leading to acceptance of the H_0. This indicates that organisational size, whether small (<250 employees), medium (250–999 employees), large (1,000–4,999 employees), or very large (>5,000 employees), does not significantly influence perceptions of LSS or AI effectiveness on production speed or quality.

This finding is important because it challenges the common assumption that larger organisations, with greater financial and technological resources, should experience stronger benefits from LSS and AI adoption. Instead, the results suggest that improvements in production speed and quality are not inherently tied to the scale of the organisation, but rather to the way these methodologies are implemented and managed (Coviello et al., 2024, p.4). Smaller firms might compensate for limited resources with faster and more agile decision-making, while larger organisations might take advantage of established systems and slower cultural change and face bureaucracy.

Lack of variation across organisation sizes represents that both AI and LSS are flexible frameworks that have the ability to be scaled significantly. Without major changes in perceived results, LSS gives structured, process-driven enhancements that have ability to be implemented in both large and small environments. Moreover, AI implementations like automation, quality tracking, and predictive maintenance, regardless of firm size, provide universal advantages. It represents training in place and adequate infrastructure.

Factor Site Manufacturing Type

Hypothesis 9 (LSS Production Speed)

- **H_0:** There is no significant difference in impact of LSS on production speed between different site manufacturing types in the pharmaceutical sector.
- **H_1: :** There is no significant difference in impact of LSS on production speed between different site manufacturing types in the pharmaceutical sector.
- **Result:** p = .106 (> .05) → Fail to reject H_0.
- **Decision: H_0 accepted; H_1: rejected.**

Hypothesis 10 (AI Production Speed)

- **H_0:** There is no significant difference in impact of AI on production speed between different site manufacturing types in the pharmaceutical sector.
- **H_1: :** There is no significant difference in impact of AI on production speed between different site manufacturing types in the pharmaceutical sector.
- **Result:** p = .156 (> .05) → Fail to reject H_0.
- **Decision: H_0 accepted; H_1: rejected.**

Hypothesis 11 (LSS Production Quality)

- **H_0:** There is no significant difference in the impact of LSS on production quality across different site manufacturing types in the pharmaceutical sector.
- **H_1:** There is a significant difference in the impact of LSS on production quality across different site manufacturing types in the pharmaceutical sector.
- **Result:** p = .007 (< .05) → Reject H_0.
- **Decision: H_0 rejected; H_1 accepted.**

Hypothesis 12 (AI Production Quality)

- **H_0:** There is no significant difference in the impact of AI on production quality across different site manufacturing types in the pharmaceutical sector.
- **H_1:** There is a significant difference in the impact of AI on production quality across different site manufacturing types in the pharmaceutical sector.

- **Result:** p = .162 (> .05) → Fail to reject H_0.
- **Decision: H_0 accepted; H_1 rejected.**

ANOVA

		Sum of Squares	df	Mean Square	F	Sig.
LSS Production Speed	Between Groups	11.185	3	3.728	2.050	.106
	Within Groups	685.686	377	1.819		
	Total	696.871	380			
AI Production Speed	Between Groups	9.163	3	3.054	1.754	.156
	Within Groups	656.621	377	1.742		
	Total	665.785	380			
LSS_Production_Quality	Between Groups	21.263	3	7.088	4.078	.007
	Within Groups	655.210	377	1.738		
	Total	676.472	380			
AI_Production_Quality	Between Groups	9.356	3	3.119	1.720	.162

	Within Groups	683.437	377	1.813		
	Total	692.793	380			

Table 4.26: Table X: ANOVA Results for LSS and AI Production Speed and Quality

The ANOVA results for site manufacturing type (biologics, fill-finish, small-molecule API, and combination products) reveal an important distinction between LSS and AI. Out of the four hypotheses tested, only LSS Production Quality ($p = .007$) showed a statistically significant difference, while the other three variables—LSS Production Speed ($p = .106$), AI Production Speed ($p = .156$), and AI Production Quality ($p = .162$)—were not significant.

The significant outcome for LSS Production Quality indicates that perceptions of how LSS improves quality differ across site types. This finding suggests that LSS is more effective in certain pharmaceutical environments, particularly those with high process standardisation such as fill-finish and small-molecule API sites, where structured problem-solving and defect reduction methods directly enhance compliance and quality assurance. In contrast, combination product biologics and facility sites involve greater process variability and emerging technologies. It might find LSS less effective because of its dependence on repeatable, stable processes (Tian et al., 2022, p.4). This divergence emphasises importance of tailor LSS aspects to operational realities of manufacturing modality.

However, no effective differences were examined for AI Production Speed, AI Production Quality, or LSS Production Speed, suggesting that AI is for quality and speed, and LSS is only for speed, which are seen in various site types. This uniformity might be explained by fact that AI aspects like predictive analytics and automated defect detection are enhancing integration of different pharmaceutical environments that are giving huge applicable advantages regardless of product type. Moreover, by regulatory requirements, enhancement in production speed with LSS might be more constrained that is causing difficulties of variation between sites.

Moreover, findings include that influence of LSS on quality highly relies on context. In comparison, advantages of AI are perceived as more applicable to site types. This represents need to implement site-specific LSS strategies. AI application can be pursued on a large scale with various manufacturing modalities.

4.4 Hypothesis Testing and Analysis

4.4.1 Factor: Current Role

Hypothesis 1 (LSS Production Speed)

- **H_0:** There is no significant difference in the impact of Lean Six Sigma (LSS) on production speed across different roles in the pharmaceutical sector.
- **H_1:** There is a significant difference in the impact of Lean Six Sigma (LSS) on production speed across different roles in the pharmaceutical sector.
- **Result:** $p = .121$ ($> .05$) → Fail to reject H_0.
- **Decision: H_0 accepted; H_1 rejected.**

Hypothesis 2 (AI Production Speed)

- **H_0:** There is no significant difference in the impact of Artificial Intelligence (AI) on production speed across different roles in the pharmaceutical sector.
- **H_1:** There is a significant difference in the impact of Artificial Intelligence (AI) on production speed across different roles in the pharmaceutical sector.
- **Result:** $p = .025$ ($< .05$) → Reject H_0.
- **Decision: H_0 rejected; H_1 accepted.**

Hypothesis 3 (LSS Production Quality)

- **H_0:** There is no significant difference in the impact of Lean Six Sigma (LSS) on production quality across different roles in the pharmaceutical sector.
- **H_1:** There is a significant difference in the impact of Lean Six Sigma (LSS) on production quality across different roles in the pharmaceutical sector.
- **Result:** $p = .059$ ($> .05$) → Fail to reject H_0.
- **Decision: H_0 accepted; H_1 rejected.**

Hypothesis 4 (AI Production Quality)

- **H_0:** There is no significant difference in the impact of Artificial Intelligence (AI) on production quality across different roles in the pharmaceutical sector.

- **H_1:** There is a significant difference in the impact of Artificial Intelligence (AI) on production quality across different roles in the pharmaceutical sector.
- **Result:** p = .186 (> .05) → Fail to reject H_0.
- **Decision: H_0 accepted; H_1 rejected.**

ANOVA

		Sum of Squares	df	Mean Square	F	Sig.
LSS Production Speed	Between Groups	13.367	4	3.342	1.838	.121
	Within Groups	683.505	376	1.818		
	Total	696.871	380			
AI Production Speed	Between Groups	19.426	4	4.857	2.825	.025
	Within Groups	646.358	376	1.719		
	Total	665.785	380			
LSS_Production_Quality	Between Groups	16.095	4	4.024	2.291	.059
	Within Groups	660.378	376	1.756		
	Total	676.472	380			
AI_Production_Quality	Between Groups	11.260	4	2.815	1.553	.186

	Within Groups	681.532	376	1.813		
	Total	692.793	380			

Table 4.24: ANOVA Results for LSS and AI Production Speed and Quality

ANOVA outcomes for variables of Current Role reveal important understandings into how different job functions in pharmaceutical sector perceive effectiveness of AI and LSS in improving production quality and speed. Out of four tests conducted, AI Production Speed ($p = .025$) was only variable to give a significant statistical difference across roles. This addresses that job position has a tangible impact on how contribution of AI to escalating production is given. For intense, process improvement engineers and specialists work with predictive scheduling and automation aspects, and may recognise increase from AI. Additionally, quality control specialists might stay cautious. Under strict regulatory frameworks, it is provided that AI-driven decisions need validation. This divergence highlights the varying levels of exposure and responsibility different roles have in relation to AI systems.

In contrast, LSS Production Speed ($p = .121$) and LSS Production Quality ($p = .059$) did not demonstrate statistically significant differences between roles. This suggests that LSS is perceived as relatively consistent across departments, regardless of whether employees are in operations, production, or quality functions (McHugh and Farrell, 2023, p.4). The near-significant result for LSS quality does, however, hint at a possible trend where quality specialists may value LSS more strongly than others due to its structured defect-reduction methods. Nonetheless, these findings support existing literature that positions LSS as a standardised, system-wide methodology, less influenced by role-specific perspectives.

Finally, AI Production Quality ($p = .186$) was not significant, meaning all roles share similar views on AI's contribution to product quality. This may be due to the universal application of AI in monitoring, defect detection, and compliance, which affects all departments equally.

Overall, the results underline that role primarily influences perceptions of AI's impact on speed, while LSS remains broadly consistent across functions. This finding suggests that role-specific training and change management are particularly critical when implementing AI in pharmaceutical manufacturing.

Factor Organisation Size

Hypothesis 5 (LSS Production Speed)

- **H_0:** There is no significant difference in the impact of Lean Six Sigma (LSS) on production speed across pharmaceutical organisations of different sizes.
- **H_1:** There is a significant difference in the impact of Lean Six Sigma (LSS) on production speed across pharmaceutical organisations of different sizes.
- **Result:** p = .319 (> .05) → Fail to reject H_0.
- **Decision: H_0 accepted; H_1 rejected.**

Hypothesis 6 (AI Production Speed)

- **H_0:** There is no significant difference in the impact of Artificial Intelligence (AI) on production speed across pharmaceutical organisations of different sizes.
- **H_1:** There is a significant difference in the impact of Artificial Intelligence (AI) on production speed across pharmaceutical organisations of different sizes.
- **Result:** p = .485 (> .05) → Fail to reject H_0.
- **Decision: H_0 accepted; H_1 rejected.**

Hypothesis 7 (LSS Production Quality)

- **H_0:** There is no significant difference in the impact of Lean Six Sigma (LSS) on production quality across pharmaceutical organisations of different sizes.
- **H_1:** There is a significant difference in the impact of Lean Six Sigma (LSS) on production quality across pharmaceutical organisations of different sizes.
- **Result:** p = .780 (> .05) → Fail to reject H_0.
- **Decision: H_0 accepted; H_1 rejected.**

Hypothesis 8 (AI Production Quality)

- **H_0:** There is no significant difference in the impact of Artificial Intelligence (AI) on production quality across pharmaceutical organisations of different sizes.

- **H_1:** There is a significant difference in the impact of Artificial Intelligence (AI) on production quality across pharmaceutical organisations of different sizes.
- **Result:** p = .308 (> .05) → Fail to reject H_0.
- **Decision: H_0 accepted; H_1 rejected.**

ANOVA

		Sum of Squares	df	Mean Square	F	Sig.
LSS Production Speed	Between Groups	6.462	3	2.154	1.176	.319
	Within Groups	690.409	377	1.831		
	Total	696.871	380			
AI Production Speed	Between Groups	4.298	3	1.433	.816	.485
	Within Groups	661.487	377	1.755		
	Total	665.785	380			
LSS_Production_Quality	Between Groups	1.945	3	.648	.362	.780
	Within Groups	674.527	377	1.789		
	Total	676.472	380			
AI_Production_Quality	Between Groups	6.575	3	2.192	1.204	.308

	Within Groups	686.217	377	1.820		
	Total	692.793	380			

Table 4.25: Table X: ANOVA Results for LSS and AI Production Speed and Quality (3 Groups)

The ANOVA results for the factor Organisation Size demonstrate that no statistically significant differences were found across all four dependent variables: LSS Production Speed (p = .319), AI Production Speed (p = .485), LSS Production Quality (p = .780), and AI Production Quality (p = .308). In each case, the p-values exceeded the 0.05 threshold, leading to acceptance of the null hypotheses (H_0). This indicates that organisational size, whether small (<250 employees), medium (250–999 employees), large (1,000–4,999 employees), or very large (>5,000 employees), does not significantly influence perceptions of LSS or AI effectiveness on production speed or quality.

This finding is important because it challenges the common assumption that larger organisations, with greater financial and technological resources, should experience stronger benefits from LSS and AI adoption. Instead, the results suggest that improvements in production speed and quality are not inherently tied to the scale of the organisation, but rather to the way these methodologies are implemented and managed. Smaller firms might compensate for limited resources with faster and more agile decision-making, while larger organisations might take advantage of established systems and slower cultural change and face bureaucracy.

Lack of variation across organisation sizes represents that both AI and LSS are flexible frameworks that have the ability to be scaled significantly. Without major changes in perceived results, LSS gives structured, process-driven enhancements that have ability to be implemented in both large and small environments (Rathi, Vakharia and Shadab, 2021, p.8). Moreover, AI implementations like automation, quality tracking, and predictive maintenance, regardless of firm size, provide universal advantages. It represents training in place and adequate infrastructure.

Outcomes indicate that organisation size is not considered a decisive variable in success of AI or LSS. It improves the idea that workforce training, cultural readiness, integration strategies, and leadership commitment are key. These tools matter significantly on a company scale in exploring effectiveness of these methodologies in pharmaceutical industry of Ireland.

4.5 Summary

This Section explore AI and LSS operate in tandem as strategic enablers' bulk drug manufacturing landscape in Ireland. LSS influenced scrap rates and tolerance ceilings downward. While AI included predictive animus with self-tuning process variables and trend visualization. Speed of velocity stays contended with regulatory scaffolding that is risky and substantial. Gradual emollience of inertia includes three interlocked courses like enterprise-grade data infrastructure, a stepwise scaling cloak that orients on verifiable and governing board are resolute champions that support gains. Comparative appraisal explores that LSS cinches rigorous process scaffolds. While AI explores malleability and cadence that strengthens template for perpetual industry ascendancy.

Chapter 5: Conclusion and Recommendations

5.1 Conclusion

This research analyses how AI and LSS influence the manufacturing speed and quality of the pharmaceutical industry in Ireland. Research strategies give a noticeable advantage and are influenced by textual variables like site employee part, application methods, and production type. The research spotlights a clear shift toward digital transformation, where AI is acquired by 38% of companies and integrated with AI and LSS acquired by 34.1% companies. By contrast, only 16.0% companies depend on LSS, displaying the increasing reliance on modern mechanisation and analytics. In spite of this, assuming levels, perceptions of benefits remain divided. 36.7% of witnesses rated it unproductive, whereas 28.9% it effective, and 10.5% it very effective. Similarly, AI integration was seen as ineffective by 32.3% and very ineffective by 24.9%, yet nearly 36% acknowledged strong effectiveness. These analyses specify that both strategies carry potential but suffer from administrative problems like cost, ability gaps, and cultural battles.

The ANOVA hypothesis tests revealed that perceptions of AI's impact on production speed significantly differ across roles ($p = .025$), showing that employees' responsibilities shape their experiences with digital tools. Site manufacturing type influenced LSS's perceived impact on quality ($p = .007$), with fill-finish and small-molecule API sites benefiting most due to their process stability. In contrast, organisation size had no significant effect on perceptions, suggesting that success is not resource-dependent but contingent on management, training, and readiness. Overall, the research concludes that LSS provides a consistent, structured improvement framework, while AI is viewed as a more dynamic but role-sensitive tool. Integration of both offers the greatest potential, combining LSS's systematic process control with AI's predictive capabilities to enhance compliance, efficiency, and competitiveness in a tightly regulated industry.

5.2 Recommendations

Based on the findings, several recommendations are proposed to pharmaceutical organisations:

Strengthen Leadership and Alignment

Leadership commitment was consistently ranked as the most critical success factor (34.6% for LSS; 19.9% for AI, p.8). Senior executives should establish clear strategies for adopting LSS and AI, ensuring that both approaches are aligned with broader organisational goals and compliance requirements (Krishnamurthy et al., 2022).

Role-Specific AI Training

Since perceptions of AI's impact vary by role, training must be tailored. Engineers and operations managers should be trained in technical deployment, while quality specialists should focus on compliance-related AI tools, bridging the trust gap identified in the ANOVA results (Dhurandhar, 2025, p.4).

Contextual LSS Deployment

LSS quality benefits varied significantly by site type. Firms should deepen LSS deployment in stable, standardised environments (e.g., fill-finish, API), while integrating AI alongside LSS in biologics and combination product sites where variability is higher.

Address Implementation Barriers

High implementation costs, lack of skilled staff, and resistance to change (Tables 4.21 & 4.22) emerged as major barriers. Organisations should pursue phased adoption strategies, pilot projects, and blended training initiatives to reduce risks and increase buy-in (Ominyi et al., 2025, p.5).

Invest in Infrastructure and Data Governance

For AI, infrastructure and secure data systems are critical (24.1% identified this as key). Strong digital foundations and governance frameworks must be prioritised to ensure compliance and maximise AI effectiveness (Onoja et al., 2021, p.7).

Promote Integration of LSS and AI

Since 34.4% of respondents perceived combined benefits, firms should integrate the two approaches. Strategies include aligning leadership objectives (24.9%), investing in both infrastructures (26.5%), and combining training (15.0%) to create a workforce skilled in both methodologies.

Together, these recommendations emphasise leadership, contextual application, training, infrastructure, and integration as the central enablers of successful adoption.

5.3 Linking with Research Objectives

5.3.1 Objective 1: To examine the effectiveness of Lean Six Sigma in improving pharmaceutical production speed and quality.

The findings demonstrate that LSS continues to be valued as a structured approach to process improvement, particularly for quality outcomes. While 31.8% of respondents rated LSS as having a high impact on quality and 13.1% rated it as very high on speed, many also expressed dissatisfaction, with 36.7% describing LSS as ineffective (Byrne, McDermott and Noonan, 2021, p.6). This divergence suggests that while the methodology is robust, its effectiveness is contingent on skilled execution, leadership support, and cultural readiness. The ANOVA results further revealed that LSS's impact on quality varies significantly by site type ($p = .007$), underscoring its dependence on process standardisation. Thus, the objective is met, but with the caveat that effectiveness is context-dependent.

5.3.2 Objective 2: To investigate the role of Artificial Intelligence in enhancing production performance.

AI emerged as the more widely implemented approach (38.8%) and was rated by 35.2% as having a high impact on speed and 32.8% as having a high impact on quality. The ANOVA results showed significant differences in perceptions of AI's speed impact across roles ($p = .025$), indicating that frontline staff and specialists experience AI differentlyc (Belhadi et al., 2021, p.9). Nonetheless, AI was consistently identified as transformative for efficiency, defect detection, and predictive insights. However, its effectiveness is undermined by high costs. This objective is fully achieved, with evidence supporting AI as a catalyst for digital transformation but requiring strong support systems to succeed.

5.3.3 Objective 3: To compare the impact of LSS and AI on production outcomes.

The data indicate that AI is perceived as slightly more effective for speed (37.5%) and quality (33.1%), but many respondents (34.4%) recognised that combining LSS and AI produces the greatest benefits for quality. Furthermore, 31% of participants viewed both methods as equally effective overall (Vashishth et al., 2023, p.3). This suggests that neither approach should be viewed as mutually exclusive; instead, their integration provides the strongest foundation for sustainable improvement. Thus, the objective is achieved with evidence favouring complementary application.

5.3.4 Objective 4: To identify barriers and strategies for successful adoption of LSS and AI.

The findings revealed significant barriers for both methods. For LSS, high implementation costs (22.0%) and lack of skilled personnel (22.0%) were primary concerns, while AI was hindered by high costs (25.2%) and data security (20.2%). At the same time, strong leadership commitment, continuous monitoring, and investment in infrastructure were identified as key strategies for

overcoming these barriers (Kumar et al., 2022, p.8). This confirms the objective, showing that successful adoption depends on leadership, resources, and change management.

5.3.4 Objective 5: To provide practical recommendations for integrating LSS and AI.

The study found strong support for integration, with 26.5% emphasising investment in both infrastructures and 24.9% highlighting leadership alignment. Although some respondents were sceptical, nearly 38% recognised clear synergies (Attia, 2025, p.6). Recommendations have been proposed to address training, contextual deployment, and data governance. Thus, the final objective is fully met.

5.4 Research Limitations

This study has several limitations. First, it relied on self-reported perceptions, which may be subject to bias, as respondents' views do not always align with objective performance outcomes. Second, while the survey captured a diverse sample of 381 respondents, the representation was uneven, with quality control specialists (33.9%) forming the largest group, which may skew findings toward quality-focused perspectives. Third, the study was conducted exclusively within the Irish pharmaceutical sector, which may limit generalisability to other geographies with different regulatory, cultural, or technological contexts (Griffin, 2024, p,5). Fourth, the research used cross-sectional data, meaning that changes over time in the adoption and effectiveness of LSS and AI were not captured. Finally, the analysis was limited to ANOVA and descriptive statistics; more advanced modelling (e.g., regression or structural equation modelling) could have provided deeper insights into causal relationships.

5.5 Future Research Scope

Firstly, longitudinal research could track the adoption of LSS and AI over time in future research by this study, and with greater experience, effectiveness, and perception evolve. Expanding the research to include the other countries for cross-national comparison helps regulatory frameworks and organisational cultures shape adoption. Thirdly, into the practical challenges and success stories of LSS and AI offers qualitative case studies. Fourthly, statistical techniques like multivariate regression or SEM could test common relationships between factors, leadership, training, and implementation (Naeem, Marko and Parida, 2024, p.1). Ethical and regulatory aspects of AI adoption, especially around data security, automated decision-making, and transparency, could be explored by the final research. These future pathways will strengthen both practical guidance and academic understanding, confirming that LSS and AI can be effectively used to meet the growing needs of the medical industry.

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