ARTIFICIAL INTELLIGENCE IN PHARMACEUTICAL MANUFACTURING: APPLICATIONS AND IMPLEMENTATION CHALLENGES

by

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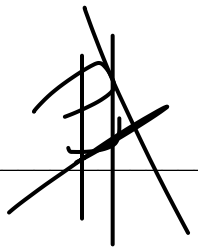

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Dedication

This dissertation is dedicated to my family members, whose boundless love, guidance, and sacrifices have been the cornerstone of my success. Their unwavering belief in my potential has inspired me to push beyond my limits and strive for excellence in all my endeavors. They have been my constant source of strength, patience, and encouragement throughout this journey, and I owe this achievement to their relentless support.

To my wife and family, thank you for your understanding and encouragement during the times when my commitments to this research took precedence over family functions and gatherings. Your constant support has meant the world to me.

I also dedicate this work to my professors and mentor who have understood my intrinsic curiosity and helped me grow both personally and professionally. Their guidance has shaped my carrier pursuits and provided me with the tools and knowledge to undertake this challenging yet fulfilling journey.

Lastly, to my friends and colleagues, for their valuable Support for making this journey meaningful.

May this study serve as a small contribution to the collective knowledge that advances our understanding of these disciplines and inspires innovation, collaboration, and excellence in professional practice.

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Lastly, I dedicate my gratitude to all my colleagues who inspired me with their dedication to learning and excellence.

ABSTRACT

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This study explored the application of "artificial intelligence" (AI) in pharmaceutical manufacturing, focusing on the challenges that may be encountered during its implementation and the potential impact on key manufacturing outcomes. Several factors, including regulatory issues, data management and integration, costs, and technological constraints, are likely to pose a challenge to the use of AI technologies in the future growth of the pharma industry as the industry relies more on AI for quality enhancement of drugs, efficiency, cost reduction, and compliance with regulatory requirements. To find out these challenges, the current research has used a survey research design and structured questionnaire survey with replies from 300 industry specialists and practitioners drawn from pharmaceutical manufacturing industries that incorporate the use of AI techniques. The data which was collected was analysed with the help of SPSS software and descriptive statistics, correlation, and regression analysis were applied to approach the expected state of AI application and its impact on the manufacturing process. The study identified both the transformative benefits and critical challenges associated with AI implementation. Key findings suggest that AI is positively impacting the sector by streamlining operations,

improving accuracy in drug production, and enabling real-time data analysis. However, challenges such as data quality and integration issues, regulatory restrictions, cybersecurity risks, and the need for specialized skills were noted as significant barriers to successful AI adoption. The study, therefore, finds that it will take AI to the next level of improving pharmaceutical manufacturing; AI challenges can only be overcome with multi-stakeholder cooperation, adoption of common data management practices, advanced cybersecurity measures and ongoing training of human capital. It also covers the need to continually adjust the regulations that govern development and use of AI technologies to the dynamic nature of the technologies to safeguard patient interest and product quality. The implications of these findings are critical for industry leaders, policymakers, and researchers. By addressing identified obstacles, pharmaceutical manufacturers can leverage AI more effectively, leading to cost savings, reduced time-to-market for new drugs, and improved drug quality.

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Abbreviations	Full Form
AI	Artificial Intelligence
PAT	Process Analytical Technology
SVM	Support Vectors Machine
ANN	Artificial Neural Network
IOT	Internet of Things
CDSS	Clinical Decision Support Systems
POS	Probability of Success
MOO	Multi-Objective Optimization
CDM	Clinical Data Management
DL	Deep Learning
EHR	Electronic Health Records
SCC	Spearman Rank-Order Correlation Coefficient
DDSs	Drug Delivery Systems
CSFs	Critical Success Factors
PSC	Pharmaceutical Supply Chain
BWM	Bayesian Best-Worst Method

CHAPTER I:
INTRODUCTION

1.1 Introduction to Artificial Intelligence (AI) in Pharmaceutical Manufacturing

Today's manufacturing industries have come under lots of transformations within the twenty-first century, especially with the effects of digitalization, automation, and data collected over the course of production. It is also known as on the same parity as Industry 4.0 or the Fourth Industrial Revolution (Citybabu and Yamini, 2024),or Pharma 4.0 in the chain of the development of the pharmaceutical industry Arden et al. (2021), The digital technologies are developing fast. Some examples include data driven manufacturing known as fourth industrial revolution, or a car manufacturing factory where devices are connected and can communicate with one another and in some cases make decisions on their own, known as the smart factory (Tiwari, Bahuguna and Srivastava, 2023). The enhancement of effective technology in the pharmaceutical industry is achieved via the use of Quality by Design (QbD) and Process Analytical Technology (PAT). QbD approach is centered on knowledge about product, and its production, specifying critical process parameters and key material characteristics that affect critical quality characteristics of the product and technological process. As a result, there is a design space when the quality level is considered acceptable.

AI and ML have become useful tools to drive industry and pharma objectives: 4.0 (Xames, Torsha and Sarwar, 2023), for a number of new challenges: developing digital twins—the virtual replica of a real system—or handling big data (Chen et al., 2020). AI can be defined in the main way as the use of computer science methods for completing tasks such as pattern analysis and program decision making that are usually associated with human intelligence. These tasks are solved by ML techniques in AI where from a given dataset a program is designed to automatically produce the required response. Using ML

in a training dataset may also modify the model behaviour to improve performance depending on the size of the increasing data, which always fit well in data-oriented manufacturing. Moreover, medical regulatory bodies are gradually opening up their outlook to AI /ML techniques. For instance, the latest recommendation list for the proper ML based models development and usage in GxP regulated environment published by the Danish Medicines Agency. Further, the United States Food and Drug Administration has introduced the action plan for establishing what they called as the 'Good ML Practice', concerning which document has also been released. However the approach (How to explain the concept and plan, How to identify & quantify robustness, bias and real world performance) can in turn be further extended to other branch of ML (Mukhamediev *et al.*, 2022).

AI recognises the issue, analyses the functional data, and offers a number of solutions. It does the analysis by using and creating new algorithms for data interpretation, learning, and analysis. It encompasses areas such as clustering, ML, pattern recognition, similarity-based techniques, and statistics, all of which indicate a bright future for the pharmaceutical sector (Singh et al., 2024). Pharmaceutical companies are coming up with fresh and creative ways to leverage potent AI technologies to address some of the main issues they confront. Algorithms that automate tasks that often need human intelligence are referred to as AI in the pharmaceutical sector (Singh et al., 2024). By more clearly defining the connections between process parameters and various formulations, AI can save a substantial amount of time and money. Two new areas of AI are contributing to further developments:

- Methods and techniques that imitate human experiences and derive judgements based on a given set of criteria, such as expert systems.

- A system that simulates how the human brain works, such as an artificial neural network (ANN).

Expert systems, which are an extension of traditional computing, are also referred to as knowledge-based systems or the fifth generation of computers. The idea of a knowledge-based system is rational thought that serves as a roadmap for making decisions and forecasting in ambiguous and unpredictable situations. It is mostly useful for diagnosing problems.

Many difficult manual chores have been mostly replaced by technology, which is highly good for humanity. In a variety of industries, human labor-intensive physical professions have been replaced by technological advancements such as AI. Building intelligent machines and computer programs to carry out a variety of tasks requiring human intelligence is known as AI. A range of human abilities can be reflected in this system. This covers everything from language processing and reasoning to learning-based applications. ML is considered one of the most popular forms of AI operations in the healthcare sector. ML is a subfield of AI that mainly relies on statistics and replaces human beings with computers to develop hypotheses or predict results (van der Lee and Swen, 2023). These days, AL is widely used in our daily lives, especially in email filters, social media, search engines, and product recommendations. AL can judge items, attributes, categories, and connections among all of them with the help of the data embedded in it (Nagendraswamy and Amogh, 2021). Decision making, diagnosing diseases, robots, and other processes have become strikingly more effective when influenced by AI within the period of healthcare's boom. Since AI can work with huge amount of data from multiple modalities, it can be still more investigated in the pharmaceutical and healthcare fields (Bhatta Misra et al., 2023).

AI, which can learn, comprehend, and predict large amounts of data, has been used in many real-world applications, such as picture categorization and speech recognition. Currently, enormous volumes of biomedical data have been gathered following a protracted period of data collection and the advancement of high-throughput RNA-seq technologies (Trapnell and Liu, 2016; Kim *et al.*, 2021; Ding, Sharon and Bar-Joseph, 2022). A wide range of sources provide biomedical data, which is highly complex and heterogeneous. These include omics data from various platforms, experimental data from chemical or biological laboratories, data produced by pharmaceutical companies, publicly available textual information, and manually compiled data from publicly accessible databases (Waring *et al.*, 2015; Manzoni *et al.*, 2018; Nam, Chaligne and Landau, 2021; Shi *et al.*, 2021). AI has the ability to uncover patterns in these enormous volumes of biomedical data, which will present both new opportunities and difficulties for the pharmaceutical businesses and sciences.

Every step of biotech production, including supply chain management, process optimization, quality assurance, and raw material procurement, can be accelerated and enhanced by AI. AI in biotechnology has improved manufacturing's precision, creativity, and productivity. Many biotech enterprises have enhanced each of the phases in the life cycle due to the automation of the predictive modelling and data analysis (Saddique et al., 2024). Predictive maintenance and linking of AI and production is one application in the biotechnology industry. For instance, machines employ actual time sensor information in identifying difficulties and cause repair before they cause a loss of time. Biotechnology manufacturing could enhance invention, ecology, and efficiency through data science and AI, as well as the Internet of Things (IoT) (Nwagwu et al., 2023). They accelerate work on innovations, which in turn changes manufacturing. Through using algorithms that dissect

complex biological data, researchers improve trial designs and evaluate drug concepts faster from the drug discovery process, hence reducing costs.

In the context of health, AI is therefore described as software and algorithms designed to improve human alertness or focus on the handling of complex medical information. AI commonly referred to as machine intelligence, is a tool that can analyze large volumes of both ordered and complex data to arrive at sound and logical decisions. That can be defined more precisely as the capability of machines to make decisions on their own without the interference of humans. All the three forms of AI are in use. They're

a) Human created algorithms
b) ML
c) Deep learning

Data is sometimes gathered, more efficient application techniques are pursued, precise or approximate conclusions are sometimes derived, and self-corrections and alterations are often included into this process (Das, Dey and Nayak, 2021). AI is typically applied to mimic human intelligently and evaluate the suitable ML (Das, Dey and Nayak, 2021). AI technology is used to analyze more accurately and then get the wise interpretation of it. According to this point of view, FFAI technology combines useful statistical models and computational intelligence. As an emerging technological solution that can be used in every scientific and technical discipline, the AI technology has recently become indispensable to the field. Pharmacies in the last quarter century have been responsive to this increasing demand for prescription pharmaceuticals, all the while facing shortages of pharmacists, system upgrading costs, and decreasing reimbursement rates. Moreover, adequate use of enabling technology automation has been evidenced in enabling all pharmacies settings to establish and maintain efficiency, accuracy and safety, reduced cost and effective workflow.

Manufacturing is on the cusp of significant disruption from robotics and automation, increasing use of sensors and the IoT, and a plethora of new data. This results in the factory to become smarter in the new age referred to as Smart Manufacturing and Industry 4.0, which force manufacturing organizations to review, re-visit and re-consider their current activities and future plans (Napoleone, Macchi and Pozzetti, 2020). AI integration in the modern production processes has largely been based on other general practices which have been consistently advanced over several years such as ML (Wang *et al.*, 2021). There is a lot of interest in the potential and benefits of these AI techniques, and their practical use has been made possible by recent advancements in sensor technologies and processing hardware for collecting crucial process/machine data. In addition, investigating the current AI tools and technologies allows us to understand particular industrial issues that AI approaches can address and thereby enhance cost-efficiency, efficiency, quality, adaptability, and work safety. This understanding and expertise are necessary for the actual application of AI in modern highly) complex industrial contexts which may be different for each company and situation.

1.2 Artificial Intelligence in Drug Discovery & Development

The estimated expense of discovering and developing a new drug is $3 billion USD (Wouters, McKee and Luyten, 2020), with an approval rate of around 13% when considering all compounds that enter clinical trials (Wong, Siah and Lo, 2019). In particular, the success rate of new medications is low when it comes to Phase I tolerance and side effects (about 66%), Phase II dosage and effectiveness (48%), and Phase III efficacy and toxicity (59%) (Wong, Siah and Lo, 2019).

They expected that the use of PM would increase the effectiveness and success of such Phase II, III clinical trials through defining treatment strategies depending on patient's genetic predisposition, lifestyle, and other factors. Ever since beginning of this paradigm,

the number of medical and healthcare application fields has increased dramatically and cancer being topmost on the list (Superchi *et al.*, 2022). Moreover, contemporary studies on cardiovascular diseases (Strianese *et al.*, 2020; Tang *et al.*, 2020) and type 2 diabetes (Angwin *et al.*, 2020) particularly pertain to neurodegenerative disorders, including Alzheimer's disease and Amyotrophic Lateral Sclerosis. Morello et al. (2019, 2020) have highlighted the increasing significance of precision medicine within the healthcare sector.

Many different types of chemical representations that are machine-readable have been developed since the invention of computers. Computers made it possible to quickly alter digital data, store and query molecules and their structures digitally, and increase the efficiency of physical storage. Compounds were visualized as 2D representations using algorithms and the creation of specialized tools popularized the computational visualization of compounds in three dimensions (David *et al.*, 2020). Between 1947 and 1964, many of the earliest examples of computer-readable notations focused on small chemical compounds (Borko, 1972). Memory efficiency had a significant influence on the evolution of chemical notations at the time. However, the majority of the popular representations used today to depict tiny molecules were created in and since the 1970s Weininger (1988), macromolecules (Siani, Weininger and Blaney, (1994); Siani et al. (1995); Zhang et al. (2012); Tanaka et al. (2014)) and chemical reactions (Varnek et al., 2005; Dugundji and Ugi, 2006).

The possible impact of AI on supply chain interactions within the pharmaceutical sector may be shown as follows (refer to figure 1.1): The work synthesises several AI research endeavours from recent decades to provide effective solutions for diverse supply chain challenges. It also delineates potential research avenues that might enhance decision-making tools in supply chain management moving forward (R. Sharma et al., 2022).

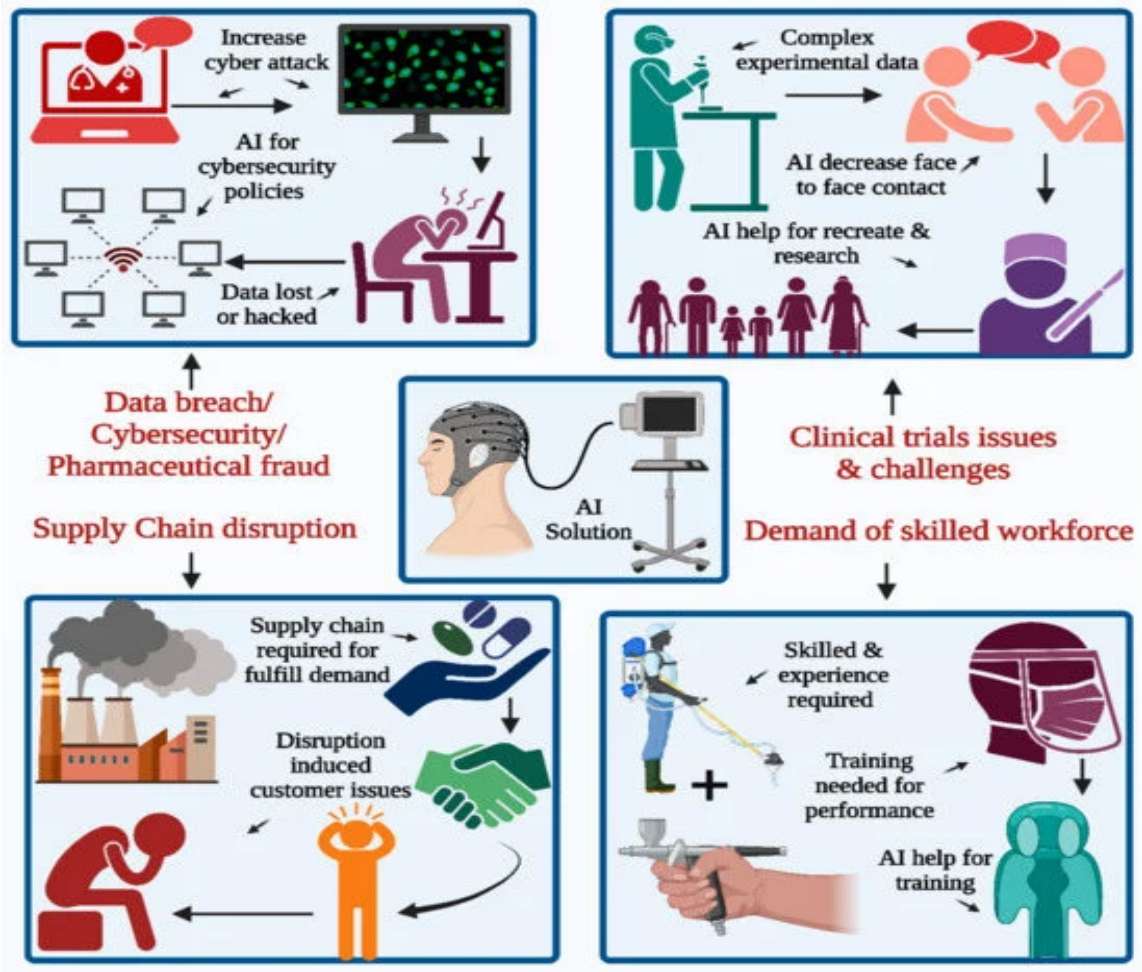

Figure 1.1: Artificial Intelligence in Drug Discovery & Development

Source: - (Vora *et al.*, 2023)

Figure 1.1 demonstrates one possible AI solution to the issues plaguing the pharmaceutical sector: many industries need to hire qualified personnel in order to benefit from their expertise, abilities, and experience in product creation. The second concerns difficulties with clinical trial testing and supply chain disruption. Cyberattacks are becoming more frequent, and the sector is becoming increasingly concerned about security and data breaches.

With less engagement than face-to-face types, these new technologies could be useful in resuming or recreating these clinical trials (Daka and Peer, (2012); Colombo et

al. (2014); Kalepu and Nekkanti, (2015); Grilo and Mantalaris, (2019); Sarpatwari et al. (2019)), like that shown in Figure 1.1. High maintenance expenses and highly skilled labor are now the biggest obstacles. Data breaches and cybersecurity concerns represent the fourth major obstacle in the search for a technology-based solution. Disjointed system engagement and data fragmentation are two major issues with traditional clinical studies. These problems occur due to dispersed data that is produced during the trial, which requires a considerable amount of manual transcription of data for both study and displays of the systems. AI uses techniques to acquire those huge volumes of data generated by such clinical trials, which reduces the required data personnel. In order to comply with the patient's, need for regular in-person connection, these technologies remotely record the patient's vital signs and other pertinent data using wearable electronics and body sensors. While the study is being conducted, wearable AI algorithms provide real-time insights.

1.3 Present Pharmaceutical Issues and AI's Contribution

Because of their many benefits, small molecules are being researched in the pharmaceutical sector to provide better goods and increase patient satisfaction. The chemical synthesis is not difficult, and the synthesis of other derivatives is cost effective. As a result, the pharmaceutical sector offers a vast array of stable and potent formulations that are packed with small molecules. With the exception of uncommon disease treatment, many novel small molecules are in competition with generic ones, and their introduction necessitates complicated data and clinical trials. Due to these processes, companies are under more financial pressure to innovate. The biomolecular drug sector is still expanding quickly, nonetheless, in order to make up for the problem brought on by tiny molecules and inadequate research and innovation dissemination. The behaviour of small molecules depends on their reactivity and conformation (Troiano *et al.*, 2016; Colombo *et al.*, 2018; Hassanzadeh, Atyabi and Dinarvand, 2019). These include biomolecules for instance large

units and nucleotides/ribonucleotides from the nucleic acid of the food and other amino acids which are derived from the protein part of the food product. Furthermore, the sequence organization of supramolecular and the spatial arrangement of functional units influence their steadiness and activity (Chavda *et al.*, 2023). Some biomolecules, like insulin and adalimumab, are tremendously successful products. The preferred and most practical method of administering these biomolecules is infusion, which makes their pharmacokinetic characteristics complicated. Nucleic acid-based research relies heavily on molecular stabilization and pharmacokinetic regulation. These molecular forms' pharmacokinetic exposure and improvement are important objectives. Modern technology could be useful in addressing these problems and resolving associated ones (Sacha and Varona, 2013; Taylor *et al.*, 2015; Wise *et al.*, 2018; Wong *et al.*, 2018). Despite the enormous potential of AI in medicine delivery and research, it still has several significant drawbacks that eventually necessitate human intervention or experts to decipher the intricate outcomes. The datasets serve as the foundation for the majority of AI predictions; nevertheless, because of the grey area, human intervention is necessary to interpret the results and arrive at the right conclusion. If the data to be analyzed has to be processed for predictions and for evaluating hypothesis AI systems may face issues related to algorithmic bias. Additionally, the fact is that relatively more often inactive compounds are detected with the use of docking simulations (Cerón-Carrasco, 2022). The critical assessment of these features is cases involved the use of human decision and cross-verification to ensure the system does not have a bias of certain features and characters. At the same time, AI is very valuable to use and with additional work it can be potentially possible to decrease the negative effects it has and make AI more reliable and effective.

In the context of AI, the method used is ML or one of its subfields which include deep learning and natural language processing. In the facet of learning processes, there are

two main categories for discussion these are the supervised learning and the unsupervised learning. Another factor that matters is the use of what kind of algorithm. While unsupervised learning can only come with an uncertain result of learning, in supervised learning the inputs or features and outputs or labels/targets are known and is part of the ML technique. The supervised approach comes with several input or features to predict the output like labels or objectives. On the other hand, the unsupervised categorization tries to form the groups with the feature similarity (Sarker, 2021).

1.4 Unsupervised AI Learning

When the algorithm does not get hand labelled data, then the ML occurs in the category known as unsupervised learning. Actually, it is responsible for seeking associations and trends of data on its own instead of making its own predictions. This type of technique is very common in EDA in that one can easily search for populations or features inside a population. This is in fact what is described in common literature as data-driven methodology – an attempt to find some pattern structure or insight in raw material. Some of the typical unsupervised learning tasks are called anomaly detection, visualization, dimensionality reduction, grouping and association rule discovery. Different types of unsupervised learning problems can generally be addressed utilizing standard methodologies like clustering methodologies like hierarchical clustering, K-means clustering, K-medoid methods, single hyperlink linking, complete hyperlink linking, BOTS; association rule learning; and feature selection and feature extraction methods such as the Pearsons correlation analysis, and the principal component analysis due to the type of data involved (Parikh et al., 2023). It shows that AI's unsupervised learning methods can be of great benefit for pattern recognition and for exploratory purposes in pharmaceuticals. In pharmaceutical applications, the use of unsupervised learning proves useful for getting the first look of the data provided and for exploratory analysis. One has

to recall that, due to the exploitative character of many unsupervised learning techniques, the process of outcome interpretation often requires specific expertise and validation.

Several AI models and methodologies have been put into practice to improve drug development. Some of the most used AI model tools in drug discovery are highlighted in the Table 1.1 below. These and more are the AI model techniques that are available for drug discovery. The industry is changing quickly, and new models and techniques are always being created to speed up the process of finding new medications.

Table 1.1: Popular AI model tools used for drug discovery

Tool/Model	**Description**
DeepChem	This library consists of many drug discoveries tools and models such as generative chemistry by deep learning, virtual screening, and molecular property prediction.
RDKit	A well-known open-source cheminformatics toolkit with capabilities for handling molecules, looking up substructures, and computing descriptors that interfaces with ML frameworks.
ChemBERTa	a Transformer architecture-based language model created especially for drug discovery tasks. Moreover, it also helps in context-aware bespoke molecular architecture and the capacity to forecast the characteristics of this couture molecular structure with conditional pretraining provided in chemical and medicinal domains.
GraphConv	a deep learning model design that can forecast the chemical properties of toxins and bioactivity based on the structure of the embedded molecules in the graph representation.

Auto Dock Vina	Virtual screening and lead optimization benefit from a well-known docking program that uses ML techniques to predict the binding affinity between tiny molecules and protein targets.
SMILES Transformer	A deep learning model applied in lead optimization and de novo drug discovery wherein the input is contained in the form of Simplified Molecular Input Line Entry Specification (SMILES) that generates chemical structures.
Schrödinger Suite	a broad range of technologies for drug discovery software using AI that includes molecular modeling, predictive modelling, ligand- and structure-based drug design and virtual screening.
IBM RXN for Chemistry	A computational tool to predict a chemical reaction using deep learning techniques and extensive libraries of reactions, with an application for innovative drugs' production and the identification of new reaction routes.
scape-DB	a knowledge base which employs NLP and ML for the purposes of extracting biological and chemical data from published articles helpful for drug discovery.
GENTRL (Generative Tensorial Reinforcement Learning)	A deep learning approach used in de novo drug design and optimization that creates new compounds with desired attributes by fusing generative chemistry and reinforcement learning.

1.5 AI in Quality Assurance and Control

New developments in AI specifically in ML and DL and the seamless inclusion of these in software-based systems across all domains make engineering modern AI systems

more complex (Chakraborty et al., 2024). These systems consume plenty of data, are self-learning, and are always improving. The non-deterministic character of their behavior has established its useful ambiguity. Given these difficulties and future evolution, SE requires new and updated constructive and analytical assurance methods throughout development and deployment. But as noted Borg (2021), In AI-based systems, the term "quality" is already ill-defined. Additionally, as previously said, software engineering and AI use different terminologies. AI-based systems are developed by combining the expertise and experience of several communities. Which of course results in new and innovative approaches, fascinating discoveries and a major leap forward in the capability of state-of-the-art AI-based systems; it also contributes to the confusion of the very concepts, terms, perspectives and underpinning assumptions and principles (Kamalov, Santandreu Calonge and Gurrib, 2023). That led to the fact that there is increasing misperception, or even entirely different approaches towards quality assurance of AI-based systems, and how those issues are to be solved (Felderer and Ramler, 2021).

Interest in applications of AI in general has grown as a result of the recent prominence of AI and ML as well as the expanding amount of clinical data that is currently available (Topol, 2019) and specifically of clinical decision support systems that are computerized (CDSS). A computerized CDSS is any program that helps patients and clinicians make clinical decisions. Wyatt and Spiegel halter consider computerized CDSSs as “active knowledge systems which use two or more items of patient data to generate case-specific advice." (Matui et al., 2014). CDSSs can make use of expert knowledge and/or models that are learnt from data through statistics and ML. Early on, CDSSs were thought to have the potential to someday take the position of clinicians in making decisions. By analysing the large quantity of available data, a more sophisticated, contemporary understanding of CDSSs' function is to help clinicians make better decisions than they or

the CDSS could independently (Mahadevaiah et al., 2020). Modern CDSSs usually provide suggestions to physicians, who are then expected to make their own choices and disregard CDSS recommendations that they feel are unsuitable.

Recent advances in big data produced new opportunities for statistical learning underpinned by AI in areas other than those previously mentioned; unlike prior AI winters, it does not appear that statistical learning-based AI has succumbed to the hype by out-performing human experts in certain domains (Schuchmann, 2019). Building AI systems necessitates evaluation, which is also known as assurance, validation, or verification, much like any other technical deployment. In the next part, we discuss this terminology controversy (Díaz-Rodríguez et al., 2023). It is worthwhile to research how to define the scope of AI assurance. AI is currently being used in many different fields, including revenue forecasting, driving automobiles, directing robots in combat, advising government leaders on policy, predicting pregnancies, and consumer classification (Batarseh, Freeman and Huang, 2021).

The Indian pharmaceutical business is gradually embracing automated technologies, even though the sector has historically relied heavily on human procedures. Success and competitiveness in a linked world depend on the use of new automated information technology (IT) and operational technology (OT) (Kimta and Dogra, 2024). The quality systems of pharmaceutical manufacturing can be improved by continuously innovating and implementing automation techniques to overcome challenges such as human error, cost considerations, quality issues, inconsistency resulting from manual manufacturing processes, and regulatory compliances. Global competition is also continuously increasing (Rodríguez-Espíndola et al., 2022). Furthermore, like any information technology (IT) project that may affect data integrity, patient safety, or product quality, the principles of the robotics and cognitive automation (R&CA) need to be rolled

out and, thereby, need to be validated for readiness for the use intended. However, R&CA validation can be a challenging undertaking (Ranebennur1, Thirumaleshwar1 and Somareddy1, 2023).

Figure 1.2: QbD Design Documents

Source: - (Ranebennur1, Thirumaleshwar1 and Somareddy1, 2023)

Because of revolutionary advancements in computational technology, AI and ML have expanded dramatically during the last ten years. This has caused a significant increase in the capability in the collection and analysis of big data. While getting new drugs to the market and to patients is still an almost impossible task today. Creating a novel drug is time-consuming, expensive, and unsuccessful, according to these estimates: Average R&D spend per drug is $1.3 billion (DiMasi, Grabowski and Hansen, 2016). In non-oncology, it usually takes 5.9 to 7.2 years to manufacture a pharmaceutical, and in oncology, it takes 13.1 years; ultimately, 13.8% of drug research projects are authorized (Wong, Siah and Lo, 2019). The predictive capabilities, automated nature, and expected efficiency improvement of AI/ML systems make them appealing to the drug development industry in light of these difficulties. It goes without saying that improving the efficiency of drug development is important for both patients and businesses. This will reduce expenses, shorten development

periods, and increase the probability of success (POS). ML techniques have been used more and more in drug research during the last 15 to 20 years. Clinical trial planning, execution, and analysis is the most recent field of drug research where AI/ML is starting to show promise.

Pharmaceutical firms have faced operational and staff recruitment obstacles, as well as external issues including inflation and supply chain instability (Brodeur *et al.*, 2021). Because of social distancing measures and lockdowns, the pandemic also prompted a shift to remote working, underscoring the necessity of digital platforms to enable teams to work together smoothly on initiatives that are vital to the organization's success. Lockdowns have decreased, but a hybrid working model and the use of digital technologies to facilitate communication and project management have remained. Ongoing digital innovation, fortunately, gives companies the chance to prepare for changing difficulties and future-proof their operations.

Stiff regulatory requirements, constantly emerging priorities for talent development, quick advances in key technologies and an unceasing demand for growth make the global pharmaceutical industry highly challenging (Miozza, Brunetta and Appio, 2024). The necessity of QRM in this context can nevertheless be understood since it is used as an anticipatory approach to risk assessment. It encompasses wide spectrum of issues including manufacturing processes, supply chain concerns and shifts in legal scenarios.

Indeed, the goal of any pharmaceutical firm is to give patient suitable treatment that is both safe and effective (Ryan et al., 2014). Effective means for reaching this goal are presented by quality risk management, which systematically considers potential risks to product quality (Vijayakumar Reddy et al., 2014). Potential problems that can arise from the manufacturing, testing, and distribution of pharmaceuticals may be minimized by

pharmaceutical companies acting in advance to assess and control different risks at the onset of the development process.

The US FDA and EMA have recognized the centrality of QRM in enhancement of product quality and safety of the patients (Lis et al., 2012). highlighting the necessity of implementing a risk assessment technique at every phase of the product development process (Cervantes-Cabrera and Briano-Turrent, 2018). In addition to securing market approval for pharmaceutical items, regulatory compliance gives patients and healthcare professionals trust.

One of the key characteristics of QRM is its dynamic nature. Not only during the pre-market phase, but throughout the entire product lifecycle, risks are identified. This flexibility guarantees that pharmaceutical firms continue to be sensitive to new issues, such as modifications in production technology, interruptions in the supply chain, or fresh safety issues (Bais and Rathod, 2024).

1.6 Challenges and Limitations of AI in Pharmaceutical Manufacturing

Pharmaceutical research has steadily progressed in an effort to improve organ targeting, stability, and drug absorption. Pharmaceutical nanocarriers are extremely versatile, submicron-sized drug delivery systems. Among them are liposomes, nanotubes, nanocomplexes, polymeric, lipidic, and inorganic nanoparticles, as well as numerous more. In theory, ligands can be affixed to nanocarrier surfaces to improve targetability and uptake (Nawaz et al., 2019; Pontes and Grenha, 2020; Zeb et al., 2020). Within the nanocarrier layers or scattered across the nanocarrier matrix are two possible drug locations. Because it is simpler to modify the size, charge, surface characteristics, and targeting moieties of nanocarriers than standard medication therapies, it is possible to control their uptake, biodistribution, targeting, and elimination (Majumder, Taratula and Minko, 2019). Many can be given by any route for example parenteral Kolluru, Atre and Rizvi (2021), nasal

Vachhani and Kleinstreuer (2021), topical Paiva-Santos et al. (2021); Tolentino et al. (2021) or oral routes (Yao et al., 2021). As mentioned above, the growth of nanocarriers with various characteristics to treat multiple diseases is becoming increasingly essential. Hence, over the few last decades, several characterization strategies have been suggested and utilized to control and predict the behavior of nanocarriers both in vitro and in vivo. The aim of using these apparatuses is to determine pharmacokinetic parameters, physicochemical properties as well as the loading efficiency, release rate, mechanical properties, stability, tissue permeability, and cytotoxicity of the nanocarrier, and its fate in the body.

Pharmaceutical industry has therefore been transformed in the wake of advances such as the AI. In thus, there have been noted more efficient and less cost-effective mechanisms due to the participation of AI in drug development and discovery (Yadav et al., 2024). AI has brought a revolution as the demand for new drugs increases. AI, a subset of computer science, develops systems that accomplish tasks that require human-like skills. For the duties that are performed in the learning organization, the duties include learning, decision making and problem-solving chores. AI is used in the pharmaceutical industry as an instrument for analysing large databases, for the identification of dependencies of outcomes and optimization of the results. And for this reason, the resource is achieved with higher velocity and accuracy of the outcomes (DiMasi, Grabowski and Hansen, 2016).

It is now a pivotal element of pharmacy science particularly in search for new drugs. AI has replaced the conventional and long drug development approach by creating smart systems that perform activities that demands human intelligence (Blanco-González *et al.*, 2023). These duties include acquiring new knowledge, establishing decisions and settling problems. AI in the pharmaceutical sector searches for new potential drugs based on available data to identify patterns and test millions of particles which through the use of

data puts forward results faster with higher efficiency (Wong, Siah and Lo, 2019). However it is a process of time in many cases, but it can be accelerated several times when using AI for data analysis obtained from genetic websites, articles, and test trails for new drugs (DiMasi, Grabowski and Hansen, 2016).

1.7 Research Problem

Due to the current upsurge in the complexity or dynamism in the production of most pharmaceutical products the use of Artificial Intelligence in the manufacturing can improve productivity, quality of the drugs, costs and most importantly compliance to regulatory requirements. However, the implementation and deployment of AI in the manufacturing of pharmaceuticals has its fair share of issues for example regulatory, data acquiring and managing, integration, cost and technology among others. These transformations present challenges that threaten the future growth of the AI industry because they make it hard for organizations not only to adopt state-of-the-art technologies but also to use them to the optimum.

This research seeks to address this important knowledge gap by providing an analysis of the contemporary state of utilization of AI in the manufacturing of pharmaceuticals; the several barriers that affect the effective implementation of the technology; and the effects of the barriers on the performance of companies in the manufacturing of pharmaceutical products.

1.8 Purpose of Research

It is in light of this that the following research questions have been designed: The focus of this study is the use of Artificial Intelligence to advance the purpose of the pharmaceutical manufacturing processes that were previously mentioned. Particularly, the study has the following sub-objectives:

- To assess the current applications of AI in pharma manufacturing.

- To identify and analyse the key challenges associated with AI implementation in the manufacturing process of the pharma industry.
- To assess the impact of AI implementation on pharmaceutical manufacturing.
- To propose actionable recommendations to overcome the identified challenges, facilitating the successful integration and utilisation of AI technologies in pharmaceutical manufacturing.

1.9 Significance of the Study

This research's relevance becomes manifest in that it is one of the first to examine how AI may potentially transform the pharmaceutical manufacturing field with regard to productivity and quality, as well as in the specific problems of this sector. With the changing dynamics of the pharma and biotech industry and rising demand for density, speed, and compliance – AI provides an exciting avenue to rethink challenging activities like formulation, quality control, and supply chain. Altogether, based on the analysis of the current AI applications, this work aims at enlightening the best practices as well as potential advances in the creation of better medications, enhanced safety and equality in AI application, thus enabling the formation of pertinent recommendations as to contribute to ultimate objective of the industry.

Moreover, this study's emphasis on the consideration of the following critical questions of AI implementation remains valid since numerous fatal barriers exist in the pharmaceutical industry, including high-cost technology, integration of data, and workforce adaptability. In this regard, the research counters the challenges mentioned above by offering recommendations that may facilitate the integration of AI technologies by industry leaders. This, in turn, could result to cutting on the manufacturing costs, enhanced shorter time to market for new drugs and enhanced manufacturing scale solutions. Finally, the conclusions derived from this study may potentially influence not

only the pharmaceutical business but also the entire world's healthcare system by guaranteeing that the state-of-the-art AI integration in production developments in this sector contribute to increased access to inexpensive and effective medications.

1.10 Research Purpose and Questions

Research Purpose

This study seeks to identify the use of AI in the context of pharma manufacturing with the view of obtaining a broad perspective on its uses, issues, and ramifications. In this study, the following objectives are pursued in an effort to provide practical recommendations for implementing AI-enhanced manufacturing to strengthen the capacity of the pharmaceutical sector: The identification of the current applications of AI in manufacturing processes examines the challenges experienced during implementation and determines the impact of AI on efficiency and innovation.

Research Questions

This study will highlight and discuss these challenges so that adequate recommendations to solve them and make AI adoption easier in the manufacturing of drugs can be provided. More specifically, the following research questions need to be addressed:

- **RQ1:** What is the current situation of AI applications in Pharmaceutical Manufacturing?
- **RQ2:** What are the key challenges associated with AI implementation in the manufacturing process of pharmaceutical industry?
- **RQ3:** How do the AI implementation influence the Pharmaceutical Manufacturing?
- **RQ4:** What are the actionable recommendations to overcome the identified challenges, facilitating the successful integration and utilization of AI technologies in pharmaceutical manufacturing?

CHAPTER II:
REVIEW OF LITERATURE

2.1 Introduction to AI in Pharmaceutical Manufacturing

There have been significant advances each time that the industry has reached a crossroad involving AI and manufacturing and the opportunity for the decision making and control of quality has never been better. Integration of AI technologies in the drug sector triggers shift of culture that is characteristic of high requirements to quality and regulation in the industry. Stressing out the cases that characterize it as a major benefactor to the improvement of quality control techniques and enhancing data-driven decisions, Saha et al. (2023) illustrated the diverse roles of AI. Two ways that AI is transforming quality control can be seen today through image recognition and computer vision systems. Due to these development, the visual inspection methods have higher accuracy than the previous methods of identifying the defects and unevenness which are not visible to naked eyes. Application of artificial intelligence enhances real-time oversight by the IoT to ensure that the product remains uncompromised by continuous interference with strict quality standards. In another area, known as enhancing decision-making by expanding on data's ability to analyze is also an area where AI shows the capacity to transform. The nature of data AI process is more comprehensive and complex to offer specific, actionable insights to the key stakeholders that guide the strategic direction and resource allocation. Positives that can emerge include less likelihood of risks associated with changes in either the supply systems, new regulations or probably, likelihood of quality changes. AI increases the rate of decision making and circumvents around the issues that arise out of manual testing the conventional fashion; with the added factor of forecasting the probability of batch releases. However, there is still some problems to solve to achieve the large-scale application of AI in the pharmaceutical industry. For AI to thrive, it is, therefore, crucial to have a quality,

diverse dataset to feed into the models, accurately. The last absurdity is that sometimes regulation imposes validation, data integrity, and transparency obligations to AI systems. Furthermore, some pre-planning is necessary to exacerbate the combination of AI into current production frameworks without threatening to disrupt production. The role of AI in the pharmacological industry and its definitive advantages seen in the enhancement of decision-making process and increasing the quality of the product are discussed. Through presenting a discussion of different uses, issues, and cases, the study provides a reflection on AI's capability to revolutionize the pharma sector, leaving behind such issues as quality and compliance and moving toward the provision of superior, efficient services.

Arden et al. (2021) explored how Industry 4.0 technologies—such as the IoT, AI, robotics, and advanced computing—are transforming pharmacological manufacturing and logistics. In the last two hundred years, medicine has progressed from humble herbal and plant remedies to highly processed pharmaceuticals with a wide variety of dosing options. The pharmaceutical sector is worth over a trillion dollars, and the production methods for medications have also progressed from simple, hand-processed batches to massive, industrial-scale operations. IoT, AI, robotics, and sophisticated computers are posing new challenges to established methods, procedures, and business models in the pharmaceutical manufacturing industry, which is driving innovation in the field. Drug manufacturing in factories might become much more nimble, efficient, adaptable, and high-quality with the use of these technologies. The study concluded that Industry 4.0 technologies are transforming platform for pharmaceutical production and logistics supported by digitalization, autonomous systems, robotics, and advances in computing. Pharmaceutical manufacturing, distribution, and inventory management could all benefit greatly from these technological advancements. More adaptability and speed in manufacturing will be made possible by the future smart factory's autonomous qualities. Most rules were created in an

Industry 2.0 paradigm; therefore, the implementation of Industry 4.0 could challenge them. Technologies like process validation for modern manufacturing systems and managing data-rich settings are examples of the kinds of innovations that the U.S. Food and Drug Administration is trying to facilitate by analysing current regulations and proposing new ones. The industrial sector will be more likely to embrace new production technology if regulations around the world converge. Patients, through safer, more dependable drug supply chains that are less likely to experience shortages, should emerge victorious from Industry 4.0's impact on pharmaceutical production.

Kulkov (2021) identified and analysed the specific ways in which AI impacts both core and ancillary business operations in pharmaceutical firms. Researchers and practitioners in the pharmaceutical business are highly interested in AI as a potential tool to accomplish the essential advancements in the field. Nevertheless, there is an absence of research on the impact of AI and methods for reforming businesses. This research aims to pinpoint the precise ways in which AI impacts the core and ancillary business operations of pharmaceutical firms. The study presents the results of a qualitative interview study with ten pharmaceutical companies ranging in size from very large to very tiny. The analysis of the little literature on AI's impact on the pharmaceutical sector led us to wonder which and how many business processes are changing within this sector. They conclude that AI has a profound impact on how small pharmaceutical businesses do research and development, manage master data, analyze and report on data, and conduct HR business activities. Big pharma is using AI to revolutionize their sales, marketing, production, and analysis operations. In contrast, medium-sized businesses fall somewhere in the center and undergo process transformations on an individual basis according to their areas of expertise.

Sumedh M Bodade et al. (2023) explored the transformative influence of Industry 4.0, or Pharma 4.0, on pharmaceutical production through the adoption of advanced

technologies such as AI, big data analytics, the IoT, and robotics. In the pharmaceutical production business, Industry 4.0, also known as Pharma 4.0, represents a significant advancement driven by digitization and automation. Utilizing state-of-the-art technology such as AI, big data analytics, the IoT, and robotics, this transition will radically change industrial practices). Pharma 4.0 has many advantages, such as increased productivity, better quality assurance, more adherence to regulations, and the faster launch of novel pharmaceuticals. Nevertheless, there are a number of obstacles to overcome when putting it into action, such as the following: the requirement for a large initial investment; compliance with regulations; worries regarding the privacy and security of data; difficulties in integrating current systems; difficulties in attracting and retaining qualified staff; concerns about costs; and the need to safeguard intellectual property. Regardless of these obstacles, pharmaceutical businesses that want to foster innovation and stay competitive in the ever-changing healthcare industry should consider adopting Industry 4.0. It could have long-term benefits.

Mehta et al. (2023) presented a novel approach to optimizing pharmaceutical manufacturing processes by integrating AI and lean management principles, with a particular focus on predictive maintenance. In the process of manufacturing pharmaceuticals as it will be expected there is a need to meet a lot of requirements such as precision, efficiency and most of all the quality must matt up to the standard. Thankfully, a concept like lean management of which can be supported by the use of such concepts like AI when practiced within a manufacturing context of the pharmaceutical industry optimizes production in a very effective manner. Predictive maintenance which is one of the components in this integration is targeted at increasing productivity of the organization and the quality of the products produced by searching for failure clues in the machinery before total system failure happens. New approach to the prediction maintenance of

equipment in the production of pharma products reveals in this study is based on recurrent neural networks and long-term memory. Lean management practices are applied in the pharmaceutical manufacturing to minimize the waste while at the same time increasing the value in the pursuant manufacturing processes. This helps in rationalization with a view of getting the best out of the existing resources within the firm. Total theoretical lean principles are improved upon by forwarded by AI especially Recurrent neural networks and long short-term memories to; predict when maintenance activities are needed hence doing so when needed is all that is needed. Since RNN and LSTM models are effective in the analysis of time series data, their application is in predictive maintenance. This method feeds the models with data obtained from various sensors and gadgets that are utilized within the manufacturing context. Because equipment performance can be unpredictable or even requires maintenance now and then, the RNN and LSTM models learn correlations as well as patterns of this data. Thus, thanks to this method, pharmaceutical producers can avoid some of the difficulties or at least predict them and forecast the maintenance of the equipment. This way it helps overcome emergent breakdowns that are prejudicial to efficacy and product quality. The benefits using of AI for maintenance prediction are; increased quality of product, reduced costs of maintenance, fewer downtimes, and increased reliability of the equipment. Also, it contributes to the occurrence of continuous process improvement and resource utilization supporting the principle of Lean management. Certain pharmaceutical medications have to be of high quality at all times and this system can ensure this to the patients on the other hand it can assist the companies that produce the medicines to enhance competitiveness. Final thoughts: optimizing operations, cutting costs, and guaranteeing product quality can be achieved by incorporating AI and lean management principles into pharmaceutical manufacturing processes. This integration will center on predictive maintenance utilizing RNN and LSTM

models. This method is in line with the pharmaceutical industry's dedication to innovation and perfection, and it signifies a big step forward for the sector.

Borisa et al. (2020) explored the various roles and applications of AI in advancing the pharmaceutical industry, particularly in drug discovery, development, and manufacturing processes. The increasing use of AI has greatly boosted the industry of pharmacy. Several pharma companies are using this technology to improve the drug discovery process of medication. As such, they will have extra means to look for other means of administering medication. Importantly, the effectiveness of this method will reduce the time for transition from drug product development to commercialization by half. A new ANN has been recently created to use and predict data correlation. Computerized decision-making and behavioral control are another application of ML and DL where the machine's performance characteristics are examined and altered to produce desired results. Hence, the AI software is quite a useful solution for the intent of pharmaceutical product development. Moreover, they are also used by clinical trials to accumulate and evaluate patient record information. AI has a very positive and significant role in various aspects of Drug Development, Medication, Clinical Research, Tablet Manufacturing, Design of Antibiotic peptides etc. There are numerous positive indications of the role that AI is playing in pharma industries.

Recently, Lodhi et al. (2022) were concerned with the increased importance of the pharmaceutical and healthcare sector about AI in drug discovery, "continuous manufacturing" (CM), design of dosage forms and quality assurance. Many positives have emerged from AI in the last week for healthcare and pharma industries. This innovative strategy can be applied to drug research, dosage form design, quality control, and CM among many other pharmaceutical fields. Although several areas are covered in this research work, the main thrust of the work is on the use of AI in the Pharmaceutical

Industry. The study begins by discussing the future possibilities of AI in healthcare. In conclusion, there are several challenges preceding the launch of the project. There has been a meteoric rise in the pharmaceutical industry's use of AI and genetic algorithms (ANNs) recently. The use of robotics and AI in the pharmaceutical business has yielded promising results. The advent of physical robots might revolutionize medical treatment. Through the provision of a framework for social interaction, it aids in keeping the minds of the elderly occupied and interested. The pharmaceutical industry stands to save significant amounts of time and money thanks to AI.

Kimta & Dogra (2024) explored the prospects and challenges of integrating AI into the Indian pharmaceutical sector. Due in large part to the country's pharmaceutical industry's prominence in the manufacturing of low-cost generic medications and vaccines, India has quickly become a world leader in this field. The sector has been successful, but it still has a long way to go before it can fully deploy to the market. The possible benefits and obstacles of implementing AI in India's pharmaceutical industry are discussed in this study. The methodology of the study is based on Primary data that has been gathered from multiple published sources, with a primary focus on the Reserve Bank of India and spans the years 2011–2019. A compound annual growth rate was used for the performance evaluation. AI may help with these perpetual problems, increase organizational efficiency and, thus, decrease the costs of finding treatments. Education and infrastructure, regulatory reforms and the development of workforce, all these have to search for their finance from the public and the commercial segment to be integrated for enhanced performance to be a success. DL has the prospect to assist the Indian pharmaceutical industry in a short time in many sections such as medicine development, drug production, and medicines standardization. Some of the barriers to the adoption of AI that the study highlights are Constraints on the financial aspect, Efficiency and competence level of the workers, Risk

of security for data, and Legal issues with the data. To promote long-term sustainable growth, and proper usage of ethical and efficiency-oriented AI applications in the context of the pharmaceutical market, therefore in line with the overall objective of the study, the greatest focus is made on the strategic partnership model.

Dangeti et al. (2023) further elaborated on the changes that AI and ML brought into formulating and developing of the pharmaceutical drugs. The ability to predict drug stability, formulation optimization and quick drug development has been greatly enhanced by the influx of AI and ML into the pharmaceutical formulation industry. This reflects how the trending use of predictive models in formulation design assist scientists in making a well-grounded judgement in matters affecting drug degradation pathways and stability performances. Based on the realization of profound correlations between the characteristics of formulation aspects and nature of excipients and pharmacology, the current treatment to a large volume of data has incorporated Machine Learning algorithms to come up with better formulations. Not only does the cost and the time consumed in experiments bear relatively low risks through this method, the probability of creating strong and effective pharmaceutical products is increased. However, the entire drug development process is being accelerated by AI based drug development platforms of a candidate selection, preclinical evaluation, and clinical trial reduction by half. Drug formulation using AI and ML is a rapidly developing area, and this study takes a look at the present state of the art, some of the obstacles it faces, and some of the opportunities it promises.

Alshawwa et al. (2022) focused on the various types of nanocarriers synthesized for targeting multiple diseases, including dendrimers, liposomes, and nanoparticles, among others. There has been a rise in the need for versatile nanocarriers that can target numerous diseases. Nanocarriers outperform traditional medication administration forms in terms of

efficacy, safety, and stability thanks to their small size, large surface area, and potential for targeting.

Numerous types of nanocarriers have been developed and designed for the practice of drug delivery. Such nanocarriers include dendrimers, solid lipid nanoparticles, polymerases, peptide nanoparticles, micelles, carbon nanotubes, gold nanoparticles and so on. The behavior of nanocarriers in vitro and in vivo condition can be controlled and predicted once few characterization techniques have been utilized in the last few decades. Over the recent past, the use of AI in the workplace has become quite rampant and particularly in the pharmaceutical sector where the technology is used to optimize drug delivery and formulation. This integration includes big data, artificial intelligence and multiscale modelling technique for predicting drug release, stability and distribution. AI can also help to genism. However, design of the most effective nanocarrier DDS is not easy. Quantitative accurate predictions from the theoretical toughness of nanocarrier structure and molecular dynamics simulations can aid in the selection of appropriate scaffolds for particular drug types. A similar resource, similar to the Protein Data Bank related to nanocarrier design, is necessary to facilitate the identification of appropriate scaffolds and functional groups for drug loading and release. However, the drawback of data loss is always present, and concerns related to pharmaceutical formulation & development can be better addressed by using interpretable ML methods. sciencedirect.com research shows that with increased fusion of AI and the pharmaceutical industry, there will be enhanced prospects for development in the area of pharmaceuticals.

Arinez et al. (2020) explored the transformative potential of AI and ML in addressing the complexities and challenges faced in modern manufacturing systems. Factory operations face challenges related to highly stochastic processes because of the profusion of interdependencies uncertainty and nonlinear processes. Modern

advancements in AI, notably ML, hold tremendous promise for revolutionizing the manufacturing industry by providing cutting-edge analytical tools to process Big Data, the enormous quantities of data produced by the manufacturing sector. To accomplish these goals, the study follows the standard procedure in manufacturing facilities and examines the interdependencies at several levels, starting from the system level and working its way down to the process streams of incoming materials on a finer scale. In the process, it delves deeply into a wide range of topics, such as quality and throughput, supervisory control in human-robotic collaboration, diagnosis, process monitoring, prognosis, and finally, material characteristic achievement in process modelling and control through improvements in materials engineering. This work reviews AI's use in manufacturing systems and processes, highlighting its potential for further opportunities. AI tools have been implemented to address various problems, but challenges remain. Supervised learning in manufacturing system control faces knowledge sparse, while AI-based diagnosis aids in classifications. When it comes to monitoring and modelling the production process, AI has also enhanced our grasp of material properties. The linkages between materials, processes, and their properties, as well as data quality, model transfer, and system-level analysis should all be the subject of future studies.

Wan et al. (2021) addressed the limitations of traditional large-batch production, which lacks flexibility for individual customer demands. When it comes to catering to individual customers' demands, the traditional paradigm of mass production leaves limited space for customizing. In the future, smart factories will supposedly be able to accommodate new types of customized production, such as multi-variety and small-batch processes. Better value-added manufacturing is one goal of AI, which is why it is speeding up the integration of production with computer, communication, and control. Features like as self-awareness, efficient operations, dynamic reconfiguration, and smart decision-

making should be included in a personalized smart factory. Thanks to AI breakthroughs, manufacturing systems will have the ability cognizant of their surroundings, responsive to outside demands, and capable of retrieving processed information. This class includes new forms of organization such as extended service models, networked cooperation, and intelligent production. Some of the more recent advancements in AI that could be useful in CM include ML, the IoT, big data, cloud computing, and multi-agent systems. A case study of customized packaging is used to test the AI-enabled technologies in a be spoke clever factory. Experiment findings show that CM combined with AI can boost manufacturing efficiency and adaptability. Also covered are the problems with AI in CM and how to fix them. The study concluded that AI technologies are transforming the manufacturing industry, particularly in smart manufacturing. An industrial packaging scenario validated AIaCM designs that use IoT, edge intelligence, and cloud computing. Future research aims to address smart manufacturing device challenges.

Debnath et al. (2023) identified and analysed the “critical success factors” (CSFs) that enable the successful implementation of Industry 4.0 (I4.0) technologies to enhance the sustainability of the “pharmaceutical supply chain” (PSC), particularly in the context of an emerging economy like Bangladesh. Industry 4.0's (I4.0) new technology is vital for the PSC's long-term sustainability practices because it allows for agility, sustainability, smartness, and competitiveness to be integrated into the business model. Pharmaceutical firms may improve the performance, efficiency, resilience, and sustainability of their supply chains (SCs) by using data-driven decisions made possible by the latest I4.0 technologies, which provide real-time visibility into SC operations. However, no studies have looked at the CSFs that make I4.0 adoption in the pharmaceutical business successful in improving SC sustainability so far. Accordingly, this research looked at the possible CSFs for applying I4.0 to boost the PSC's sustainability in every way, particularly from the

standpoint of a developing country like Bangladesh. After a thorough literature search and expert validation, sixteen CSFs were initially identified. Afterwards, a "multi-criteria decision-making" (MCDM) framework based on the "Bayesian best-worst method" (BWM) was used to assess the finalized CSFs, which were then clustered into three relevant groups. Three CSFs stood out as having a strong commitment to research and development (R&D), digitalized product monitoring and traceability, and sufficient investment for technological advancement in the PSC, according to the report. To secure the pharmaceutical industry's long-term viability, industrial practitioners, managers, and legislators can utilize the study's results to devise strategies for the efficient adoption of Industry 4.0 in PSC.

Gautam et al. (2022) examined the present state of AI-based technological applications in healthcare. This study examined many real-world uses of AI in healthcare, in addition to a comprehensive literature analysis. The results indicate that major hospitals are already using AI-powered technologies to aid doctors in the diagnosis and treatment of a variety of ailments. AI tools are also helping to streamline hospital administration and care. Healthcare professionals are enthusiastically embracing AI, but the technology also presents both utopian and apocalyptic possibilities. The goal of outlining these pros and cons is to give readers an even-handed assessment of the benefits and drawbacks of AI in healthcare. Healthcare providers will be able to enhance operational efficiency and deliver patients more value as a result of the fast development of AI and related technologies. However, to profit from AI, the entire care service and operations will need to undergo a complete transformation, which in turn will necessitate careful planning and strategy.

Kumar et al. (2023) provided an inclusive understanding of the current and future role of AI and ML in transforming healthcare practices and infrastructure. The deadline for algorithm development has never been shorter, and the heat is on for those when it comes

to AI and ML in the biological sciences. It is possible to speed up discoveries and discover new insights by using enormous datasets that are interconnected on numerous levels. A negligible percentage of the data that is available is being used for analysis, blending, and processing. The brains behind this tech development are the researchers working on ML and its ability to simulate human reasoning. The combination of AI and ML has two revolutionary effects on the healthcare industry: first, it increases the learning capacity; and second, it provides a large-scale decision support system. This research offers a thorough synopsis of the many uses of AI and ML in healthcare, with an emphasis on these fields' contributions to clinical, developmental, administrative, and international health contexts. For each of these healthcare domains, it delves into the consequences and forecasts as well. The discussion explores potential future directions and the extent to which this technology's application in healthcare infrastructure has already been addressed.

M. Sharma et al. (2022) examined the challenges associated with the application of AI in the PMS of India and explored the interrelationships among these challenges. Many new developments in algorithmic ML have emerged in the era of rapidly expanding AI, and these developments could have far-reaching consequences for many different sectors, including medicine, food production, schools, businesses, and shopping. Nonetheless, AI applications in developing countries is scarce or constrained with poor data quality, privacy, and PMS employees' insufficient training. Therefore, this research examines the current challenges and their connection with the use of AI in the Indian PMS to help fill the knowledge gap in the literature. This study has explored the cause-and-effect group factors using the DEMATEL method as found above. Based on the results, five significant barriers that have emerged for adopting AI in India's PMS include, data privacy, expensive devices, poor quality data, and managerially unaware of cognitive technologies. Also, a

model is suggested to help managers and decision-makers in the manufacturing sector in developing nations create smart AI-enabled systems for their manufacturing organizations.

2.2 AI in Drug Discovery

The process of identifying and producing new pharmaceutical chemicals for the market is known as drug discovery. Usually, this multi-step process takes 15 years to finish. Finding a target that could alter the condition and deciding which disease to target are the first steps in the drug discovery process. Subsequently, exploratory research commences, wherein extensive screening procedures aid in the identification of HIT molecules—chemical entities that exhibit encouraging affinity for the target. A chemical that binds to the target specifically and selectively and can alter its typical mechanism of action is selected following more research. The LEAD compound is the name of this molecule. The lead compound moves toward better biological performance and enhanced ADME (absorption, distribution, metabolism, and excretion) features. After testing promising compounds, the medication progresses through preclinical stages for formulation advancement and animal testing followed by clinical trials. The medicine cannot be commercialized until regulatory agencies like “European Medicines Agency” (EMA) or “Food and Medicine Administration” (FDA) have authorized it following the conclusion of clinical trials. Following the drug's release onto the market, pharmacovigilance will be used to track its safety throughout its distribution (Figure 2.1).

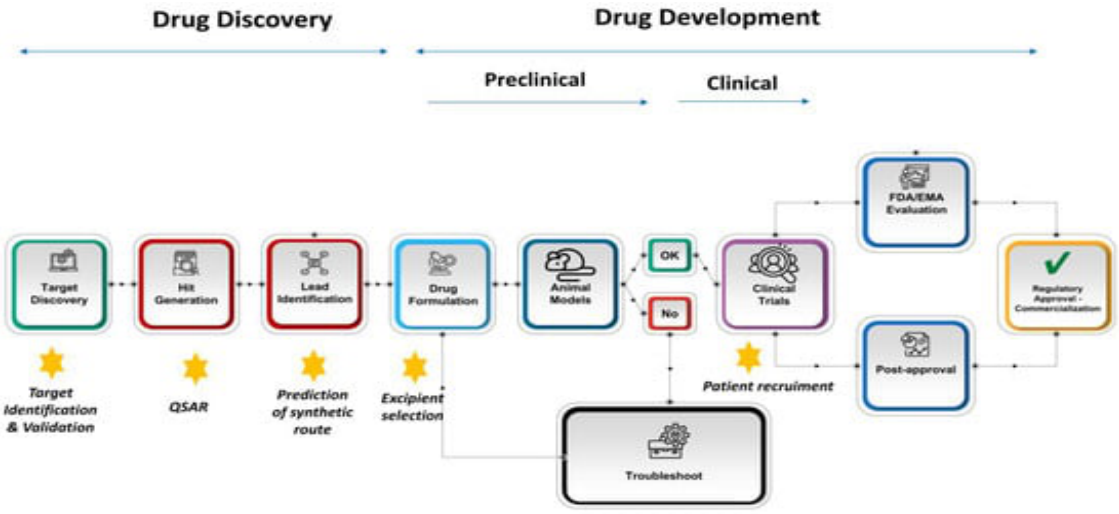

Figure 2.1. A schematic illustration of the key phases involved in the drug development and discovery process. The star stands for the phases in pharmaceutical processes where AI is crucial.

Source: (Serrano et al., 2024)

The enormous amount of chemical space that needs to be investigated in order to find viable drug candidates is one of the main obstacles in drug discovery. Conventional approaches to screening big chemical libraries are time-consuming, labour-intensive, and frequently produce few positives. Nevertheless, machine learning algorithms used in AI-driven virtual screening techniques are capable of quickly sorting through enormous chemical compound datasets and predicting their biological activity against particular therapeutic targets. To rank molecules with the best chance of being therapeutically effective, these algorithms can examine molecular interactions, physicochemical characteristics, and structural traits. This can considerably speed up the optimisation of the hit-to-lead process.

2.3 AI in Formulation and Drug Delivery

Drug formulation and distribution are challenging issues that the pharmaceutical industry has long struggled with. To optimise formulations and delivery systems, traditional methods frequently entail expensive and time-consuming trial-and-error

procedures (Walsh et al., 2018)(Serrano et al., 2018)(Lamy et al., 2018). Predictive models created by artificial intelligence enable drug formulation optimization to deliver active agents precisely where they need to go in the body. AI algorithms predict drug release profiles from formulations to enable controlled-release medication design with consistent therapeutic outcomes throughout time (Figure 2.2). Similar to this, AI can be used to build drug delivery systems that can carry medications straight to particular cells or tissues, such as liposomes and nanoparticles. More efficient and focused medication delivery methods can be developed by forecasting how these systems would interact with the body (Aundhia et al., 2024).

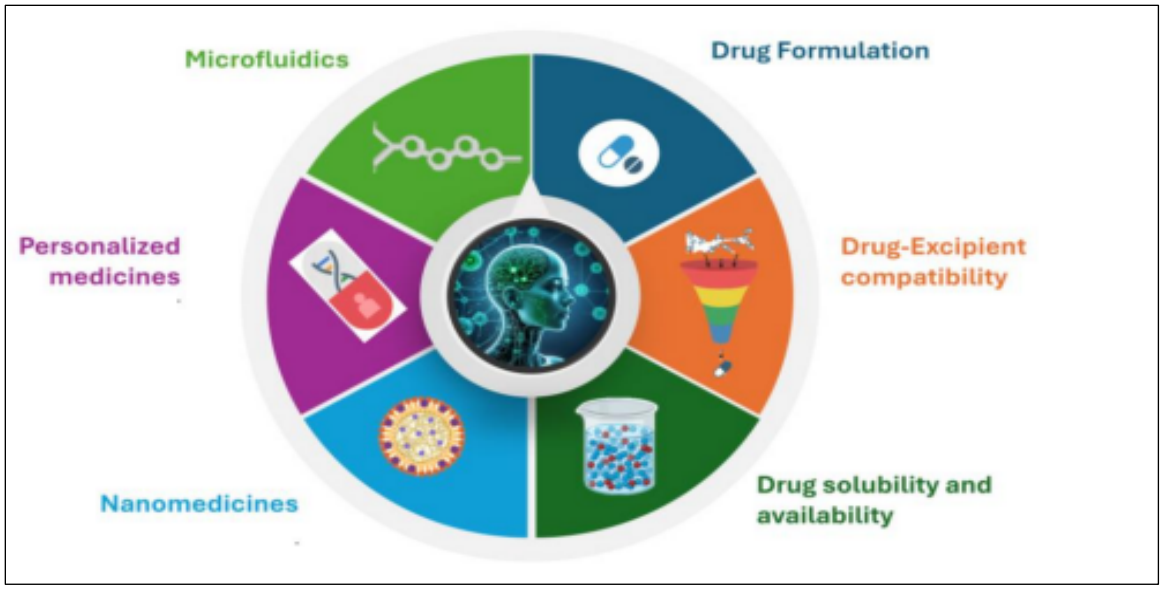

Figure 2.2. The application of AI predictive modeling enables personalized medicine creation as well as drug formulation work alongside drug–extipient compatibility, drug solubility inspections, bioavailability assessments, nanomedicines and microfluidics analysis.

Source: (Serrano et al., 2024)

2.4 Pharmaceutical Industry Applications of AI Examples

AI has transformed pharmaceutical manufacturing by changing how experts make excipient selections and predict synthetic pathways while optimizing workflows and

designing drugs and managing supply chains. AI implementations in pharmaceutical operations can generate large cost and time reductions throughout different pharmaceutical product development phases.

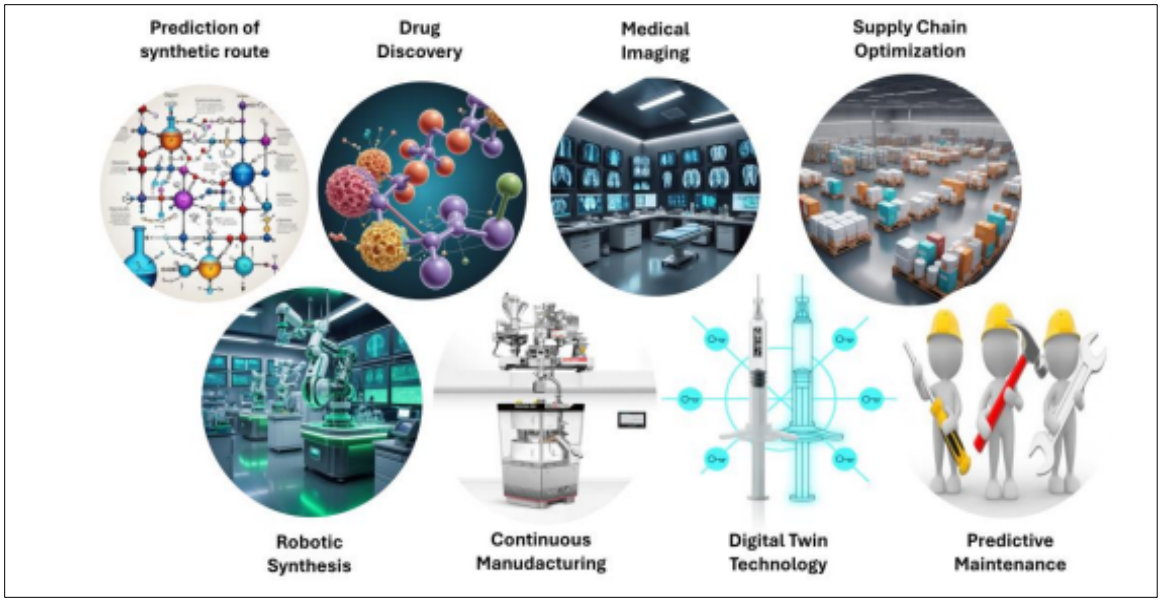

Figure 2.3. Applications of AI in the pharmaceutical sector, for instance.

1. **Target Identification:** The AstraZeneca Centre for Genomics Research plans to analyze two million genomes up to 2026 to discover genetic mutations together with disease-triggering genes and molecular transport paths that will advance drug development. This technology improves drug discovery by enabling the identification of new targets and productive CRISPR gene editing experiments to advance cancer drug resistance knowledge.
2. **Drug Design:** The technique uses artificial intelligence to predict drug signals from biological databases to engineer effective candidate molecules. Insilico Medicine created a drug treatment for idiopathic pulmonary fibrosis within eighteen months through the use of Artificial Intelligence that scanned more than nine billion molecules (Zhavoronkov *et al.*, 2019).
3. **Compound Selection:** The analysis involves AI tools examining extensive chemical libraries to discover medications with optimal characteristics, including solubility

features and toxicity aspects. After 11 months of synthesizing 150 molecules, AI at Scientia identified EXS4318 as a selective PKC-theta inhibitor for autoimmune diseases.

4. **Synthesis Route Prediction:** Deep learning algorithms embedded in IBM's "RXN for Chemistry" program help scientists optimize retrosynthesis pathways to simplify complex chemical reactant sequences. The system processes millions of reactions and then predicts outcomes by effectively optimizing experimental approaches.(Schwaller *et al.*, 2019).
5. **Robotic Synthesis:** Artificial intelligence in robotics allows for the removal of manual synthesis work which leads to rapid drug discovery through accelerated high-throughput experimentation. Scientists at the University of Glasgow created "Champêtre" which utilizes AI algorithms to steer robot scientists in drug molecule synthesis automation. (Gromski, Granda and Cronin, 2020)(Leonov *et al.*, 2024).
6. **Process Optimization:** By processing manufacturing data, AI tools optimize drug production while minimizing expenses and production issues. Pfizer applied AI technologies to enhance COVID-19 vaccine production, simultaneously boosting output capabilities while minimizing production cycles and ensuring continuous monitoring across 3,000 vaccine storage freezers (A. Sharma *et al.*, 2022).
7. **Continuous Manufacturing and PAT Technology**: AI enables real-time factory parameter monitoring via Raman and NIR sensors thus ensuring continuous manufacturing operates with greater effectiveness and product quality. Continuous manufacturing methods produce better results than standard batch manufacturing through full-time operation. (Lee *et al.*, 2015)(Roggo *et al.*, 2020).
8. **Digital Twin Technology:** Digital Twins generate manufacturing process copies in virtual space through which operators can improve and optimize operations even while production continues. Johnson & Johnson employs this approach for simultaneous process integration and site-to-site comparison.
9. **Predictive Maintenance**: By analyzing equipment sensor data with AI software organizations can forecast maintenance requirements thus minimizing equipment

downtime and operational expenses. Pharmaceutical firms including Pfizer conduct preventive maintenance using this approach(Kavasidis *et al.*, 2023).

10. **Supply Chain Optimization:** To improve supply chain performance, AI systems deliver projections of market demand while optimizing storage and delivery systems. Novartis implemented AI to improve its inventory operations, maximize cost savings and introduce a unified procurement infrastructure.
11. **Medical Imaging**: Bayer takes advantage of natural language processing (NLP) technologies to perform medical coding which transforms case report data into standardized medical information. The AI model from Bayer has processed millions of terms since its introduction in 2017 with a 96% accuracy rate, which allows efficient time savings.

2.5 AI in Process Optimization and Quality Control

Okuyelu & Adaji (2024) explored the addition of AI into manufacturing processes, specifically focusing on AI-driven real-time monitoring and process optimization. Quality assurance and process optimization have been transformed by the incorporation of AI into production processes. Improving manufacturing performance is the primary emphasis of this research, which explores the subject of process optimization and the use of AI to power real-time monitoring. The study examines current AI developments, with a special emphasis on their applications in manufacturing settings. The suggested system enables continuous monitoring of production parameters using data from sensors, algorithms for ML, and connectivity to the IoT. With early problem diagnostics provided by the AI-driven framework, disruptions and the possibility of suboptimal performance are reduced. To enhance productivity, resource utilization, and product quality, the study delves further into how AI can enhance manufacturing in real time through adaptive control, intelligent decision-making, predictive maintenance, and real-time analytics. By analysing data in real-time, implementing an ERP system, and being ready for Industry 4.0, Krones and Kleven Maritime AS show how AI-assisted CM maximizes customization and production

efficiency. Upon careful review of case studies, relevant literature, and experimental results, this enables the simultaneous execution of several tasks that are customized to meet consumer preferences (Wan et al., 2021).

Podder et al. (2023) provided a comprehensive review of the applications of AI in "Micro-electromechanical Systems" (MEMS)-based sensors, focusing on both product-level and system-level adaptability. Thanks to developments in semiconductor manufacturing technology, which creates sensitive, powerful, and inexpensive sensors, sensors based on MEMS with the technology used to make semiconductors, allow for the creation of cheap, sensitive, and powerful sensors. Technology has discovered numerous uses. The intricate manufacturing processes and integration of multiple electrical and mechanical components in MEMS sensors make them susceptible to both random and predictable mistakes. As a result, keeping the sensors' quality and dependability under check now requires testing, calibration, and quality management. Here is where AI shines, with its many useful applications including but not limited to automating tasks, improving products, optimizing processes, de-noising signals, handling complex data, and performing root cause analyses. Despite its many advantages, the physical manifestation of AI presents some obstacles. As a result of searching literature, this review provides an inclusive analysis of the topic under consideration – AI and its product- and system-level adaptive applications in the MEMS-based sensors industry. This study offers a brief literature review discussing advanced development in AI for MEMS sensors and a discussion of challenges in deploying AI in manufacturing. All the results were then discussed while referring to the three questions which the study posed to determine the scope of the future research.

Md Abu Taher (2024) researched a wider scheme that concerns the impact of AI and ML in manufacturing and supply chain inventory systems for industries all over the

world. The study assesses the use and application of such technologies, and how they influence supply chain improvement, through the utilization of cross-national quantitative and qualitative data comparison. The study process/ requirements include undertaking expert interviews with specified time horizons as well as a literature review where programs and databases are utilized. The research also shows that the actual implementation of AI and ML increases productivity and at the same time cuts down on operating expenses and improves the capability of predictive maintenance alongside the critical time to response ratios of actual-time data examination. Because of this reality, the industry tends to the practical application of opportunities that have been afforded more to data and compliance. However, this work is devoted to the discussion of the AI and ML applications in the strategic management of the processes and the proposals for the use of Industry 4.0 enablers as an integrated supply chain application. Supply chain academicians and practitioners can benefit from this study because it highlights both the advantages and limitations of AI and ML in the analysed topic. Lastly, the stressed capability that illustrates AI and ML in the supply chain network and the potential of these technologies to cause changes in supply chain infrastructure and effectively utilize them to strength supply chain networks.

Nsisong Louis Eyo-Udo (2024) wrote a systematic literature on the adoption of AI in “Supply Chain Management” (SCM) highlighting its reaction to operations performance and innovative and sustainable strategies. Concerning the impacts of AI on Operational Efficiency, Strategic Creativity, and Sustainability, this work investigates the integration of AI in Inventory Control (IMC). The data for this study has been collected from a methodical literature review and content analysis of journal articles that are available in peer-reviewed indexed journals and articles presented in conferences from 2013 to 2023. The study discusses important aspects and trends where new AI technologies, including

ML, natural language processing, and robots, have enhanced many aspects of SCs including demand planning, inventory control and logistics. Decision-making enhancement as well as lower costs and better resource utilization makes AI increase supply chain effectiveness, as numerous crucial studies suggest. The following are challenges associated with AI use in supply chain management; Privacy of personal information, ethical issues, and scarcity of qualified personnel. The arising future of supply chain integration supported by AI is bright, full of opportunities and new initiatives which have to be challenged to overcome obstacles we face today. The final policy implications and recommendations directed at policymakers and practitioners regard the development of the right culture for innovation, digital skills, and the right, non-prescriptive regulatory environment necessary for successful AI integration and deployment.

2.6 Automation and Robotics in Pharmaceutical Manufacturing

Ranebennur et al. (2023) examined the transformative influence of automation on the pharmaceutical manufacturing industry, highlighting its applications and benefits across various processes. In the pharmaceutical manufacturing business, automation has come to a standstill due to numerous applications such as Quality by Design (QoDs), Anti-counterfeit technology, Process Analytical Technology (PAT), and High-Quality Risk management. This study present concrete instances of how pharmaceutical manufacturing has been automated. These examples encompass a wide range of applications, such as research with a wealth of data collected through in-situ sampling and automated lab reactors, solutions for tamper-evident packaging that use ML and DL to inspect foil, and analysis in-process during integrated continuous manufacturing systems with PAT. The possibilities for customized pharmaceuticals and drug development have been enhanced by automation, which enables faster and more precise data processing from which further development of individual patient treatments could occur. There is now a reduced margin

for latex cost and a reduced incidence of fakes within the market due to automated filing, packing, and labelling. Due to the application of automated continuous manufacturing the management and control of the manufacturing process in real time, the quality of the product has improved with the use of less time on the production. Computerized laboratory reactors that incorporate information-gathering experiments and grab sampling have reduced the time considered to create new medication preparations by enhancing process control and curtailing information analysis time. This study finds that automation has led to a change in roles of pharmaceutical quality assurance systems. Some of the current ones include data and information protection, data acquisition, electronic batch records, digital data processing and analyses. Automation has made it possible to establish good anti-counterfeiting measures, medicine that is tailored to individual needs, process analysis and high-quality risk management which has brought a change in the pharmaceutical production business. The pharmaceutical industry has been among the major benefactors of automation since it displays a positive impact on efficiency, product quality, and patient safety in coming up with the products, the filling, packaging, labeling, and continuous manufacturing of the medicine. In modern quality assurance systems, digital data management, automated data collecting, and data integrity maintenance are all part of the job description.

Cioffi et al. (2020) analysed the technical literature on the application of AI and ML in the manufacturing industry When it comes to production, adaptation and innovation are king. New environmentally friendly technologies should be the result of this production growth. Smart manufacturing can't help the environment unless it has a worldwide view of smart production technologies. Here, numerous Intense studies into to accomplish sustainable manufacturing, the industry has established AI-based methodologies, such as ML, thanks to AI. The goal of this research is to systematically examine previous works

that have addressed the use of AI and ML in commercial contexts. AI and ML are believed to be driving the smart industrial revolution, which is a result of Industry 4.0. Classifying the works according to publication year, author, subject area, country, university, and keyword was the primary objective of this literature review. The SCOPUS database and the Web of Science were used to conduct the analysis. Additionally, NVivo 12 and UCINET were utilized to complete them. The topic's development was highlighted in a literature review on ML and AI empirical research during the past 100 years. both before and after the introduction of Industry 4.0, from 1999 to the present. One interesting consequence of Industry 4.0 is the dramatic increase in publishing activity and focus on the United States.

Mannan & Mubeen (2018) explored and review various strategies for digitalization and automation throughout the entire process of pharmaceutical development, from drug discovery to administration. From medication discovery to delivery, digitization and automation have accelerated the pharmaceutical industry's rapid progress. There is a direct correlation between developments in digitization and improvements in the creation of pharmaceutical items. It takes a long time for a medicine or drug product to make it from the discovery stage all the way through pre-clinical testing, clinical trials, and more product development in R&D for it to be safe to administer and effective. Following the research and development (R&D) department's instructions, the medicine formulation is assembled by the production and manufacturing systems using suitable digitalization and automation. Then, digitalization is used by quality assurance and control systems to keep the drug product's quality and standard. Afterwards, the medication product is efficiently packaged and labelled using automation. Also, distributors and pharmacies are kept apprised of the marketing and supply of pharmaceutical products through digital monitoring. In the end, the medication will be given to the patient in a way that is both safe and effective, all while

being closely monitored by digital technology. Consequently, this study provides a concise overview of numerous approaches to digitalization and automation in the pharmaceutical industry, including topics such as drug development and medication administration.

Kashni (2022) examined the effects of automation on the workforce within various industries, particularly in the context of the fourth industrial revolution. The workforce is affected in both good and bad ways by automation in the sector. Within the next several years, the influence of automation will alter the culture of the workplace. The function of all industries is being impacted by the unprecedented rapid spread of industrial disruption caused by the fourth industrial revolution. Manufacturers are utilizing cutting-edge data analytics, digitizing and automating processes, and installing state-of-the-art machinery. Disruptions to pharmaceutical businesses' business models and cutting-edge IT gear are also on the rise. Companies and workers alike are being forced to adapt to new ways of working as a result of this shift, which necessitates a different set of skills for essential tasks. There can be no way to survive the fourth industrial revolution without automation. The human workforce is still vital, but industrial technology is quickly replacing them.

Algorri et al. (2022) analysed the potential for agile manufacturing methodologies in the pharmaceutical industry and to address the associated regulatory challenges. Centralized facilities that allow for mass production and distribution have traditionally been the primary emphasis of pharmaceutical manufacture. Although this approach consistently ensures high-quality and reproducible products, it hinders the introduction of innovative production processes that may boost efficiency and strengthen supply chain resilience due to its rigidity. Manufacturers can adapt to patient demands on demand with agile production processes, which harness flexibility through mobility and decentralization. This could be a strategy to ensure crucial medicines are accessible quickly. Producing small-batch, personalized treatments that are tailored to each patient

near the point of service is an ideal application for agile methodologies. Nevertheless, the pharmaceutical business faces considerable global regulatory hurdles that prevent the adoption of agile production practices, even if agile-enabling technology have advanced significantly across other industries. Challenges to the non-adoption of agile manufacturing systems include; new regulations governing pharmaceuticals and opportunities for adopting agile manufacturing systems in the pharmaceutical product manufacture. Also proposed for the future are approaches that inscribe agile methods into the international legal framework. This can only be understood when the relationship between the producers and the regulators places a strong emphasis on cooperation to chart its course through the affirmative regulatory terrain.

Calitz & Mugwagwa (2023) proposed a system-focused method to drive the implementation of CM in the pharmaceutical industry, specifically for small molecule drug production. There is a pressing demand for smart manufacturing due to the difficulties that digital transformation has introduced. In light of these difficulties associated with digital transformation, the idea of Industry 4.0 has evolved. Academic and practical interest in smart factory implementation has grown worldwide; nevertheless, most studies have ignored the pharmaceutical industry in favour of generic manufacturing facilities. This research set out to fill knowledge gaps in smart factory applications in the pharmaceutical sector. One hundred and six respondents from a South African pharmaceutical industry filled out a questionnaire that was operationalised from the literature as part of an empirical investigation. Statistical analyses, including exploratory factor analysis, were performed on the responses. In this work, the Technology Acceptance Model served as the theoretical foundation, and a conceptual model was then presented. The findings point to the fact that the readiness of both employees and management to embrace change brought about by technology is crucial for its successful adoption in the pharmaceutical industry.

Management should reassure workers that the introduction of new technologies will not put their jobs in jeopardy by providing them with training and ongoing information sessions on the benefits of these changes.

Patil et al. (2023a) explore the potential role of AI in simplifying and improving the efficiency of pharmaceutical regulatory affairs. The healthcare and pharmaceutical industries are among the many that will be affected by the increasing prevalence of ML. Among the several worldwide trends impacting the pharmaceutical business, the adoption of AI will significantly change pharmaceutical product research and development, the efficiency and speed with which these products reach patients in need, and many other aspects. Of all the possible uses of AI in the pharmaceutical industry, pharmaceutical regulatory affairs (RA) has the most to gain. If AI could streamline the therapeutic process, more patients in need of treatment could get it faster. AI is used by the RA to increase efficiency, decision-making, and process streamlining, which in turn would shorten the time it takes to submit and approve marketing authorisation applications and get the product to market. Examining the present, past, and future of AI in pharmaceutical regulatory concerns is the primary goal of this literature analysis. There has been some early success with AI in RA procedures, but with the help of stakeholders, this area is poised to undergo digital transformation. To achieve this, an agile regulatory ecosystem must be developed to support innovation while ensuring public safety, which involves integrating AI into regulatory processes in a manner that harmonizes risk-based regulations. Even though there are still certain obstacles to overcome when implementing AI, the majority of companies use AI in some capacity since they know it will be crucial to their growth and future success.

Reinhardt et al. (2020) examined how companies operating in the pharmaceutical and biopharmaceutical industries, in Ireland but from a global perspective, adopted,

integrated, and were aware of Industry 4.0 concepts. Industry 4.0 refers to the adoption of the digital environment, cloud services, IoT, and big data as means for gaining a competitive advantage in local and inter-national markets. Studies are conducted in Ireland and then the data is analysed internationally to give comparison information that is useful when implementing 4.0 principles. Another outcome is a comparison of the attitudes of the pharmaceutical and biopharmaceutical sectors towards the adoption of 4.0, the degree to which manufacturing facilities currently utilize 4.0 technologies, and the planned 4.0 projects. Additionally, the study looked into any statistically significant correlations based on the answers. The findings of this study provide new light on how well numerous sectors are preparing to implement Industry 4.0. Only 42% of people who took the survey knew what version 4.0 was. Those in the Automation or Engineering departments were the most likely to know about 4.0, according to the answers. A whopping 82% of long-term employees with 8+ years on the job claimed to be familiar with the 4.0 framework. Nearly all respondents (98%) who held the positions of vice president or director were aware of version 4.0. An important takeaway from this study is that there is a significant gap in 4.0 knowledge across departments, industries, and levels of seniority. So, although 4.0 is becoming more important in the pharmaceutical and biopharmaceutical industries' modernisation efforts, there are still obstacles to fully integrating 4.0 into company culture.

2.7 Supply Chain Management in Pharmaceuticals Using AI

Guo (2023) explored the role of AI in optimizing SCM within the pharmaceutical industry. Pharmaceutical manufacturing stands to gain a great deal by implementing AI into its supply chain management systems. This technology can enhance product quality and patient safety by optimising logistics and production processes. This study delves into the benefits of AI technology for pharmaceutical business's supply chain data optimisation and implementation. Case studies from major pharmaceutical firms are reviewed, including

Pfizer, Amgen, GlaxoSmithKline, Merck, and Roche. The applications being used by these companies to improve their manufacturing and supply-chain processes and quality assurance are based on AI. Integrated approaches based on AI allow for enhancing the accuracy, speed and effectiveness of SCM, reduce costs, and ensure compliance with regulatory requirements – these and other benefits can be found in the study. The authors note that to fully capture value of these solutions, more investment in AI must be made in the pharmaceutical business. This study also concludes that in the current dynamic healthcare system, for the commercial success of pharmaceuticals and the promotion of better patient care and outcomes, AI must be adopted for the management of supply chain in the pharmaceutical businesses. This research aims to explore how the sector of pharmaceuticals is deploying artificial intelligence and data analysis in handling its supply chain. The study's author conducts experiments and audits to determine how well various artificial intelligence algorithms—such as DL Neural Networks, Linear Regression, Random Forest Regression, and K-means clustering—perform in order estimation, stock optimization, generation planning, and coordination optimization. In terms of request determination, the results demonstrate that Random Forest Relapse outperforms Direct Relapse. This study adds to the knowledge of how AI and data analytics can help the pharmaceutical industry's supply chains be more efficient, cheaper, and more maintainable.

P. Shah (2021) examined the tests faced by the Indian pharmaceutical industry during the COVID-19 pandemic, particularly focusing on supply chain disruptions, and to propose strategies for improving supply chain management. Worldwide, healthcare systems have been overwhelmed by the COVID-19 epidemic, which has an indirect influence on the treatment of other illnesses. During these extraordinary times, the Indian pharmaceutical business has been occupied with addressing the unexpected healthcare difficulties caused by disruptions in supply chains. As a result, there is a clear need to

enhance the industry's efficiency. However, this epidemic has brought to light numerous shortcomings in the Indian supply chain system that have persisted over the last decade, even though India is among the most rapidly growing pharmaceutical markets. This study goes over the fundamentals of a supply chain and the different approaches a pharmaceutical firm can use to run smoothly. Supply chain optimisation using AI and ML tools is one of the most contemporary methodologies employed by corporations. The introduction of these cutting-edge technology has a multiplicative effect on lowering costs, improving route prediction, and shortening lead times. The study continues by dissecting paracetamol, an API that is extensively manufactured in India. This study analyses the present state of the API supply chain in India and makes recommendations for how to enhance it. Overall, organisations in India stand to gain from better supply chain management that prioritises data-driven decision-making and cohesive strategy development.

Abdollahi et al. (2023) identified the mechanisms of an intelligent distributed supply chain and to establish a structure of causal relations among these components. The way people express themselves and engage with their environment has been significantly altered by the advent of new technology. Almost every part of human existence has been impacted by digitalisation, and supply chain procedures are no exception. Distributed and centralised supply chains are both made possible by the fourth generation of industrial technology, which can transform the supply chain from one to the other. Finding out what makes up an intelligent distributed supply chain, outlining the relationships between its many parts, and then analysing those parts within that framework is what this study is all about. Using the grounded method to identify codes and categories, the present research moved on to uncover causal-effect linkages using the fuzzy cognitive mapping method. The intelligent distributed supply chain's cause-and-effect relationship structure was derived using the fuzzy cognitive mapping method. By averaging the views of specialists,

collective mapping was produced. Distributed decentralised supply chains have the potential to improve information flows, advance healthcare, and ensure equitable access to medical services, as stated in their components. In addition, the company can be impacted by issues such as prioritising patients' treatment based on their physical condition, adhering to production line terms and conditions, detecting authorised hazardous substances, reducing fraud, and removing drugs licensed outside of legal criteria. The nation's supply, prescription, and treatment are heavily impacted by high rents.

Gaurav Kumar (2023) explored how pharmaceutical organizations can cost-effectively integrate, implement, and manage digital technologies across their supply chains to combat the growing issue of counterfeit medications. Technology has caused a dramatic and ever-increasing transformation in the pharmaceutical supply chain environment during the last several decades. The efficient and economical integration, implementation, and management of technology throughout an organization's supply chain is a major focus for business practitioners. False pharmaceuticals can more easily enter the system since pharmaceutical organisations that manufacture, transport, and distribute their commodities have problems tracking their items. An important stage in the long fight against the explosion of counterfeit pharmaceuticals and other healthcare items would be the development and implementation of a strict technical system. There may be some benefits to using digital technology in SCM. With the help of the IoT, supply chains can become transparent, allowing for the real-time identification of the location and specifications of any item or component.

Shashi (2023) explored strategies that pharmaceutical managers use to digitalize integrated supply chain systems to enhance profitability and sustainability. A pharmaceutical firm can save operational sustainably digitalise supply chain management; improve assets; raise shareholder value; respond effectively to consumer demand; and earn

profits. This qualitative multiple-case study aimed to find out how managers in the pharmaceutical sector are using digitisation to make integrated supply chain systems more sustainable and profitable by using the concept of constraints as a framework. The topic of digitising the integrated supply chain systems of numerous US-based pharmaceutical businesses' senior supply chain managers was covered during the conversation. The research team used semi-structured interviews and reviewed the company's publicly available records to gather data. Following a six-step thematic analysis of the data, three overarching themes emerged: (a) digital technology enablers, (b) limits in the current, and (c) supply chain systems that are sustainable, robust, and flexible. Based on the findings, a system model was created. The most important thing for pharmaceutical supply chain managers to do is to find the bottlenecks in their current system, create a digital road map with the help of digital enablers, and keep their system sustainable, resilient, and adaptable. Potentially better patient access to high-quality pharmaceuticals without sacrificing social, economic, or environmental sustainability is one good social development that could result from this.

Long et al. (2023) explored and proposed the use of AI systems for making intelligent decisions in selecting optimal healthcare supply chain modes. Finding a sustainable development mode to keep up with the massive changes occurring in global public health and the economy, the healthcare supply chain must move swiftly from its existing inefficient and costly way of operation. To intelligently choose modes of the healthcare supply chain, this study introduces AI algorithms. Various healthcare supply chain patterns powered by AI are first described in this research, with the benefits to society, the environment, and the bottom line listed in descending order. In addition, the study lays out a deep reinforcement learning algorithm-based intelligent choice optimisation approach for the healthcare supply chain. Finally, simulation tests have shown

that AI does affect healthcare supply chain mode selection. When it comes to selecting modes for medical supply chains, the testing findings demonstrate that AI is the best option. The selected mode using AI aligns with the goal mode, in contrast to the basic selection technique, the BP neural network approach, and the big data method. This study fully fills the need for AI applications in the healthcare supply chain by tackling the limitations of previous methods. The suggested AI algorithm and framework are the study's scientific meat and potatoes; they build on existing ideas in healthcare supply chain research and offer methodological recommendations for smart healthcare supply chain decision-making. At the same time, medical companies can use this study as a fresh, actionable standard for applying AI to current healthcare supply chain management and sustainable development.

Wang (2021) developed and implemented advanced simulation and AI methodologies to enhance the understanding and efficiency of end-to-end bioprocessing in the biopharmaceutical industry. It considers chemical kinetics and physical interactions. This simulation model can help with managing the risks associated with biomanufacturing and consistently making operational decisions. Secondly, the study provides a blockchain-enabled interoperability architecture that utilises state-sharding and reputation-based Proof-of-Authority smart contracts to maximise the utilisation of supply chain surveillance resources and to concurrently process jobs from several areas. The objectives of this structure are openness, responsiveness, data integrity, healthcare safety, and dependable delivery. Building a simulation-based system to manage risks in the biopharmaceutical supply chain is the next step. Thirdly, the study offers a new Bayesian sequential trial approach for simulation calibration to reduce the impact of computing time and calibration mistakes. With this, we can create digital twins of biopharmaceutical systems that are highly accurate representations of the actual thing. Optimal decision-making and real-time

digital twin calibration are both aided by it. The quantile estimator accurately and effectively evaluates risk behaviours, which gives the fourth recommendation. This estimate is based on combining exhaustive simulation output trajectories through the coordination of parallel computing. Then, to further enhance the efficacy and accuracy of system risk performance prediction, the study presents a distributional metamodel that may mimic a sequence of percentile surfaces. Furthermore, utilising a novel probabilistic knowledge network, author elucidates the intrinsic spatiotemporal causal interdependencies of the bioprocess. Taking model risk into account, this study introduces a reinforcement learning system based on bioprocess models. In addition to guiding the individualised stopping strategy for the multi-phase fermentation process, this technology can aid in bioprocess online learning. Comprehensive safety and responsiveness assessments can help with accelerating quality by design, identifying and removing bottlenecks, and guiding process specifications and risk control, all of which contribute to the automation of biomanufacturing. Through the use of structural and sensitivity analysis as well as extensive empirical studies, the study explores how model risk affects the ideal policy and offers valuable recommendations for controlling the fermentation process.

Duarte et al. (2022) propose a framework for efficient distribution of pharmaceutical products through enhancing the issues of availability and accessibility in the pharmaceutical supply chain. One of the most pressing issues facing pharmaceutical supply chains today is ensuring the continuous accessibility and availability of medicinal products. Thus, this study focuses on this topic to find out how it can organise for a better and sustainable distribution of pharmaceuticals and attempts to develop a decision model. Since access to health care is being spread equally across the disease markets with a higher burden of disease, an equitable access statistic based on the DALY is used. Moreover, there should be a minimum set stock of therapeutic products in any given area. The decision-

making involves two aspects of sustainability are economically sustainable defined by NPV or Net Present Value method while environmentally sustainable defined by LCA or Life Cycle Assessment method. This is a guide tool, which is based on MILP paradigm, IAS, and incorporates supply chain strategy and tactics to accomplish several missions at a time. The model is applied in Meningococcal meningitis vaccine chain of supply wherein the processes of production of the vaccine have been considered. The different decision-making cases are applied in order to compare them and the impact that they may have on supply chain goals and objectives. The vicinity, the two economies and the society are all domains where issues can be identified.

Ajala (2024b) discussed and extended the pharmaceutical SCM during the introduction of new drugs. High and complex activity of supply chain management is typical for the pharma sector because of its strict regulation. If a new drug is being introduced into the market, it is very crucial to ensure that its supply chain is well. Controlled to ensure that the drug is delivered on time but at the same time it has to meet all the legal requirements in this line. This will define the success or otherwise of the drug in the marketplace. Exploring the principles of the best supply chain performance and ultimately promising practices and applications of the latest technologies, this study investigates the issue of pharmaceutical SCM during the introduction of new drugs. The study provides a comprehensive framework for enhancing the logistical flow of drugs for new products Brand through case analysis, benchmarking, and identification of emerging technology solutions.

Bø et al. (2023) investigated the influence of an analysis of the COVID-19 pandemic on delivery security, as well as the readiness and actions of Norwegian businesses, with an emphasis on supply chains that played a pivotal role in ensuring the availability of necessities amid broad social closures. Examining the effects of the COVID-

19 pandemic on delivery security and the readiness and reaction of Norwegian businesses is the goal of this research. Supply networks are the centre of attention because of how important they were in keeping key items available when many sectors of society went dark. The four companies included here are all involved in some aspect of the food or pharmaceutical supply chain, whether it is exports, imports, domestic distribution, or home delivery. What makes their approach to resilience, supply chain risk management, and reliability theoretical models unique is that they apply them all at once, instead of using them separately. By systematically utilising the models and taking note of their interdependencies, this study was able to fill in gaps, prioritise areas for improvement, and gather data for thorough, implementable risk mitigation strategies by taking advantage of synergies that allow for more thorough evaluations of the supply chains of firms. Consistent with the guiding principles of each model, the investigations expand upon semi-structured interviews. author examined the companies using the models together to find out what happened as a result of disruptions caused by the epidemic and how each company dealt with the problems that arose. In the early stages of the pandemic, firms faced significant difficulties due to unexpected shifts in demand. While each company's pre-pandemic strategies were unique, they were rarely adequate in terms of depth or action, and they certainly weren't ready for the length of the epidemic. In light of the significance and interdependencies of supply chain risk management, resilience, and dependability components, it is important to have more comprehensive and long-term standards. Maintaining positive, long-term relations with supply chain partners both upstream and downstream, as well as working to strengthen backup plans and future resilience, are characteristics shared by all businesses and essential for dealing with disruptions.

Shashi et al. (2022) examined the digitalisation strategy for reducing disruption in pharma supply chain and how it is affected by disruptions. A decline in profitability and

an increase in supply chain uncertainty are the end outcomes of disruptive events. Part of what makes a supply chain robust is its capacity to respond rapidly to new information or conditions. Reduced disruptions are a direct result of the increased agility and flexibility made possible by digitalising the supply chain. Pharmaceutical managers who had previously used digital strategies to mitigate disruptive events were interviewed for the study. This is the philosophy of constraint that underpinned this qualitative multiple-case study investigation. The interview and supplemental material data were analysed thru thematic analysis. Two main topics emerged from the data analysis: The issues are: (a) the inadequacies of the current supply chain system and (b) the flexibility of the new method.

Chbani & Bouarfa (2024) focus on the application of the developed models in improving the supply chain of aromatic and medicinal plants. Opportunities of AI for enhancing medicinal and aromatic plant supply chain. The research questions stem from understanding how AI could improve the supply chain processes of this industry, the benefits, drawbacks as well as the feasibility of AI integration. Methodology of this research employed included a vigorous review of the literatures, developing and validating models based on artificial intelligence and in-depth case studies. Overall, the study shows that AI implementation could significantly enhance the supply chain factors for medicinal and aromatic plant. These enhancements address some of the oldest issues in the industry such as wasted fruits & vegetables, inefficient administration, and no methods of real time tracking & forecasting. Nevertheless, AI can face several challenges that hinder effective implementation. This has following concerns, which people consider and they are concern with the privacy of data, initial cost, and technical know-how. More investments and researches are required to grasp the opportunities and overcome challenges described here, yet this study is evidence for the role of AI in transforming agri-food supply chains. The present investigation identified methods that can be deployed to enhance sustainability and

resilience of the aromatic and medicinal plant supply chain including the use of Artificial Intelligence.

Malik (2024) When doing business on a global scale, supply chain management takes centre stage. Companies' supply chain management suffered as a result of the temporary suspension of the Indian transportation system caused by the COVID-19 pant. In addition, the pandemic has boosted the utilisation of cloud computing and AI in the SCM system. The term cloud computing describes a set of online services that have made it easier for businesses to communicate with their suppliers using video chat. To better understand and implement SCM, this study set out to identify existing and future AI methods that can do just that. The existing SCM service can be sub-fielded and run with the help of possible AI approaches and cloud computing technologies. Results from a thorough evaluation and synthesis are presented in this work. Examining how AI and cloud computing affected pandemic communication and SCM is the main goal of this research piece. To learn more about cloud computing and AI's role in COVID-19, the researcher has turned to secondary sources. Similarly, all of the data was analysed using qualitative methodologies by the resources. Thanks to the researcher's use of appropriate research procedures, the study yielded better results. The study as a whole will also allow readers to comprehend the pros and cons of using cloud computing and AI in SCM systems.

Hansen et al. (2023) addressed the gap in the existing literature regarding inventory management in pharmaceutical supply chains by identifying key drivers that influence inventory levels and developing a framework for assessing inventory configurations. So far, research on how to best optimise pharmaceutical supply chain inventory levels has only looked at a few of factors. To find lucrative inventory configurations that meet needs and safety margins, a more sophisticated understanding of the dynamics in this sector is needed, as the COVID-19 epidemic disrupted global supply chains. This research fills that need in

the literature by outlining a framework for evaluating pharmaceutical supply chain inventory configurations and identifying critical drivers influencing inventory levels. The study used a one-case study approach to test the framework. Although the case study acknowledged the importance of external and downstream supply chain elements in reducing inventory, it also demonstrated that internal factors were more influential in inventory management decision-making. Presently, practitioners may find this study's concept useful for determining which aspects of a given pharmaceutical supply chain design have the most influence on inventory levels.

2.8 AI in Personalized Medicine and Precision Pharmaceuticals

Boniolo et al. (2021) provided an inclusive review of the current landscape of precision medicine, particularly in the context of drug discovery, and highlighted the potential role of AI in advancing this field. A patient's molecular profile, lifestyle choices, and environmental factors can all play a role in the precision medicine approach to illness treatment. Clinical trial success rates and drug approval timeliness are both improved by this method. Unfortunately, clinics are getting ready to record patients' complete genomic landscapes soon, whereas decisions are made using only a small number of molecular biomarkers in precision medicine applications used for early drug discovery. They expect AI to be at the forefront of developing novel analysis tools to tackle the challenge of deep multi-omics characterisation and find the best treatment regimens. This study looks at the existing situation of precision medicine drug discovery and presents the predictions for the future of AI in the fields of biomarker identification and medication design. Although Precision medicine is poised to revolutionise the healthcare sector, current methods are unable to fully harness the potential of molecular landscapes because they are overly focused on a small number of biomarkers. Next in line for advancements in precision

medicine is the use of AI algorithms to better understand patient heterogeneity across molecular profiles.

Sampene & Nyirenda (2024) examined the opportunities and risks highlighted by the use of AI in Chinese pharma sector. Recently, the pharmaceutical industry has seen a revolutionary advance and transition towards AI in the distribution of drugs and pharmaceutical procedures. Therefore, the purpose of this study is to investigate the pros and cons of AI for Chinese pharmaceutical companies. When it comes to pharmaceutical R&D, China is universally acknowledged as a world leader. The nation has integrated AI methods and tools to enhance the efficiency, development, and cost of the pharmaceutical business. To that end, this research examines the pros and cons of AI in the pharmaceutical and drug industries using a case study approach and a review of previous research. The study assessed AI throughout the drug discovery process in great detail. Drug repurposing, target identification, control, quality assurance, clinical trial optimisation, and an effective means of drug distribution are among the advantages listed by the research as AI's benefits. The research did find, however, that China's pharmaceutical business encounters some obstacles that affect the rate and depth of AI integration. Data and privacy concerns, a scarcity of trained workers, and an absence of standardised data are all obstacles. This study also includes three case studies: f XtalPi-AI-Enhanced Drug Discover, bio map: AI-accelerated drug development, and carbon: AI-driven precision medicine. and offered an in-depth evaluation of how these companies have boosted their drug discovery process through the application of AI. In addition to outlining best practices for pharmaceutical and drug delivery AI integration, the research offers policy recommendations.

Yadav et al. (2024) provided an outline of the ways in which artificial intelligence is changing the pharmaceutical industry, specifically in the area of medication research and discovery. New drug research and the treatment of complex disorders are two areas where

the pharmaceutical sector is vital. Nevertheless, the process of discovering new drugs is fraught with risk, expense, and delay. In the last few years AI has been a buzzword that has disrupted many industries and the health care business is not an exception. If you want to learn the general ideas of how AI helps in drug discovery, transforms pharma and boosts the speed of new drugs' development, you can read this brief. Contrary to organizational research, it is with AI that the research of drugs has made its revolution especially at the pharmaceutical level. Among the AI techniques, two of them that are rewiring and/or repositioning several stages of drug discovery are ML and DL. This study show how AI can identify targets, for leads, drugs design, drugs reposition and improve trials. Thus, there is a significant benefit in the integration of AI in the ability to improve the speed of new product development, reduce costs, and what is most important, improve the outcomes of treatment. The three primary constraints were identified as data accessibility, algorithm explanation ability, and legal issues as regards utilization of AI in pharmaceutical R&D.

Singh et al. (2023) explored the potential of personalized medicine, particularly in the context of "cardiovascular diseases" (CVD), by leveraging AI systems such as ML and DL. The dream of personalized medicine changes the diagnosis, treatment and prognosis assessing procedures, using the patient's specific methods. To do this, author used huge multivariate biological databases containing many variables that can include a person's genes, his or her phenotypes and the environment. Doctors can use this method to individualise early interventions for patients depending on the nature of their ailment or to prevent it in the future. In the case of risk assessment of specific types of cancer and CVD, AI technologies, including ML and DL have been highly effective. The study performed an in-depth analysis of the term "personalized medicine," exploring its basic concepts, the challenges it faces as a new field, and the revolutionary implications it could have in the field of CVD. Using the PRISMA criteria, 228 studies were chosen for inclusion. A scoping

review on the use of AI, and DL in CVD risk assessment for individuals is presented here. It highlights the potential for AI-powered personalised medicine to drastically enhance the precision and effectiveness of CVD control, hence transforming patient results. In addition to outlining possible future study topics, the page provides examples from real-world case studies.

Sourajyoti Goswami & Mohit Kumar Singh (2023) explored and highlight the transformative impact of AI on the pharmaceutical and healthcare sectors. Because AI has increased efficiency and accelerated innovation in many fields, it has revolutionized the healthcare and pharmaceutical industries. AI aids in the discovery and development of new medicines by predicting which drugs could be effective and by simulating their interactions with living systems. Improving patient care, AI-driven data analysis allows for more precise diagnoses, earlier illness detection, and individualized treatment plans. The precision of robotic surgery is greatly enhanced by AI-powered devices. The use of predictive analytics has helped cut down on pharmaceutical supply chain waste and medicine shortages. Because it can identify potential issues, AI is crucial for pharmaceutical safety monitoring. Chatbots make scheduling visits and asking medical queries easier, while AI-powered virtual health assistants are available 24/7 to provide information and advice. There are, however, ongoing concerns around data privacy, regulatory compliance, and ethical considerations. There is great potential for healthcare delivery and pharmaceutical innovation to be revolutionized by the growing convergence of AI with both industries.

2.9 Regulatory Compliance and AI in Pharmaceuticals

shaki et al. (2024) explored the significant influence of AI on the pharmaceutical sciences, particularly in drug discovery and development. New developments in AI might have far-reaching consequences for the biological and medicinal sciences. There are few

sectors as promising as the pharmaceutical business for the widespread use of AI. In comparison to more conventional methods, AI algorithms enable the efficient analysis of large datasets, which in turn shortens the time it takes to find potential new medicine candidates. Because AI can expedite the drug discovery process, new medicines for many ailments may become available. The research provides an analysis of how the law has developed with reference to AI and the different uses of the technology in the pharmaceutical industry. Analyzing the application of AI in pharmaceutical sector, the essay describes the major ethical and legal concern emerging from the uses. Another success story is AI, whose use in the identification of patients' data and possible lines of effective treatment can significantly enhance the approach to individualization of the treatment process. Machine learning can help doctors make better treatment recommendations as algorithms based on AI technologies take into account the individual genetic background and prior health history of a patient. Several health care sectors would gain a lot from the integration of AI such as drug discovery, targeted treatment, and drug manufacturing. With the use of data monitor and analysis through the help of AI, it is possible to manage a production line that will cater to quality control with little tolerance for error. Analysing real-world data will potentially greatly contribute to pharmacovigilance because AI will identify adverse medication reactions and other safety issues. This strategy should be advantageous to regulatory bodies together with businesses in the pharmaceutical industry since they can accurately identify and address medication risks. AI, if employed in the pharmaceutical industry, may significantly enhance, pharmacovigilance, and drug development, clinical and preclinical research, manufacturing, individualized medications and clinical trials, and other fields. HCAs can leverage the opportunity to enhance their medical interventions for patients, enhance their services' efficacy, and yet reduce costs by applying AI.

Vora et al. (2023) offered a theoretical and practical discussion of the role of AI already deployed in the field of pharmaceutics focusing on medicine development, formulation, and trialing. From the given data, it is now possible to turn to human knowledge to solve complex problems far faster leading up to the revolutionary advancement of AI. In recent years, there has been rapid advancement in AI and ML and this can be of immense benefit to Uganda's pharmaceutical dosage form testing, research and formulation industries. By applying artificial intelligence algorithms to billions of bytes of biological information, from genomics and proteomics to metabolomics, it might be feasible to discover disease-linked targets and predict how these targets will interact with probable medication candidates. Due to this, there is enhanced focuses and efficiency especially in medication research hence the improved odds on the pharmaceutical approvals in Uganda. Furthermore, with AI enabled enhancements of pharmaceutical R&D procedures in Uganda, the development costs reduce. It is now possible to predict Uganda's drug candidate pharmacokinetics and toxicity using ML abilities that also assist in trial design. With this capability, lead compounds can be enhanced and sorted out to reduce time and money used in animal testing in Uganda. The trends include using AI algorithms to analyze real patients' data for the development of individual medical taking. This will lead to better treatment regimens, more patient compliance in Uganda and thus better treatment outcomes. This study discusses how AI is generally applied in all areas of Ugandan drug research such as PK/PD, testing, optimization, delivery and development. This study, therefore, adopts this balance by analysing the advantages and disadvantages of various AI-based technologies applied in pharmaceutical technology in Uganda. Pharmaceutical business is continuously pursuing investment in and research on AI which will be of great benefit to enhancing medicine development processes and patient care in Uganda.

Wei & Nurhaliza (2024) analysed the measures and tools that companies in the pharmaceutical sector use to conform to the requirements within processes to guarantee the safety, efficiency, and quality of the pharmaceutical products. The efficacy and quality attributes of the pharmaceutical products that are in the market depend on the pharmaceutical process that must meet regulations. This work looks at the strategies and techniques that pharmaceutical businesses apply to obey all those strict requirements. This part provides thorough coverage related to the regulation landscape with a focus on key regulations guiding quality management systems like ICH Q10, EMA Guidelines and the FDA 21 CFR Part 11. The research extends focus on the role of advanced technology tools like; compliance management systems, documentation systems, and data analytics systems. The study finds out the best practices and challenges likely to be encountered in improving compliance by comparing case and current practices. Last but not the least it has highlighted how the pharmaceutical businesses can make their RCM mechanism more robust and urged to update it frequently as per the changing regulatory environment.

2.10 Ethical Considerations and Challenges in AI Application

Huriye (2023) discussed the principles in relative to the use and design of AI systems. It can be difficult to comprehend the decision-making process of AI systems due to their complexity and opacity. Since humans might not comprehend the elements that impact AI conclusions, this brings up questions of justice and responsibility. Concerns about AI's development and use were the focus of this research. A desktop research design was used for the investigation. Google Scholar was used to find books and journals that were relevant to the investigation. Other criteria included information concerning the use of AI, and its attributes; the specific subject matter involved ethics of AI. Of all the findings, it was identified that the most crucial ethical concerns in deploying AI include; inclusion and exclusion bias, privacy, responsibility and transparency. The study therefore

called upon all stakeholders – communities, researchers and lawmakers to understand and commit themselves to good ethical benchmarks. In case of ethical AI, several political, economic, and cultural issues, specific to Africa, should not be disregarded by the researchers. The primary topical ethical concerns applied to the area concern questions of bias, privacy of data, and the impact on employment. Much as it may be challenging, it is essential to bring together researchers, developers, and policymakers to set and enforce ethical guidelines to be adopted by these AI systems. These standards should be allied with the enhancement of people's well-being and the common welfare; they should address issues related to privacy, openness, responsibility, and prejudice.

Tatineni (2024) A Case of Harnessing Data Science and AI on the Ideas of Bias, Justice, and Responsibility. The first part is an introduction to the AI and data science proposals; the development of the field across years; and the ethical issues of modern technology. The study then goes on to build and expand the broad and somewhat confusing notion of prejudice and the various categories of bias, how the prejudice is realized the forms it takes in decision making and what is considered as prejudice in this regard. Following is the analysis of the issues concerning the definition of fairness in the context of AI, as well as its obstacles, and measures for evaluation. Accountability study identifies who is at fault for what and what the ethic and law implications are. Several samples of ethical integration in cases and the most significant ethical norms and guidelines of ethical issues are described. Therefore, this research seeks to offer its input into the current ongoing debate on how best the development of ethical technology should be continued by cautioning all the stakeholders.

Karimian et al. (2022) systematically identify and review the ethical issues associated with the request of AI in healthcare, highlight existing gaps in the literature, and propose steps towards an evidence-informed approach for addressing these ethical

concerns. Researchers must immediately address the significant ethical concerns raised by the increasing use of AI in healthcare. This comprehensive scoping review set out to do just that—to uncover the benefits and drawbacks of AI in healthcare, along with any ethical issues, knowledge gaps, and possible remedies supported by evidence. A PRISMA flowchart and previously defined inclusion criteria were used to identify the studies. Privacy, security, fairness, and respect for individual agency were among the outlined ethical principles. Out of 2,166 research returned by the search, 18 met the inclusion requirements and were thus chosen for data charting. A plethora research focused on a broad discussion about AI ethics. Nevertheless, most of the studies that were located failed to conduct comprehensive investigations of ethical issues pertaining to the creation or application of AI. When, on rare occasions, moral issues were considered, they were all given similar weight: privacy, fairness, explain ability, and the protection of human autonomy. There was a noticeable lack of emphasis on the idea of harm prevention. There is a serious dearth of evidence in practical tools that can be used to assess and maintain ethical standards over the whole lifecycle of AI-based technology. Furthermore, there is a significant lack of consideration for various stakeholders' viewpoints.

D'antonoli (2020) discussed the possible dangers and ethical concerns regarding the application of machine learning in radiology as well as underlined a point that governing AI should occur according to the same norms as the standard ethical and legal demands set for patients to prevent harm to them. Applications in the use of AI are likely to transform the use of healthcare and accelerate the research processes. There is nothing that can capture the heart of radiology in integrating AI into clinical practice, it has some implications in the diagnostic process. However, not every application of AI is a field of pride. It is very crucial to understand what hazards and risks relate to this new technology. This is because the patient's interests need to be safeguarded while applying AI in the

manner that has been widely held as ethical and legal over the years. When outlining the claims that make this literature, these matters are discussed based on the standards of biomedical ethics and concepts of general and specific artificial intelligence ethics.

Gao et al. (2023) With AI technology advancing at such a rapid pace, the advertising sector is facing both new opportunities and new challenges. The four main components of AI in advertising—targeting, personalisation, content creation, and ad optimization—are thoroughly examined in this ground-breaking study. The in-depth exploration of these areas reveals how AI can transform the advertising industry. Through a comprehensive literature review conducted using the VOS viewer software, this study identifies the inherent relationships between the following four components of AI advertising that rely on computational advertising: Who sees which ads is a mutual decision between targeting and personalisation. Ad Optimisation uses the results of the preceding three components to optimise ad displays for maximum return on investment; Content Creation uses AI during Personalisation to create engaging advertising content. Thus, to promote ethical and efficient use of AI technology for enhanced delivery of advertisement messages to the target audiences, this study presents a novel perspective of AI in the advertising domain.

Khanna et al. (2020) As noted many ethical issues have been raised concerning the use of AI in cancer research and therefore require scrutiny and analysis. Some of the research foci that this study examines ethical concerns about the application of DL and other types of AI in cancer care include screening, diagnosis, grading, prognosis, treatment response, precision cancer medicine, radiation, as well as classification of cancers. New advancements in CNNs and other DL algorithms have gone quite a long way in modifying the way of identifying and analysing the early symptoms of breast, colorectal, lung, and cervical cancer in cancer screening programs. However, with the appearance of such

an advancement, there are several ethical concerns; including matters concerning privacy, and consent, probable distribution of such applications that employ artificial intelligence in screening, and the reliability of the systems. Some new ethical concerns arise when DL is applied in cancer diagnosis, specifically about the interpretation of histopathology slides and other imaging. Issues include issues regarding prejudice of datasets utilized in training, the worst approach to guarantee the reliability of models once deployed for practice within a different population of patients and enormous pressure of searching for the balance between opportunities that come along with applying AI tools in healthcare decision-making and the value that comes with applying human intelligence in the same. Precision medicine, treatment response prediction, and AI models all contribute significantly to the process of customising medications for particular individuals. Important ethical factors to keep in mind include preventing unfair treatment by limiting AI biases, having open and honest conversations with patients about how AI might impact their treatment choices, safeguarding patient data and obtaining informed consent. Improvements in AI and DL have led to more exact planning and delivery of radiation treatments. As AI develops further, moral questions about its dependability in important domains, such as determining target volume and identifying organs at risk, will inevitably arise. Equal access to these cutting-edge technologies is another issue that has to be addressed, as is the integration of AI tools with the clinical competence of healthcare personnel settings. Moreover, this study emphasises the importance of legislation for data governance, AI systems that are clear and easy to understand, and ongoing collaboration between technology developers, healthcare practitioners, and ethicists.

Camilleri (2024) An increasing number of studies are bringing attention to the various ways in which organisations and customers can benefit from AI technologies. The pros and cons are covered by many writers. There is a dearth of contemporary research on

AI principles and controlling requirements for developers of expert systems, particularly those involved in ML and DL technologies. This study addresses a gap in the academic literature. The primary objectives of this donation are threefold: (i) Several players, such as technology corporations, governments, and “non-governmental organisations” (NGOs), have put forward proposals for AI governance frameworks. (ii) This section presents an inclusive analysis of the existing body of literature on AI governance and its connection to “corporate social responsibility” (CSR). (iii) The document outlines the fundamental aspects of AI governance and provides a comprehensive explanation of strategies to encourage principles such as transparency and responsibility, equity and inclusiveness, confidentiality and protection for users, as well as the mitigation of risks and cyber security concerns arising from AI systems. All stakeholders involved in the research, development, and upkeep of AI systems have social and ethical responsibilities and obligations to society's stakeholders, including customers, according to this study.

Chikhaoui et al. (2022) One of the most talked-about issues in the IT industry as of late has been ML. Despite its extensive participation in other industries, its entry into healthcare is relatively new. In the future, AI will have many uses, including diagnostics, drug discovery, personalised treatment, gene editing, illness prediction, and many more. In the long run, this innovation improves healthcare for everyone involved: doctors, hospitals, and patients. Investing in AI research and development is one of Saudi Arabia's long-term objectives, which is reflected in the country's healthcare focus. AI studies in Saudi healthcare are few and mostly centre on healthcare providers' points of view. There is a lack of discussion of this specific topic in the existing literature. First, to introduce the new “Personal Data Protection Law” (PDPL) in Saudi Arabia. Second, to study the use of AI in Saudi healthcare. Third, to discuss the policy questions, ethical and legal challenges, and benefits of AI in Saudi healthcare. Fourth, to study the acceptance of AI by professionals.

Fifth, to introduce the recently enacted Saudi Arabian PDPL. Sixth, to talk about the future of AI in Saudi healthcare. This is why four well-known hospitals in Saudi Arabia were polled. There was hope that AI may improve health, reduce healthcare costs, and increase operational efficiency. Nearly everyone who participated in the poll saw parallels and differences between AI and innate human intelligence.

Ibrahim et al. (2024) Thanks to AI's rapid development, it is now used extensively in many fields, including banking, healthcare, the military, and even the workplace in industrialised nations. Nevertheless, this dependence has sparked worries about the regulation of AI, specifically around gender, age, race, and skin colour biases in algorithms. Regulators and ethical frameworks have been put in place by numerous nations to tackle these problems. A major step forward is the incorporation of AI into Jordan's 2022 plan by the Ministry of Digital Economy and Entrepreneurship. An example of this dedication is the use of AI in educational programs. Nevertheless, it is critical to deal with the possible negative effects of AI. The study provides rules and ethical considerations for AI to go along with what Jordan is doing. The research is focused on creating ethical norms in Jordan to encourage responsible usage of AI. It lays out methods for detecting and reducing age, gender, and race bias in AI results and datasets. Results from the study's comprehensive testing on datasets and analysis of around 100 photographs show significant error rates, such as 16% when it comes to skin colour detection, 4% when it comes to white face detection, and 6% when it comes to female over male identification. Consequently, Jordan has to establish rules and ethical guidelines for AI uses.

Guo Hong (2022) Extensive ethical considerations have been stimulated by the widespread use of AI in various areas of medicine, including diagnostic imaging, mental health, rehabilitative medicine, and home health support. This research examines topics such as data accessibility and privacy protection from a medical ethics standpoint, value

judgements and trust issues about AI technology, the concept of various relationships that arise from machine use, and the contentious status of moral subjects of AI machines. Additionally, it highlights the possibility of unfairness, discrimination, and risk liability stemming from AI and demands the creation of a collaborative governance framework for AI that is thoroughly integrated with technology, as well as an ethical review process.

2.11 Critical Analysis and Synthesis of Existing Studies on AI in Pharmaceutical Manufacturing

The literature on Artificial Intelligence (AI) in pharmaceutical manufacturing highlights a transformative impact across various domains, including quality control, decision-making, process optimization, supply chain management, and personalized medicine. However, significant gaps persist, particularly regarding the challenges of AI implementation, regulatory compliance, data management, and cost considerations.

1. AI's Role in Pharmaceutical Manufacturing and Its Challenges

Several studies affirm the potential of AI in enhancing pharmaceutical production efficiency. Saha et al. (2023) and Arden et al. (2021) emphasize how AI-driven quality control techniques, such as image recognition and computer vision, improve defect detection and data-driven decision-making. Similarly, Sumedh M Bodade et al. (2023) introduce the concept of Pharma 4.0, where AI and Industry 4.0 technologies revolutionize pharmaceutical production. However, these studies acknowledge critical barriers, including regulatory constraints, integration difficulties, and workforce skill gaps.

While studies like Mehta et al. (2023) advocate AI's role in predictive maintenance and production optimization, others, such as Kulkov (2021), indicate that AI adoption is fragmented across different business sizes, with large firms leading in AI-driven sales, marketing, and production, while smaller firms struggle with resource constraints.

2. Regulatory and Ethical Barriers to AI Adoption

Regulatory challenges emerge as a recurring theme across multiple studies. Arden et al. (2021) and Patil et al. (2023a) highlight the friction between Industry 4.0 regulations and legacy compliance frameworks, which were designed for traditional manufacturing. Similarly, Lodhi et al. (2022) and Kimta & Dogra (2024) underscore how compliance requirements, data privacy, and security concerns hinder AI adoption, particularly in emerging markets like India.

Karimian et al. (2022) and Tatineni (2024) identify ethical issues, including bias in AI algorithms, transparency concerns, and the potential for AI-driven automation to displace human workers. These studies advocate for AI governance frameworks but fail to provide concrete, actionable strategies to ensure compliance while enabling innovation.

3. Impact on Pharmaceutical Supply Chains

AI's integration into supply chain management (SCM) has been widely studied, with Guo (2023) demonstrating AI's role in optimizing logistics, inventory, and quality assuranc for pharmaceutical firms like Pfizer and Merck. However, Abdollahi et al. (2023) and P. Shah (2021) highlight vulnerabilities in supply chain digitization, especially concerning disruptions during the COVID-19 pandemic. While AI can enhance supply chain transparency and fraud detection, concerns remain over high implementation costs, interoperability challenges, and data governance issue.

4. AI in Drug Discovery and Personalized Medicine

Advancements in AI-driven drug discovery and precision medicine are well-documented (Boniolo *et al.*, 2021; Yadav *et al.*, 2024). AI accelerates drug screening, formulation, and clinical trials, significantly reducing time and costs. However, Singh et al. (2023) caution that AI-based personalized medicine still faces hurdles, such as data

standardization and algorithmic bias. These concerns align with D'antonoli (2020), who stresses the lack of regulatory clarity in AI-driven drug development.

5. Gaps in the Literature

Despite these extensive discussions, the literature reveals several critical gaps:

- **Lack of empirical validation:** Many studies present theoretical benefits of AI but lack real-world case studies or longitudinal data to assess long-term impacts.
- **Limited focus on SMEs:** Research predominantly examines AI adoption by large pharmaceutical firms, with minimal exploration of how small and medium-sized enterprises (SMEs) navigate AI integration.
- **Regulatory harmonization challenges:** Studies emphasize compliance barriers but do not propose clear pathways for global regulatory alignment to facilitate AI adoption.
- **Human-AI collaboration:** While automation is extensively covered, there is insufficient discussion on how AI and human expertise can coexist to enhance decision-making and minimize risks.

The existing body of literature affirms AI's transformative potential in pharmaceutical manufacturing, but significant hurdles remain. Future research should focus on empirical case studies, regulatory harmonization strategies, SME adoption models, and AI-human collaboration frameworks to bridge these gaps and facilitate AI's seamless integration into the pharmaceutical industry.

CHAPTER III:
METHODOLOGY

3.1 Overview of the Research Problem

Since the current production of pharmaceutical products is characterised by high dynamism, integration of AI in pharmaceutical production can improve productivity, quality of the product, cost and compliance with regulatory standards. Nevertheless, the application and instantiation of open source of AI in manufacturing pharma products has not been without its problems such as regulatory, data acquisition and management, integration, cost and technological among others. These are transformations that pose risks to the future growth of the AI industry because it makes it difficult for organisations to not just adopt best in class technologies, but also to utilise the technologies to the maximum.

This is an exciting period for the pharmaceutical industry, especially considering the ways that the industry is bringing in new technologies for production, including AI. Using AI within the pharmaceutical manufacturing process benefits include better productivity, better quality of drugs produced, reduced costs, and compliance to set standards. Such advantages have established AI as an appealing approach to mitigating the challenges that are an inevitable precondition of drug manufacturing, which relies on calculated accuracy, sectoral effectiveness, and innovative comparative benefit. However, the application of ai in the production of medical products in the pharmacy is characterized by some challenges which hinder is growth and its full utilization.

Some of the main issues include compliance with various regulatory requirements. The pharmaceutical industry is highly controlled, and automation through the use of AI in manufacturing processes has to comprise regulatory facets to produce safe and effective products. Currently, there is no clear regulation for using AI in drug manufacturing;

authorities, including the Europe, have not figured out how to regulate AI in drug manufacturing (Stingl, Fuglsig and Hoveling, 2023).

Another key challenge is data management. For AI to be effective it requires extensive data sets to implement its functionalities. Further, acquiring and managing high-quality data in the pharmaceutical market is difficult and time-consuming (Hole, Hole and McFalone-Shaw, 2021). Challenges that involve data handling, including privacy and security, as well as compatibility with other computer programs, hinder the effective integration of AI solutions as organisations have to address these hurdles while protecting such information.

Moreover, the expenses incurred during the integration of AI present a significant threat since pharma majors and newly established SMEs cannot afford such investments easily. Coming with a price tag, the capital intensity involved in procuring the technologies, the constant capital outlay required to sustain and enhance the systems, and the prospect of potentially huge expenses place a check on organisations from going all out to embrace AI. This is made worse by technological growth that is very fast, and this just makes some systems outdated within a short period (van der Loos et al., 2024).

However, AI implementation in pharmaceutical manufacturing is not smooth due to other technological integration problems. AI's implementation with legacy systems and making them compatible with the existing production setting is quite intensive and complex. Lack of procedure in handling patients and requiring professional skills and services may take much time, leading to a slow manufacturing process flow (Dinçkol, Ozcan and Zachariadis, 2023).

This imply that there is a need for future studies on the antecedents and consequences of AI adoption in the context of pharmaceutical manufacturing (Sampene and Nyirenda, 2024). These are the obstacles that should be unfolded in order to make the

introduction of new artificial intelligence technologies possible – these technologies are essential for creation of new, safer and more effective drugs.

3.2 Operationalisation of Theoretical Constructs

In other words, the operationalization of theoretical constructs means making theoretical concepts actionable and measurable so that they could be tested statistically. For the purpose of the research on the issues arising from AI implementation in pharmaceutical manufacturing industry, constructs such as regulatory implications, data management concerns, integration struggles, cost and investment concerns, technological limitations and impacts on performance metrics that enables the measurement of the level of efficiency, quality and regulatory compliance are important.

Regulations, in general, can be detected by items that reflect views relating to the extent to which receptive and transparent the regulations for AI developments (Palaniappan, Lin and Vogel, 2024). For instance, the assessment of a statement like "The regulatory environment is gradually becoming more AI friendly in pharmaceutical manufacturing," may have responses from a Likert scale that include Strongly Disagree, Disagree, Neutral, Agree, Strongly Agree. This approach is very helpful indeed because it is able to capture some form of agreement in relation to the changes in regulation at varying degrees.

Among them, the issues can be measured by statements that capture effects of data in relation to some factors such as the quality of data and how to address big data are important factors to be considered in AI project. For instance, "Data quality issues has hindered the progress of the AI project" and "Data management systems are well suited depending on amount of data generated by the AI applications" assesses Data readiness systems.

Integration challenges, therefore, are captured by questions such as: “Our current infrastructure allows for the integration of AI technologies’’(Blanco-González *et al.*, 2023). Likewise, the financial issues such as, the rationale of having to justify expenses for AI and the available resources can be articulated as “The capital needed to put in place the AI technologies is justifiable based on associated value of such investment.”

Technological factors such as performance of the AI systems and reliability are measured by statements made about investment made in technology and incidence of technical problems. These constructs are essential in defining the level of effectiveness of AI in pharmaceutical environments.

Other outcomes with specific performance measures such as quality, productivity, cost reduction and sustainability are also captured by Likert scale items. For instance, “AI systems have enhanced reduced cases of defects in drug products” is an example of quality, while “use of AI in automation has reduced on man-caused mishaps in the process of production” is an example of the increase in production efficiency (Davenport and Ronanki, 2018). Sustainability/regulation phrases which are ‘With the use of AI technologies, our manufacturing is more sustainable now’ and ‘AI technology in the manufacturing industry makes it easier to achieve better regulatory standards of compliance.

If these constructs are adopted, it is possible to determine and compare the statistic results of the enumerated AI implementation challenges to the performance outcomes using other approaches such as Spearman Rank-Order Correlation Coefficient (SCC) and Simple Linear Regressions.

3.3 Research Purpose and Questions

This study aims at filling this knowledge gap by undertaking an analysis of the current state of integration of AI in pharmaceutical manufacturing; various challenges that

hinder the optimal utilization of this technology; and impact of the challenges on firm performance in the production of pharmaceuticals.

Thus, this study was highlight and discuss these challenges so that adequate recommendations to solve them and make AI adoption easier in the manufacturing of drugs can be provided. More specifically, the following research questions have been addressed:

- **RQ1:** What is the Current situation of AI applications in Pharmaceutical Manufacturing?
- **RQ2:** What are the Key Challenges Associated with AI Implementation in the manufacturing process of pharmaceutical industry?
- **RQ3:** How do the AI Implementation influence the Pharmaceutical Manufacturing?
- **RQ4:** What are the actionable recommendations to overcome the identified challenges and facilitate the successful integration and utilization of AI technologies in pharmaceutical manufacturing?

3.4 Research Design

The research method for investigating the state and prospects of AI in the pharmaceutical manufacturing process entails using a quantitative method (Long, 2013) to survey the degree of AI implementation, the problems associated with implementation, and the extent of the problems' effects on organisational performance. The research used a structured survey method to gather information from a sample of pharmaceutical manufacturing firms with integrated artificial intelligence applications. Some of the variables that the survey needed to address include the current status of AI use, the different categories of AI applications that exist (for instance, predictive modelling, automation, and quality assurance), and general and concrete implementation problems that firms may

encounter (for instance, technology compatibility troubles, regulatory requirements, training of employees) (Lee, 2023).

Quantitative research enables objective measurement, statistical analysis, and generalization of findings, making it suitable for examining relationships between key variables such as regulatory compliance, data management, cost, and technological integration (Saunders, Lewis and Thornhill, 2009; Weyant, 2022). This approach enhances reliability and validity by minimizing researcher bias and ensuring replicability through structured data collection methods. Given the data-driven nature of pharmaceutical manufacturing, quantitative analysis facilitates empirical evaluation and evidence-based recommendations. Furthermore, it supports hypothesis testing and predictive analysis, essential for understanding AI's impact on operational efficiency and product quality (Hair et al., 2022). Thus, this design aligns with the study's objective of providing structured, measurable insights into AI adoption and its associated challenges.

The quantitative data was descriptive and therefore analysed using statistical tools to establish trends in the responses concerning the estimated level of AI application and the challenges encountered. Regression analysis was used to establish how these challenges affected the business's overall goals, mainly regarding productivity, reduced costs, and quality of products (Sarstedt and Mooi, 2014). The frequency and distribution of various challenges that firms encounter were summarised using descriptive statistics. Moreover, Spearman's rho correlation analysis was used the same studies the level for various challenges and level of AI integration.

3.5 Population and Sample

According to the type of research conducted in the pharmaceutical manufacturing with applications in Artificial Intelligence, the target population comprises of firms operating in the pharmaceutical industries with Inc. and adoption of AI in manufacturing

their products. This population comprises large multinationals and small specialized firms, and it forms a diverse group (Ghoshal and Bartlett, 1990). To increase the generalizability of the findings, the research adopted the stratified sampling technique where the population is divided into categories also known as strata based on company size, geographical location and the type of application of AI. This approach enables a cross sectional analysis of the level of AI implementation within various contexts within the pharmaceutical industry.

The sample was derived from a population list of pharmaceutical manufacturers who integrate AI in production. Out of this list some few companies were selected in proportionate to the number to represent their respective industries. The survey was conducted using a structured questionnaire that was responded to by IT managers and other organizational personnel most directly involved in implementing the use of AI in the company. This survey collects details about AI usage intensity, AI application types, and problems encountered during implementation (Regona et al., 2022). Through landmarking these stakeholders, this study will be able to offer comprehensive insight on how the application of AI in pharmaceutical manufacturing, the challenges faced in the process and thus ensuring the study offer a holistic view of AI in the context of the pharmaceutical manufacturing industry. In the present study, the participants were 300 in number.

The chosen population and sample size ensure a comprehensive analysis of AI integration in pharmaceutical manufacturing. By targeting firms that adopt AI, including both large multinationals and specialized SMEs, the study captures diverse industry perspectives. The use of stratified sampling enhances representativeness by categorizing firms based on size, location, and AI application type, allowing for a more nuanced cross-sectional analysis. A structured questionnaire targeting Research & Development SMEs, Regulatory SMEs, Manufacturing SMEs, IT managers and key personnel ensures data

reliability, as these stakeholders directly influence AI implementation. The selected sample of 300 participants provides sufficient statistical power to derive meaningful insights into AI adoption, challenges, and its impact on pharmaceutical manufacturing.

Participant Selection

Inclusion Criteria:

1. **Pharmaceutical Industry Firms:** Participants include the membership of a firm in the pharmaceutical manufacturing and management business.
2. **Experience with AI Technologies:** The participants should have prior experience with use of AI technologies, more so in production where they can work for instance in data analysis, drug discovery, quality control, or predictive maintenance.
3. **Decision-making Roles:** The participants were expected to be decision-makers or supervisors implementing, planning or performing AI solutions (such as managers, researchers, or developers).
4. **Geographical Scope:** This means that, based on the study's objective, participants may be selected from firms in certain areas of operation or certain countries where pharmaceutical firms are implementing AI.
5. **Company Size:** The study considered companies of any size, regardless of their size, if they could continue to engage in the process of integrating AI technologies.

Exclusion Criteria:

1. **No AI Exposure:** Companies or actors which do not implement or have no contact with AI technologies in their production line.
2. **Non-manufacturing Roles:** People who do not work directly for a manufacturing company in pharmaceutical operations or technology management, as well as employees in other pharmaceutical subsectors such as marketing and distribution.

3. **Lack of Decision-making Authority:** The remaining employees may not have any input on the strategies their firm applies to AI or the issues faced in this application of the technology.
4. **Firms in Early Adoption:** Companies that have not gone beyond the exploration or even the conceptualisation stage of AI use but do not have live applications in manufacturing may be candidates.

3.6 Instrumentation

Challenges:

Statement	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
The regulatory environment is evolving in a way that supports AI innovations in pharmaceutical manufacturing.					
Regulatory requirements for AI in pharmaceutical manufacturing are clear and well-defined.					
Data quality issues have caused delays in AI project development.					
Data Management Challenges					
Data quality issues have caused delays in AI project development.					
The quality of data used for AI projects is consistently high.					

Data management systems are well-suited to handle the volume of data generated by AI applications.					
Integration Challenges					
Our current infrastructure supports seamless integration of AI technologies.					
Integration of AI solutions has caused disruptions to our manufacturing operations.					
Technical support for AI integration is readily available and effective.					
Cost and Investment Challenges					
The initial investment required for AI technologies is justifiable by the expected benefits.					
Our organization has access to sufficient financial resources for AI adoption.					
Technological Challenges					
AI systems we use have high levels of reliability and performance.					
Our organization invests adequately in technological advancements for AI.					

Implementation of AI in Pharmaceutical Manufacturing

Statement	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

The technology required for AI implementation is readily available and accessible.					
There is a lack of skilled personnel to manage and maintain AI systems.					
Our organization invests adequately in technological advancements for AI.					
AI systems we use have high levels of reliability and performance.					
Upgrading our technology infrastructure to support AI is challenging and resource-intensive.					
We face frequent technical difficulties when implementing AI technologies.					

Statement	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
Quality of Drug Products					
AI systems have contributed to reducing the number of defects in drug products.					
AI-driven quality control processes are more reliable than traditional methods.					
Production Efficiency					
AI systems have reduced the time required for drug manufacturing.					

AI-driven automation has reduced human errors in the production process.					
Cost of Manufacturing					
Long-term cost savings have offset the initial investment in AI.					
Implementing AI has minimized waste, contributing to cost reduction.					
Sustainability					
AI technologies have contributed to making our manufacturing processes more sustainable.					
AI-driven optimisation has led to a reduction in energy consumption during production.					
Regulatory Compliance					
Implementing AI has improved our ability to adhere to industry regulations.					
AI implementation has helped reduce the risk of non-compliance in our operations.					

3.7 Data Collection Procedures

In this study the data was collected in a systematic manner. The survey was designed to collect metrics key to AI adoption and the original types of technologies and the typical issues organizations experience. In order to reduce the ambiguity of the questions, the survey was pre-tested on a small group of people.

The survey was then conducted using Google Forms since it is accessible and easily manageable regarding the responses received (Vasantha Raju and N.S., 2016). Participants were recruited through e-mail invitations, where insistence was made to only those who

offer their services to a pharmaceutical manufacturing firm with experience in AI technologies. The distribution was done using email or a professional network that provided an opportunity to respond within two to four weeks with additional follow-ups to encourage high respondent rates.

Using Google Forms, questionnaires were created and responses were always checked frequently. Upon the completion of the collection period the collected data was sorted and checked for the completeness and accuracy of the data collected. It was appropriately archive and backed up to enhance its security and ensure privacy. Regarding the study's objectives, preliminary reviews and statistical analysis were done to examine the effect of innovation Adoption of AI and Implementation Challenges.

3.8 Data Analysis

The study involved data analysis using SPSS software (Nagaiah and Ayyanar, 2016). To this end, several statistical tools were deemed adequate to integrate data understanding.

To commence with, Descriptive Statistics were used to ‘describe’ the research data, that is, presenting basic analysis of the gathered data (Kaur, Stoltzfus and Yellapu, 2018). This involved calculating means, medians, standard deviations and frequencies to determine rates of AI uptake, type of technologies most organisations were using and the level of implementation challenges they faced. This was done using descriptive analysis as it helped in general observations of the data sample in the data set.

Correlation was also used in order to compare the correlation between some of the studies as indicated below (Senthilnathan, 2019). In this research work, the researcher desired to find out how some variables are related and they include; the level of AI application and the particular issue dealt on. Coefficients of correlation as to how strong

and the direction of these relationships would come out indicating how aspects of implementing AI are related.

In addition, the study used Regression Analysis to analyse the impact of AI adoption towards the organisational performance factors and the potential impact of the challenges toward the success of the AI application (Aviral Gupta, Akshay Sharma and Dr. Amita Goel, 2017). Thus, this technique allowed for modelling the dependent and independent variables and, thus, defined which of these variables might be potential predictors of successful integration of AI as well as what certain challenges could impact the results.

In general, the application of the SPSS software helped provide organized insight into the analysis of the data collected, a view into the use of AI in the pharmaceutical manufacturing industries and the issues that may surface during the process.

3.9 Research Design Limitations

This section discusses the limitations experienced during this research.

1. **Sample Size and Representativeness**: Organizational effects are one of the potential limitations of the study since the sample could not necessarily represent the variability in the industry. Thus, while stratified sampling helped include different sizes and types of companies, stronger, larger or more advanced firms would be overrepresented, while smaller, less tech companies would be underrepresented. This limitation can limit the generality of the results across all the pharmaceutical manufacturing firms.
2. **Response Bias:** This can lead to response bias since the results depend on people's responses to survey questions. The problem with this is that participants may give socially desirable responses or may not be truthful about the issues they encounter

while employing AI. This could reduce the reliability of the conclusions about the current situational analysis of the AI implementation and the issues involved.

3. **Survey Design Constraints**: The issues arising from the implementation of AI might elude some facets, which may be hard to grasp even after pre-testing the survey (Maragno *et al.*, 2023). Despite the advantage of a structured format that enables a quantitative approach, this may obscure more detailed or firm-specific issues that may be loadings that vary according to context and which may be important factors influencing the use of AI.
4. **Regulatory and Technological Evolution:** The study was done within an environment that sometimes has fixed rules and regulations and, other times, can be rapidly advancing in the field of technology. This means that by the time the results are out, some other regulations may have changed, or there might be new developments in AI technology that was alter the results. Therefore, it is applicable that the conclusions drawn from this study could be out-dated by current conditions.
5. **Data Management and Quality:** Because such concerns pertain to data quality and data management, where there can be data discrepancies or missing data, the validity of the analysis might be compromised (Munappy *et al.*, 2022). As much as some measures were put in place to ensure that the data collected was complete and accurate, any issues with data quality that may have been experienced may affect the statistical tests.
6. **Generalizability of Findings:** It may also be pertinent to indicate that this study's focus on the AI implementation issues within pharmaceutical manufacturing may not be generalisable to other industries or sectors. More general findings cannot be made due to the specific nature of the study's context, namely, the pharmaceutical manufacturing industry and its regulatory and technological characteristics.

3.10 Conclusion

The research methodology successfully addresses the issues of AI deployment in pharmaceutical production by using a quantitative method, including structured questionnaires and descriptive statistics. Through a cross-sectional survey of pharmaceutical firms, the study examines AI adoption, perceived challenges which include regulatory concerns, data handling, costs, and technology, and their effects on performance. Regression analysis and Spearman's correlation were used to examine the impact of these challenges on productivity, cost and quality. While there are limitations in the form of response bias and evolving regulations, the methodology provided some valuable understanding; results are not necessarily generalizable across industries.

CHAPTER IV:

RESULTS

4.1 Reliability Statistics

Table 4.1: Reliability Statistics

Cronbach's Alpha	N of Items
0.918	26

A Cronbach's Alpha of 0.918 for 26 items shows excellent reliability, meaning items consistently measure the same construct and are suitable for use.

4.2 Frequency Analysis

Table 4.2: Demography Details

		Frequency	Percent
What is your Gender?	Male	273	91
	Female	27	9
What is your age?	18-24 Years	16	5.3
	25-34 Years	60	20
	35-44 Years	147	49
	45-54 Years	75	25
	55 Years and above	2	0.7
What is your highest level of education?	High School Diploma	14	4.7
	Bachelor’s Degree	94	31.3
	Master’s Degree	160	53.3
	PhD or Doctorate	27	9
	Other	5	1.7
What is your current role in the pharmaceutical industry?	Research & Development	59	19.7
	Manufacturing Operations	117	39

	Quality Control/Assurance	67	22.3
	Regulatory Affairs	5	1.7
	Other	52	17.3
How many years of experience do you have in pharmaceutical manufacturing?	Less than 1 year	16	5.3
	1-5 years	31	10.3
	6-10 years	42	14
	11-15 years	71	23.7
	More than 15 years	140	46.7

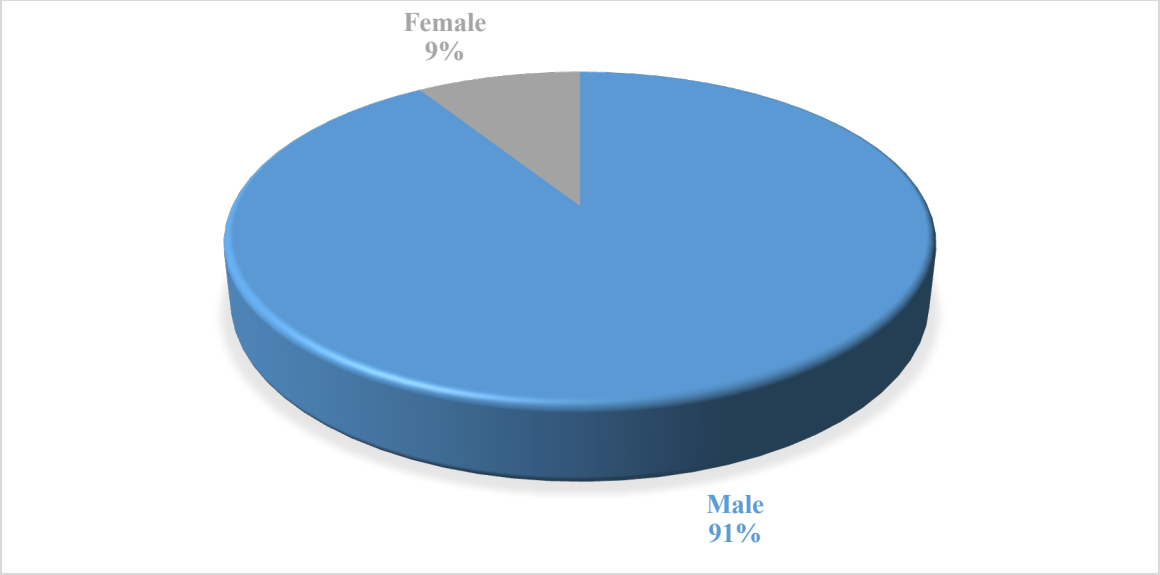

Figure 4.1: What is your Gender?

The gender distribution shows that out of 300 respondents, a significant majority are male, with 273 participants (91%), while only 27 participants (9%) are female. The findings indicate that there are significantly more men than women in the sample.

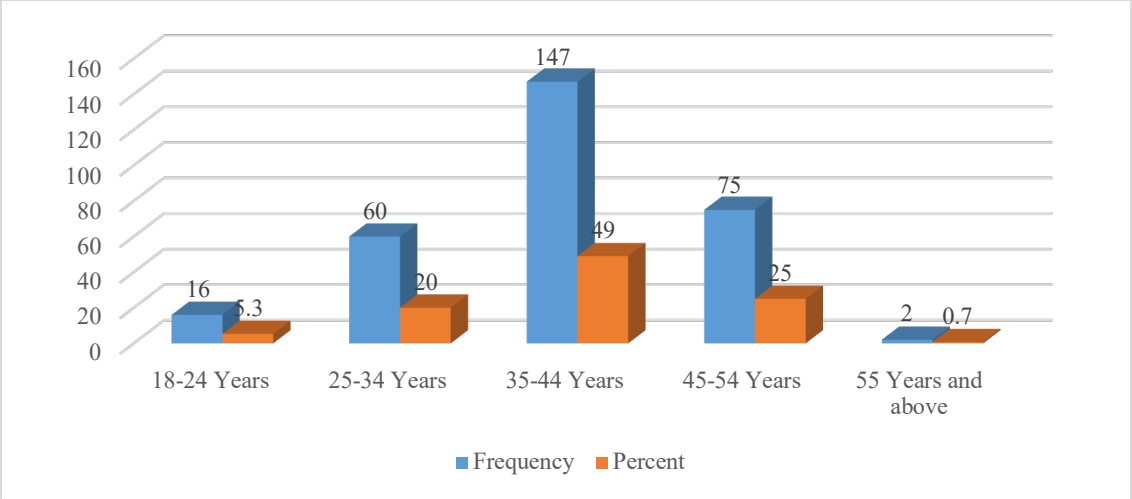

Figure 4.2: What is your age?

Among the respondents, those between the ages of 35 and 44 make up the biggest demographic, accounting for 49% of the total sample size (147 individuals). Next, there are 75 people in the 45-54 age bracket, making up 25% of the total, and 60 people in the 25-34 age bracket, making up 20%. Younger respondents aged 18-24 make up only 5.3% (16 participants), while those aged 55 and above represent the smallest portion, with just 0.7% (2 participants).

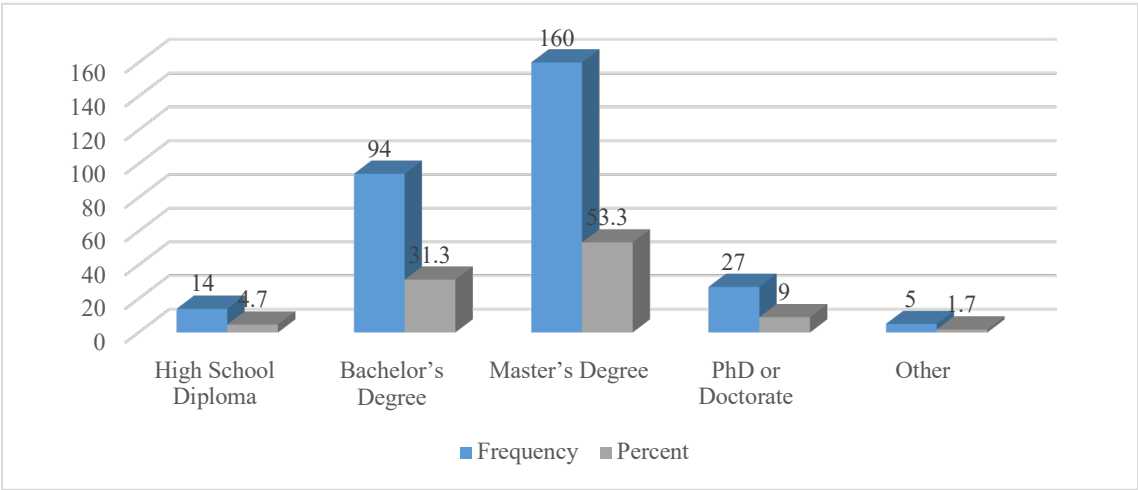

Figure 4.3: What is your highest level of education?

The educational background of respondents reveals that the majority hold a Master's Degree, accounting for 53.3% (160 participants) of sample. This is followed by those with

a Bachelor's Degree at 31.3% (94 participants). Respondents with a PhD or Doctorate make up 9% (27 participants), while 4.7% (14 participants) have a High School Diploma, and 1.7% (5 participants) selected "Other."

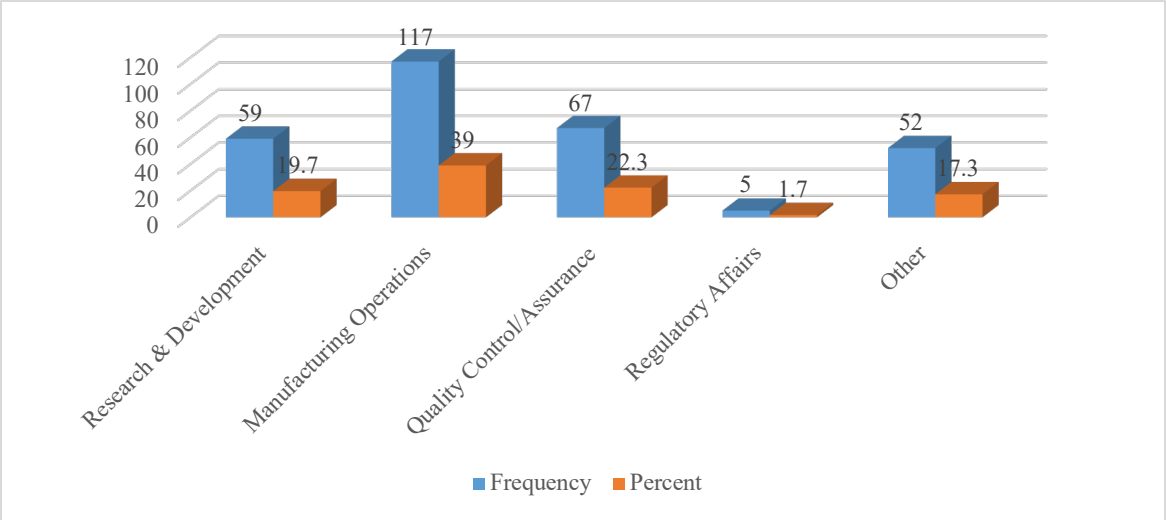

Figure 4.4: What is your current role in the pharmaceutical industry?

The respondents' roles in pharmaceutical industry show that the largest group works in Manufacturing Operations, comprising 39% (117 participants). This is followed by those in Quality Control/Assurance, making up 22.3% (67 participants), and Research & Development, with 19.7% (59 participants). A smaller proportion, 17.3% (52 participants), selected "Other," while only 1.7% (5 participants) are involved in Regulatory Affairs.

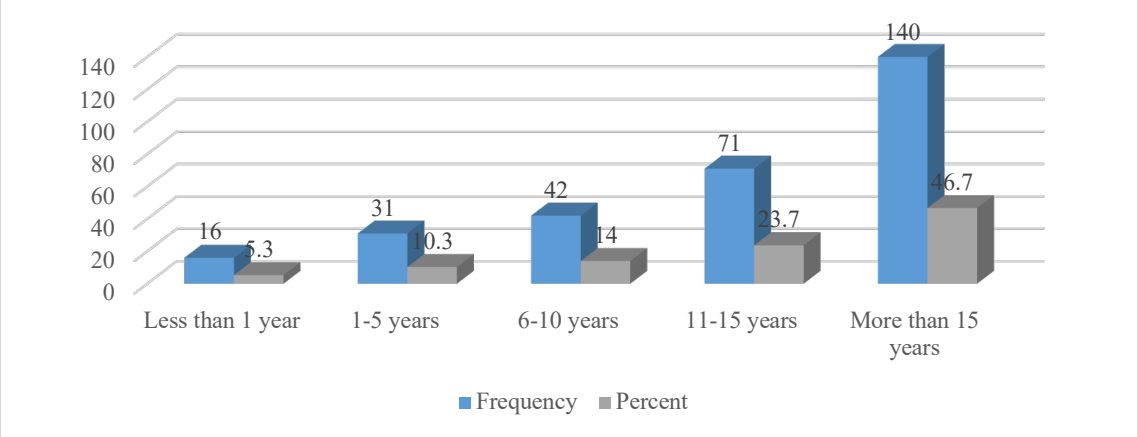

Figure 4.5: How many years of experience do you have in pharmaceutical manufacturing?

The experience distribution in pharmaceutical manufacturing shows that the majority of respondents (46.7%, 140 participants) have more than 15 years of experience. This is followed by those with 11-15 years of experience, comprising 23.7% (71 participants). A smaller proportion of respondents have 6-10 years of skill (14%, 42 participants), 1-5 years (10.3%, 31 participants), and less than 1 year (5.3%, 16 participants).

Table 4.3: Challenges in Implementations of AI in Pharmaceutical Manufacturing

		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
Regulatory guidelines hinder AI adoption in pharmaceutical manufacturing.	Frequency	40	43	82	62	73
	Percent	13.3	14.3	27.3	20.7	24.3
The approval process for AI-based systems is time-consuming and complex.	Frequency	60	54	71	65	50
	Percent	20	18	23.7	21.7	16.7
Data quality issues have caused delays in AI project development.	Frequency	50	46	78	73	53
	Percent	16.7	15.3	26	24.3	17.7
The quality of data used for AI projects is consistently high.	Frequency	20	22	55	93	110
	Percent	6.7	7.3	18.3	31	36.7
Integration of AI solutions has caused disruptions to our manufacturing operations.	Frequency	73	64	81	42	40
	Percent	24.3	21.3	27	14	13.3
Technical support for AI integration is readily available and effective.	Frequency	28	47	74	69	82
	Percent	9.3	15.7	24.7	23	27.3
The initial investment required for AI technologies is justifiable by the expected benefits.	Frequency	24	26	60	94	96
	Percent	8	8.7	20	31.3	32
	Frequency	26	46	71	83	74

Our organization has access to sufficient financial resources for AI adoption.	Percent	8.7	15.3	23.7	27.7	24.7
AI technologies are not fully mature for use in pharmaceutical manufacturing.	Frequency	36	51	87	58	68
	Percent	12	17	29	19.3	22.7
Lack of skilled personnel to operate AI systems is a significant challenge.	Frequency	23	23	52	86	116
	Percent	7.7	7.7	17.3	28.7	38.7

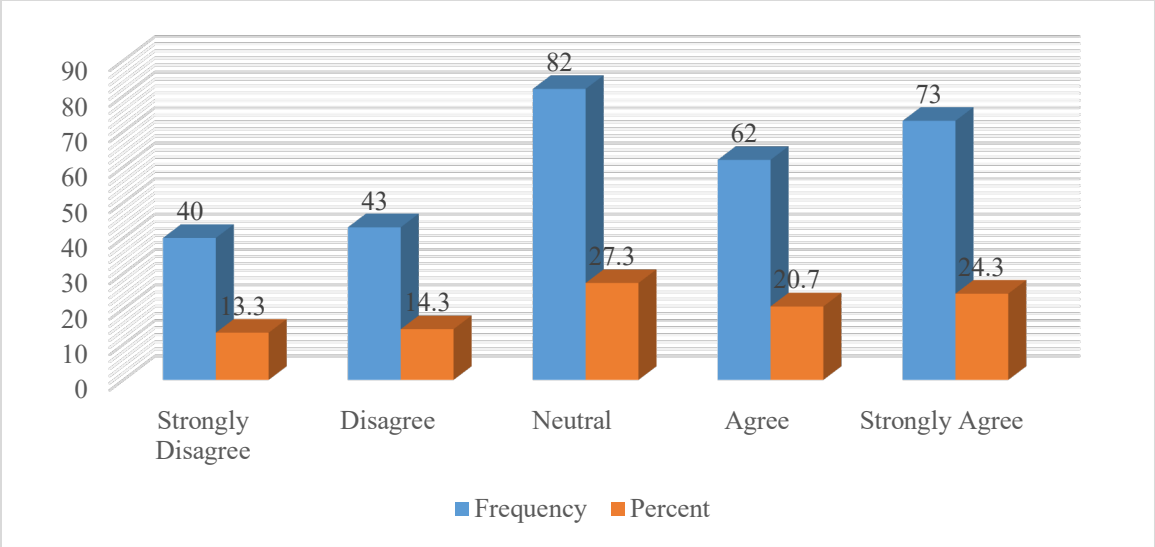

Figure 4.6: Regulatory guidelines hinder AI adoption in pharmaceutical manufacturing.

The responses to the statement "Regulatory guidelines hinder AI adoption in pharmaceutical manufacturing" show a mixed opinion. A significant portion of respondents strongly agree (24.3%, 73 participants) or agree (20.7%, 62 participants) with the statement, suggesting that they believe regulatory guidelines pose a barrier to AI adoption in the industry. On the other hand, 13.3% (40 participants) strongly disagree, and 14.3% (43 participants) disagree, indicating that a smaller proportion do not view regulatory guidelines as an obstacle. Additionally, 27.3% (82 participants) remained neutral, neither agreeing nor disagreeing.

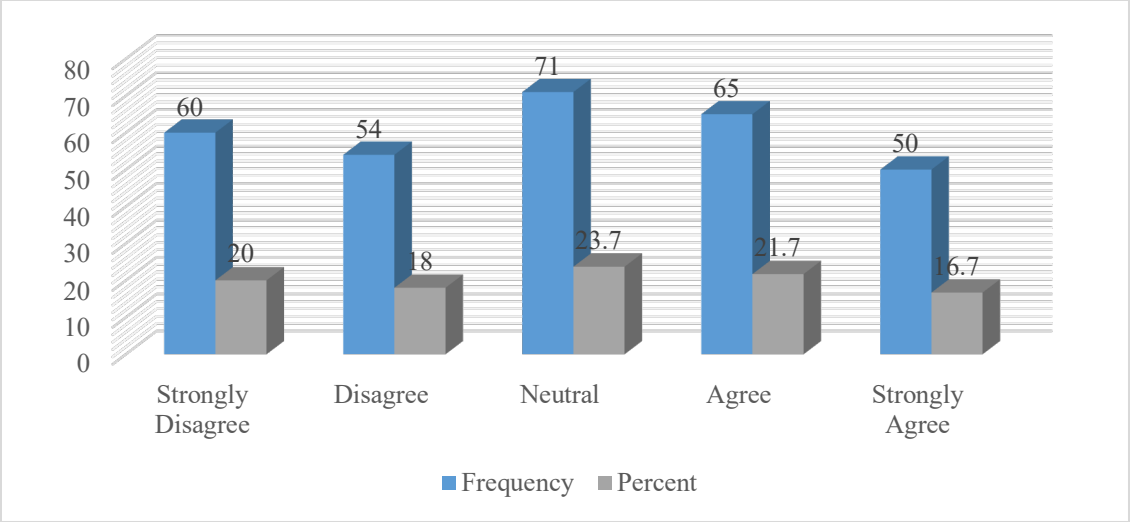

Figure 4.7: The approval process for AI-based systems is time-consuming and complex.

The responses to the statement "The approval process for AI-based systems is time-consuming and complex" show a divided perspective. A notable portion of respondents disagree with the statement, with 20% (60 participants) strongly disagreeing and 18% (54 participants) disagreeing, suggesting that they do not find the approval process overly time-consuming or complex. However, 21.7% (65 participants) agree and 16.7% (50 participants) strongly agree, indicating that a significant number believe the process is indeed challenging. Additionally, 23.7% (71 participants) remain neutral.

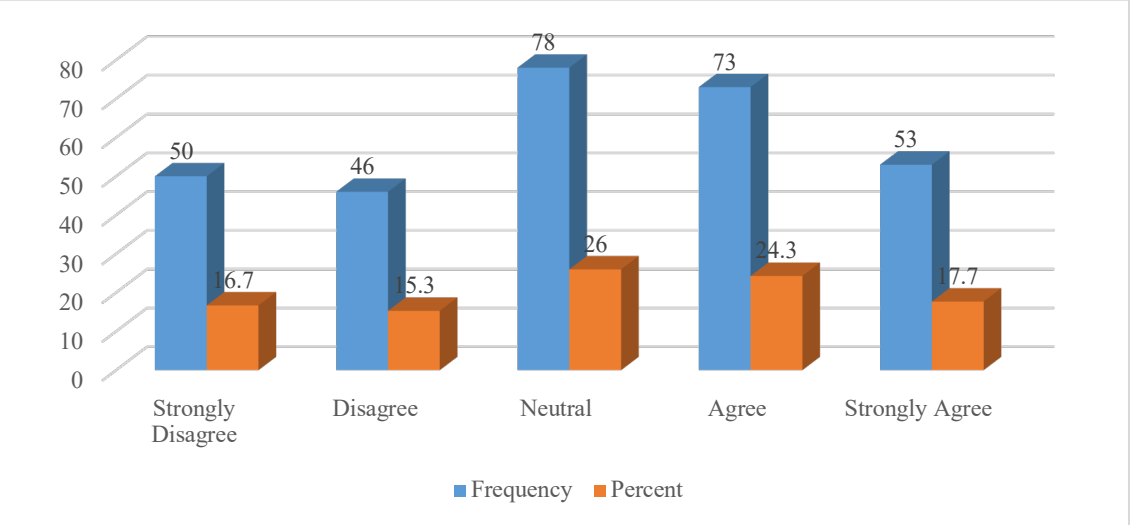

Figure 4.8: Data quality issues have caused delays in AI project development.

The responses to the statement "Data quality issues have caused delays in AI project development" show a range of opinions. A combined total of 32% (50 strongly disagree and 46 disagree) indicates that a portion of respondents do not believe data quality issues are significant barriers to AI project development. However, a considerable number of respondents agree (24.3%, 73 participants) or strongly agree (17.7%, 53 participants), suggesting that they view data quality issues as a notable cause of delays. Additionally, 26% (78 participants) were neutral, neither agreeing nor disagreeing.

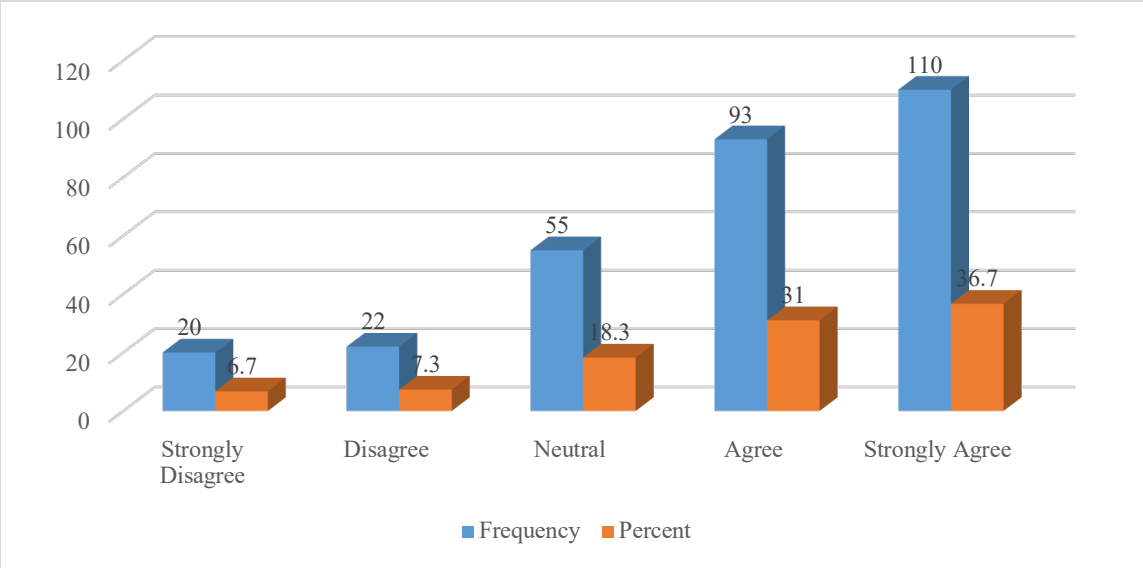

Figure 4.9: The quality of data used for AI projects is consistently high.

The responses to the statement "The quality of data used for AI projects is consistently high" indicate a positive perception of data quality in AI projects. A significant portion of respondents strongly agree (36.7%, 110 participants) and agree (31%, 93 participants), suggesting that the majority believe the data used in AI projects is of high quality. A smaller proportion, 6.7% (20 participants), strongly disagree, and 7.3% (22 participants) disagree, indicating some concerns about data quality. Additionally, 18.3% (55 participants) remain neutral.

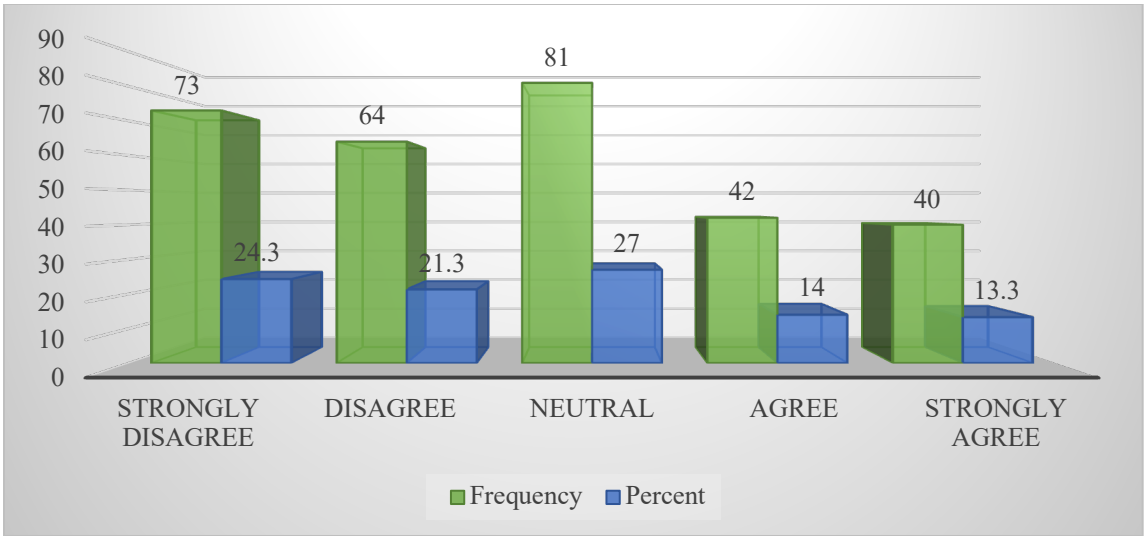

Figure 4.10: Integration of AI solutions has caused disruptions to our manufacturing operations.

The responses to the statement "Integration of AI solutions has caused disruptions to our manufacturing operations" show a mixed view. A significant portion of respondents, 24.3% (73 participants) strongly disagree and 21.3% (64 participants) disagree, suggesting that they do not perceive AI integration as disruptive. However, 13.3% (40 participants) strongly agree and 14% (42 participants) agree, indicating that some believe AI solutions have caused disruptions. Additionally, 27% (81 participants) remain neutral.

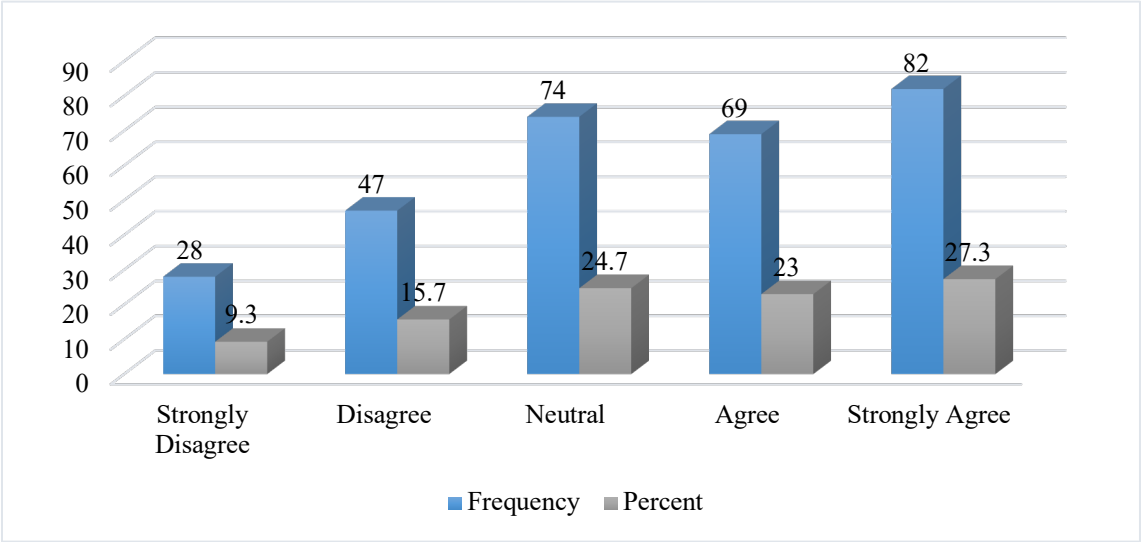

Figure 4.11: Technical support for AI integration is readily available and effective.

A total of 50.3% of respondents (27.3% strongly agree and 23% agree) believe that technical support for AI integration is readily available and effective. However, 25% of respondents (9.3% strongly disagree and 15.7% disagree) feel that technical support is either inadequate or ineffective. Additionally, 24.7% remain neutral, indicating no strong opinion on the matter. This suggests that while a majority find technical support for AI integration satisfactory, there is still a notable portion who face challenges or have concerns regarding its availability and effectiveness.

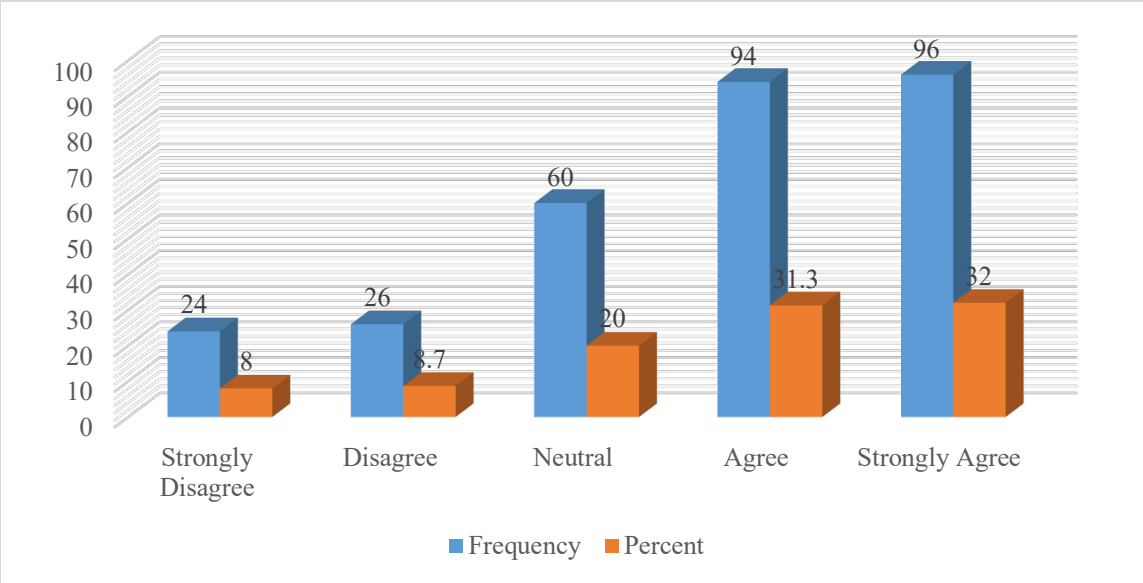

Figure 4.12: The initial investment required for AI technologies is justifiable by the expected benefits.

The responses to the statement "The initial investment required for AI technologies is justifiable by the expected benefits" show a generally positive view. A total of 63.3% of respondents (32% strongly agree and 31.3% agree) believe that the benefits of AI technologies justify their initial investment. However, 16.7% (8% strongly disagree and 8.7% disagree) do not agree with this, indicating that some consider the investment not worth the expected benefits. Additionally, 20% (60 participants) remain neutral.

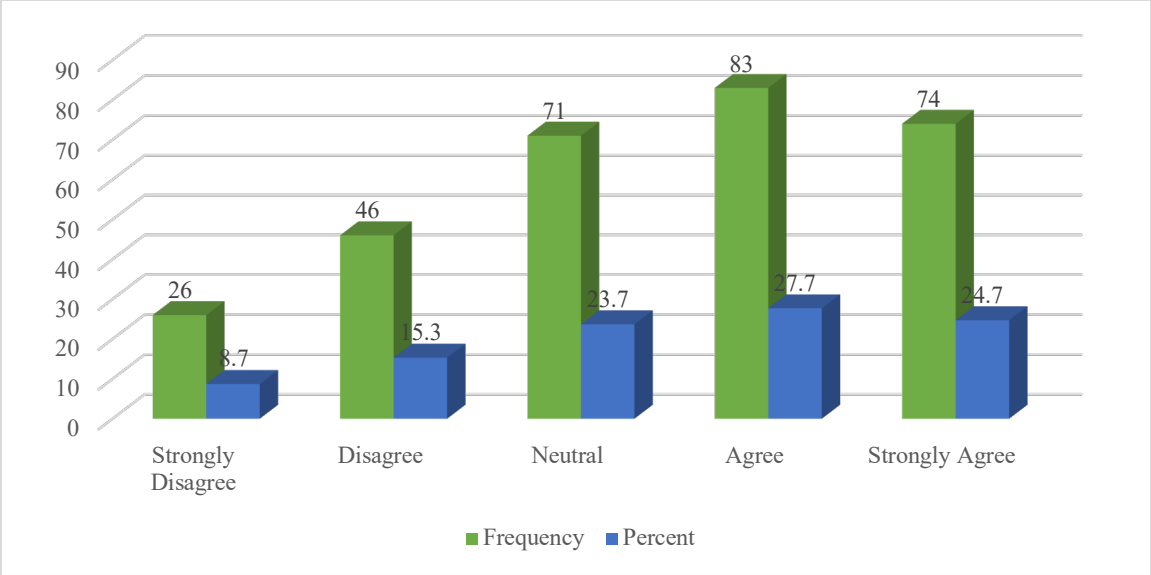

Figure 4.13: Our organization has access to sufficient financial resources for AI adoption.

The responses to the statement "Our organization has access to sufficient financial resources for AI adoption" show a mixed perception. A total of 52.4% of respondents (24.7% strongly agree and 27.7% agree) believe that their organization has sufficient financial resources for AI adoption. However, 24% of respondents (8.7% strongly disagree and 15.3% disagree) feel that financial resources are insufficient. Additionally, 23.7% (71 participants) remain neutral.

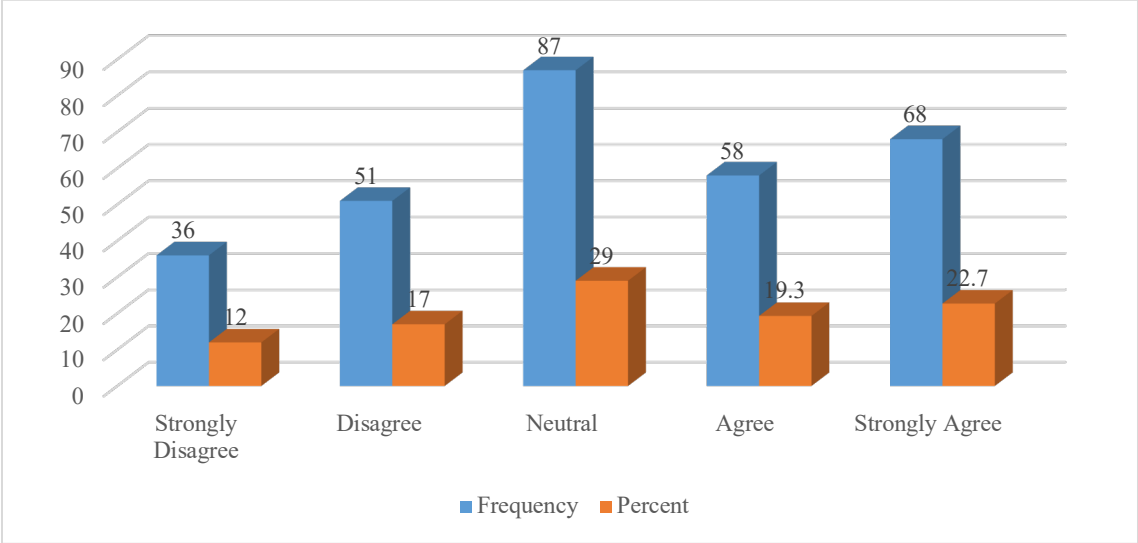

Figure 4.14: AI technologies are not fully mature for use in pharmaceutical manufacturing.

A total of 42% of respondents (22.7% strongly agree and 19.3% agree) feel that AI technologies are not fully mature for use in pharmaceutical manufacturing. However, 29% (12% strongly disagree and 17% disagree) disagree with this view, suggesting that some consider AI to be sufficiently mature for the industry. Additionally, 29% (87 participants) remain neutral. This indicates a divide in opinions, with a significant portion of respondents expressing concerns about AI's maturity in pharmaceutical manufacturing, while others either disagree or are uncertain.

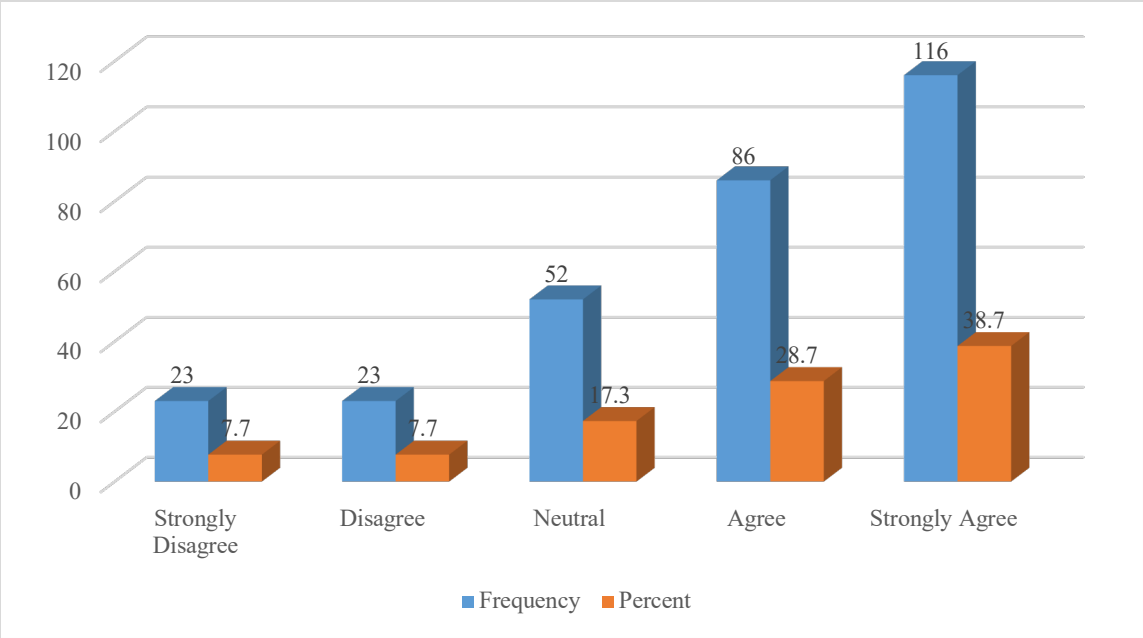

Figure 4.15: Lack of skilled personnel to operate AI systems is a significant challenge.

A total of 67.4% of respondents (38.7% strongly agree and 28.7% agree) believe that lack of skilled personnel to operate AI systems is a significant challenge. On the other hand, 15.4% (7.7% strongly disagree and 7.7% disagree) do not view it as a major issue. Additionally, 17.3% (52 participants) remain neutral. This indicates that while the majority consider the shortage of skilled personnel a significant challenge, a smaller portion disagrees or remains uncertain about its impact.

Table 4.4: Implementation of AI in Pharmaceutical Manufacturing

		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
AI may significantly improve the quality of drug products in the future.	Frequency	8	23	42	88	139
	Percent	2.7	7.7	14	29.3	46.3
The implementation of AI may increase production efficiency in pharmaceutical manufacturing.	Frequency	6	23	35	99	137
	Percent	2	7.7	11.7	33	45.7
AI technologies may contribute to the sustainability of pharmaceutical manufacturing.	Frequency	7	13	40	106	134
	Percent	2.3	4.3	13.3	35.3	44.7
Regulatory compliance may be enhanced through AI applications in the pharmaceutical industry.	Frequency	6	20	39	109	126
	Percent	2	6.7	13	36.3	42
The integration of AI may lead to more consistent and reliable manufacturing processes.	Frequency	7	19	38	98	138
	Percent	2.3	6.3	12.7	32.7	46
AI may play a crucial role in optimizing pharmaceutical supply chain management.	Frequency	7	15	43	85	150
	Percent	2.3	5	14.3	28.3	50

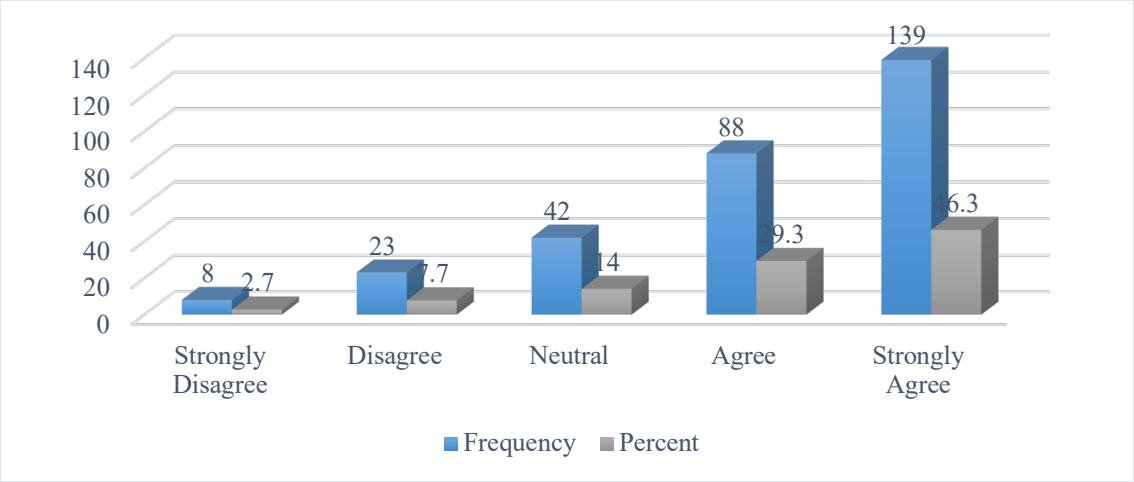

Figure 4.16: AI may significantly improve the quality of drug products in the future.

A total of 75.6% of respondents (46.3% strongly agree and 29.3% agree) believe that AI may significantly improve the quality of drug products in the future. Only 10.4% (2.7% strongly disagree and 7.7% disagree) do not share this view, while 14% (42 participants) remain neutral.

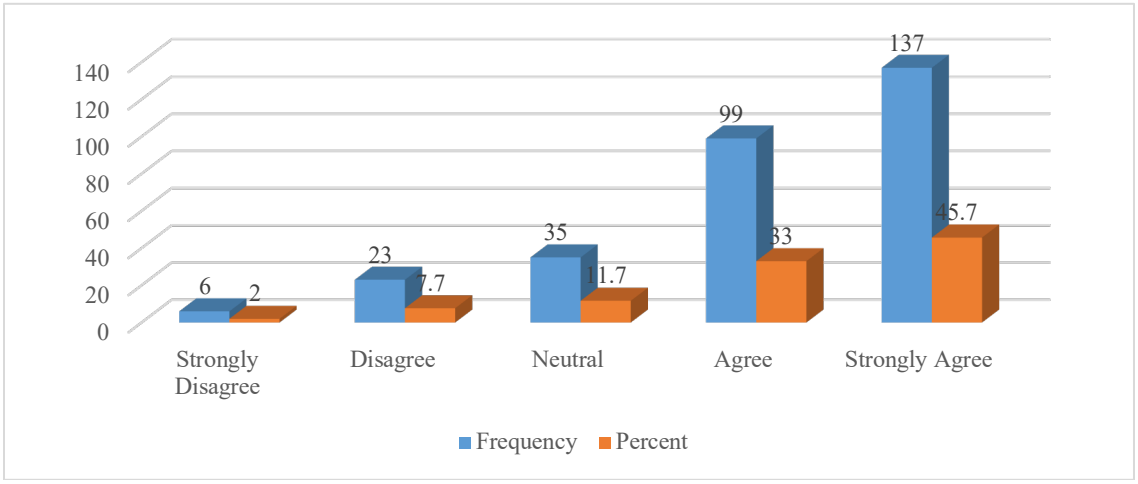

Figure 4.17: The implementation of AI may increase production efficiency in pharmaceutical manufacturing.

A total of 78.7% of respondents (45.7% strongly agree and 33% agree) believe that the implementation of AI may increase production efficiency in pharmaceutical manufacturing. In contrast, only 9.7% (2% strongly disagree and 7.7% disagree) disagree with this statement, and 11.7% (35 participants) remain neutral.

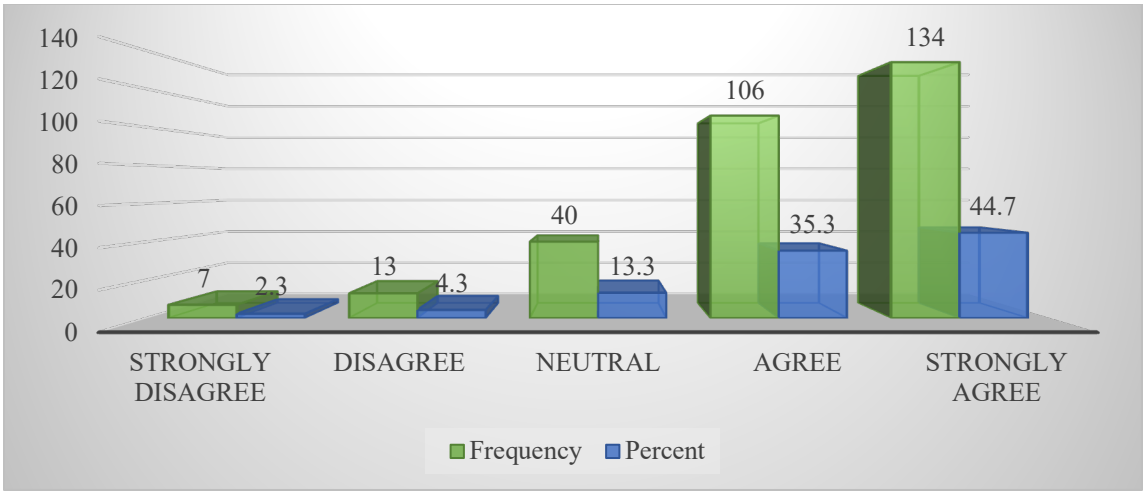

Figure 4.18: AI technologies may contribute to the sustainability of pharmaceutical manufacturing.

A total of 80% of respondents (44.7% strongly agree and 35.3% agree) believe that AI technologies may contribute to the sustainability of pharmaceutical manufacturing. Only 6.6% (2.3% strongly disagree and 4.3% disagree) do not agree with this statement, while 13.3% (40 participants) remain neutral.

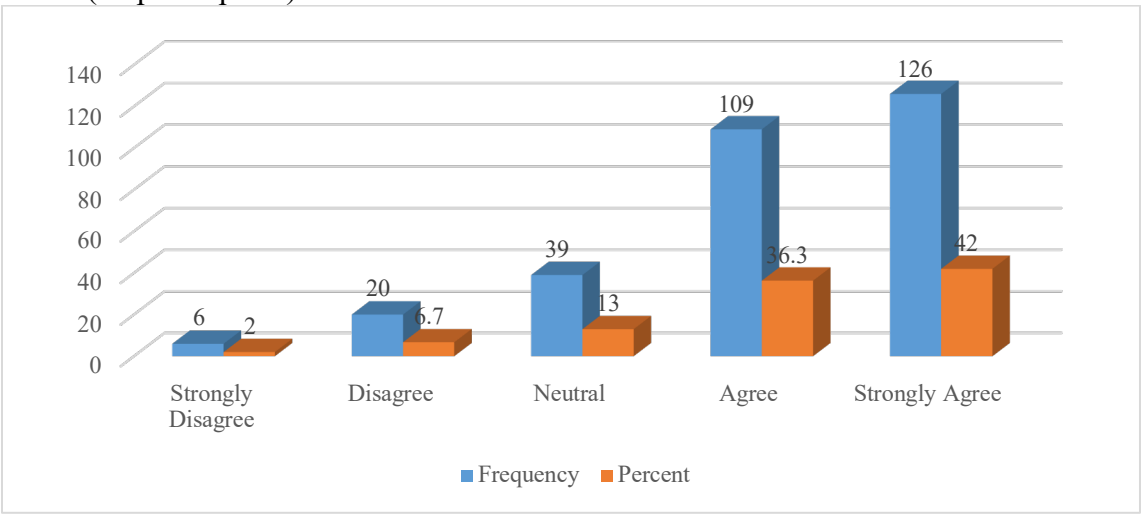

Figure 4.19: Regulatory compliance may be enhanced through AI applications in the pharmaceutical industry.

A total of 78.3% of respondents (42% strongly agree and 36.3% agree) believe that regulatory compliance may be enhanced through AI applications in the pharmaceutical

industry. In contrast, only 8.7% (2% strongly disagree and 6.7% disagree) disagree with this statement, while 13% (39 participants) remain neutral.

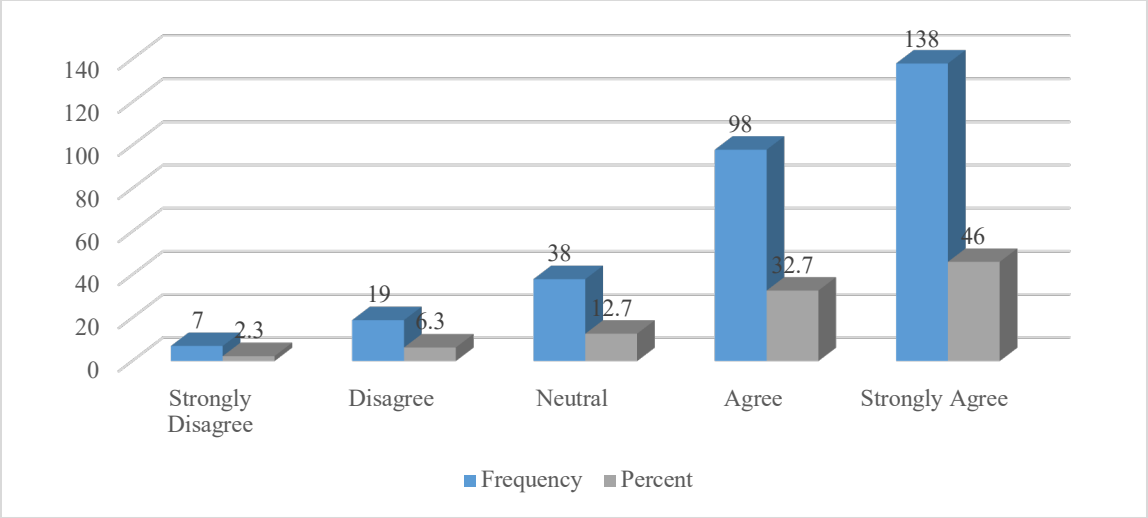

Figure 4.20: The integration of AI may lead to more consistent and reliable manufacturing processes.

The integration of AI may lead to more dependable and constant manufacturing procedures, according to 78.7% of respondents (46% strongly agree and 32.7% agree). On the other hand, 8.6% of participants (2.3% strongly disagree and 6.3% disagree) do not share this belief, while 12.7% (38 participants) are neutral on the matter.

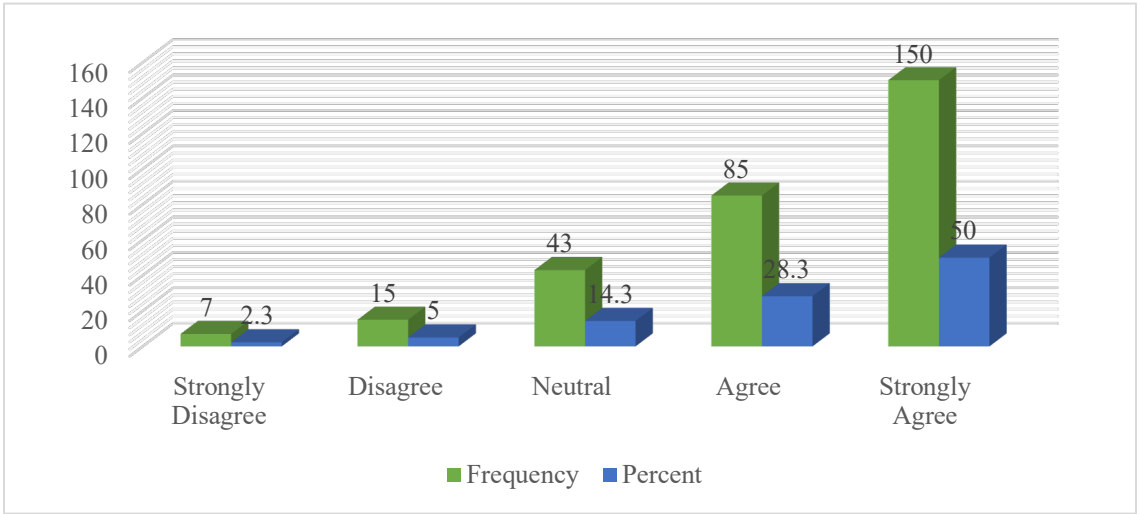

Figure 4.21: AI may play a crucial role in optimizing pharmaceutical supply chain management.

The majority of respondents (78.3%) believe that AI may play a crucial role in optimizing pharmaceutical supply chain management, with 50% strongly agreeing and 28.3% agreeing. In contrast, 7.3% (2.3% strongly disagree and 5% disagree) do not agree with this statement, while 14.3% (43 participants) remain neutral.

Table 4.5: Perceptions of the Impact of AI on Key Aspects of Pharmaceutical Manufacturing

		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
AI has the potential to significantly improve the quality of drug products.	Frequency	12	28	43	104	113
	Percent	4	9.3	14.3	34.7	37.7
AI may help to reduce errors in drug manufacturing, leading to better quality.	Frequency	10	14	39	107	130
	Percent	3.3	4.7	13	35.7	43.3
AI implementation may enhance production efficiency in pharmaceutical manufacturing.	Frequency	7	18	49	90	136
	Percent	2.3	6	16.3	30	45.3
AI can streamline manufacturing processes, reducing delays and inefficiencies.	Frequency	6	22	50	97	125
	Percent	2	7.3	16.7	32.3	41.7
AI may reduce overall manufacturing costs by optimizing resource allocation.	Frequency	8	21	66	82	123
	Percent	2.7	7	22	27.3	41
AI might help in cutting down the costs related to manual labour and human error.	Frequency	7	24	57	99	113
	Percent	2.3	8	19	33	37.7
	Frequency	6	20	55	103	116

AI implementation may contribute to making pharmaceutical manufacturing more sustainable.	Percent	2	6.7	18.3	34.3	38.7
AI may optimize energy use and minimize waste in the manufacturing process.	Frequency	7	14	50	111	118
	Percent	2.3	4.7	16.7	37	39.3
AI can help companies better adhere to regulatory requirements.	Frequency	5	20	48	111	116
	Percent	1.7	6.7	16	37	38.7
AI systems may simplify the process of compliance monitoring and reporting.	Frequency	7	15	45	104	129
	Percent	2.3	5	15	34.7	43

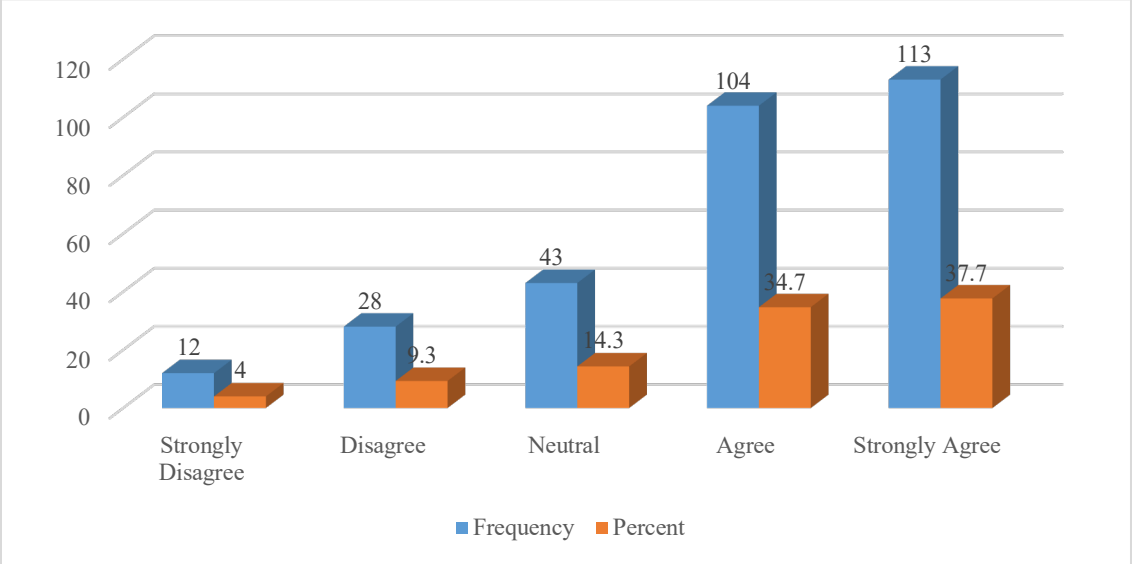

Figure 4.22: AI has the potential to significantly improve the quality of drug products.

A total of 72.4% of respondents (37.7% strongly agree and 34.7% agree) believe that AI has potential to significantly enhance the quality of drug products. In contrast, 13.3% (4% strongly disagree and 9.3% disagree) do not agree with this statement, while 14.3% (43 participants) remain neutral.

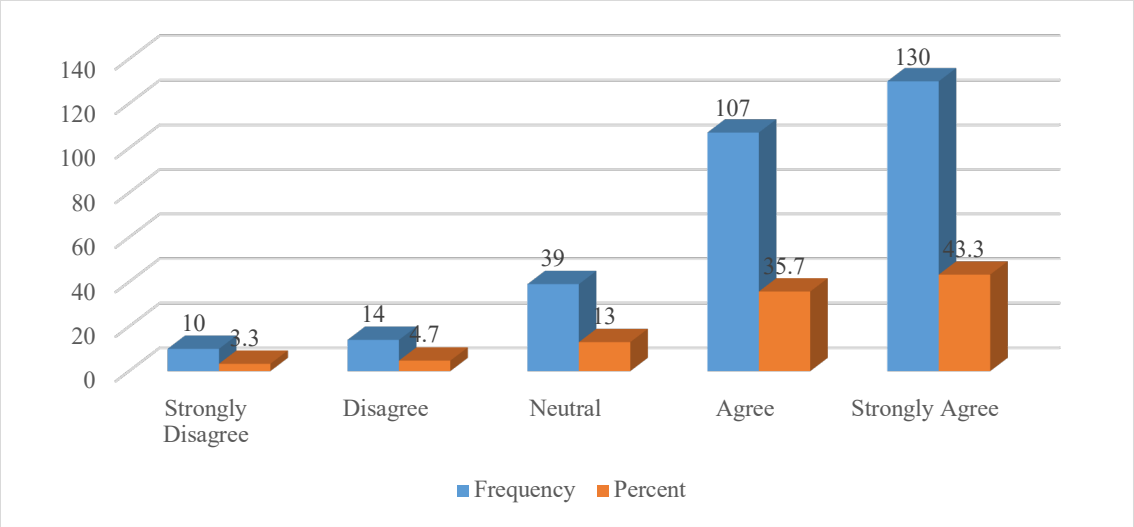

Figure 4.23: AI may help to reduce errors in drug manufacturing, leading to better quality.

A total of 78.7% of respondents (43.3% strongly agree and 35.7% agree) believe that AI may help reduce errors in drug manufacturing, leading to better quality. In contrast, 8% (3.3% strongly disagree and 4.7% disagree) do not agree with this statement, while 13% (39 participants) remain neutral.

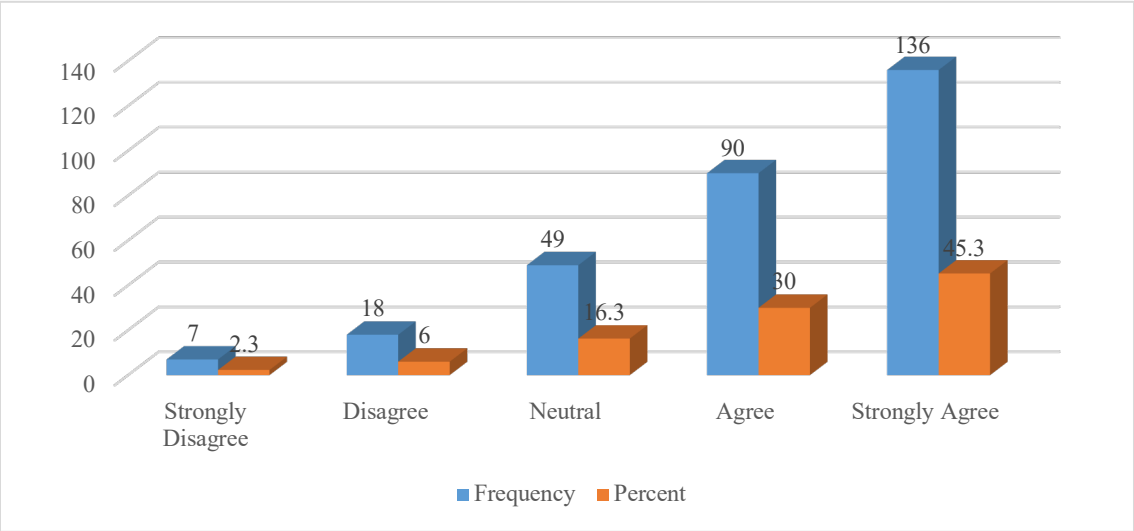

Figure 4.24: AI implementation may enhance production efficiency in pharmaceutical manufacturing.

A total of 75.3% of respondents (45.3% strongly agree and 30% agree) believe that AI implementation may enhance production efficiency in pharmaceutical manufacturing. In

contrast, 8.3% (2.3% strongly disagree and 6% disagree) do not agree with this statement, while 16.3% (49 participants) remain neutral.

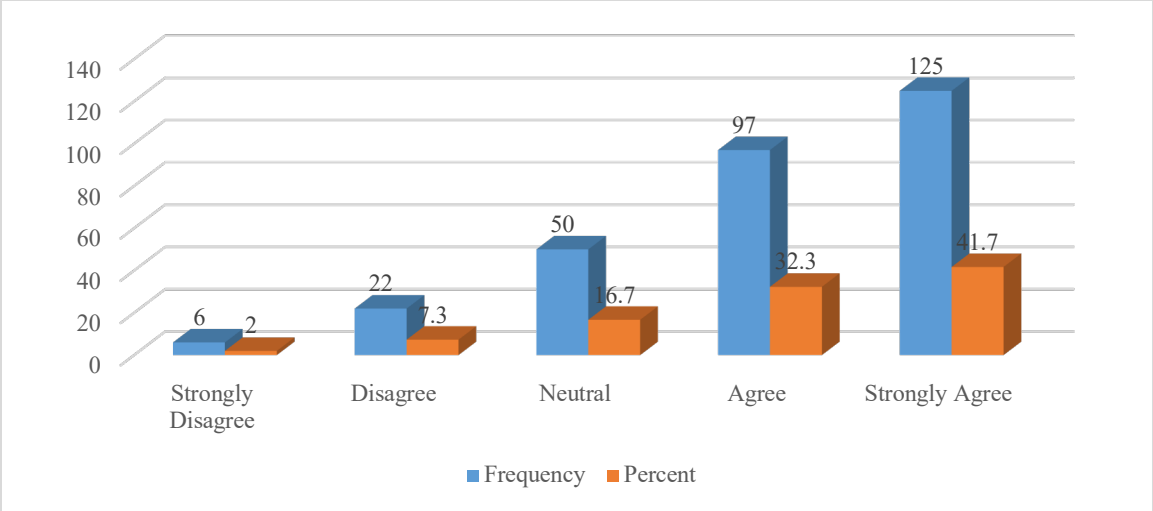

Figure 4.25: AI can streamline manufacturing processes, reducing delays and inefficiencies.

A total of 74% of respondents (41.7% strongly agree and 32.3% agree) believe that AI can streamline manufacturing processes, reducing delays and inefficiencies. In contrast, 9.3% (2% strongly disagree and 7.3% disagree) do not agree with this statement, while 16.7% (50 participants) remain neutral.

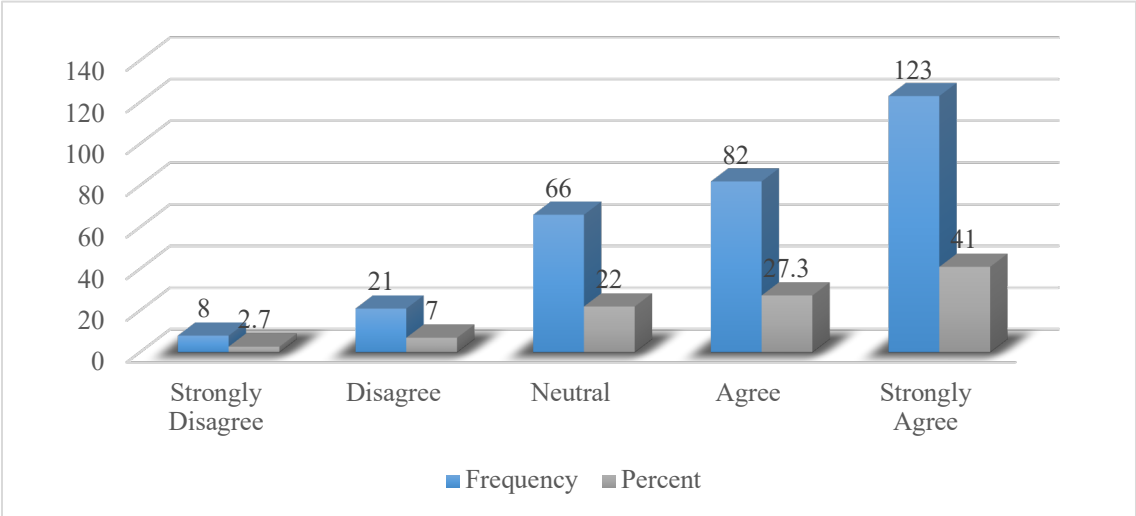

Figure 4.26: AI may reduce overall manufacturing costs by optimizing resource allocation.

The majority of respondents (68.3%) believe that AI can reduce overall manufacturing costs by optimizing resource allocation, with 41% strongly agreeing and 27.3% agreeing. On the other hand, 9.7% (2.7% strongly disagree and 7% disagree) do not agree with this statement, while 22% (66 participants) remain neutral.

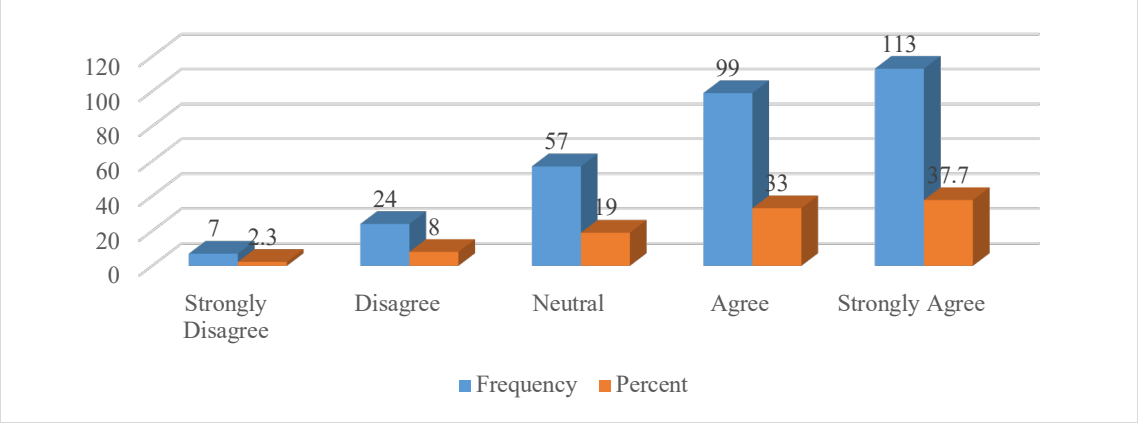

Figure 4.27: AI might help in cutting down the costs related to manual labor and human error.

A total of 70.7% of respondents (37.7% strongly agree and 33% agree) believe that AI might help in cutting down costs related to manual labor and human error. In contrast, 10.3% (2.3% strongly disagree and 8% disagree) do not agree with this statement, while 19% (57 participants) remain neutral.

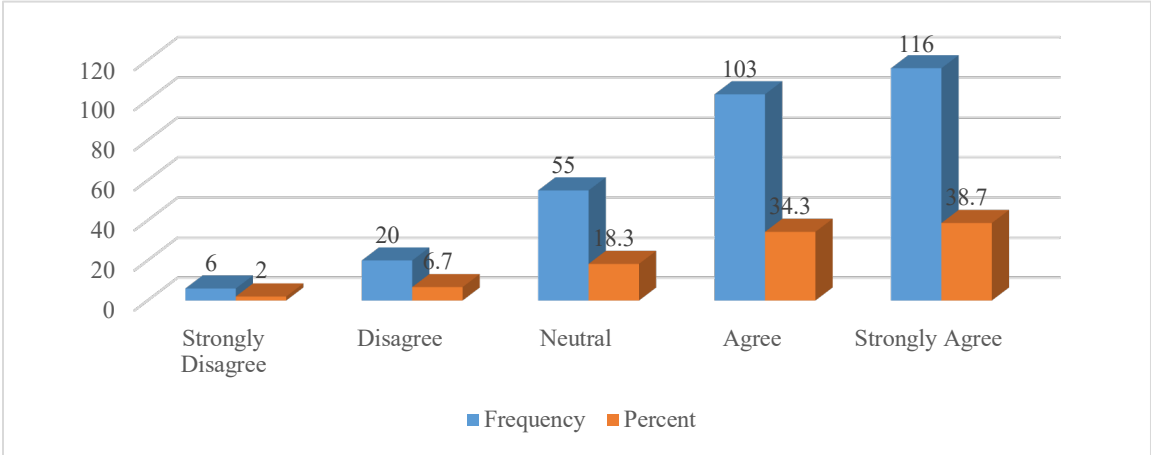

Figure 4.28: AI implementation may contribute to making pharmaceutical manufacturing more sustainable.

A majority of respondents, totaling 73%, expressed the belief that AI implementation could lead to more sustainable pharmaceutical manufacturing, with 38.7% strongly agreeing and 34.3% agreeing. In contrast, 8.7% of respondents (2% strongly disagreeing and 6.7% disagreeing) disagreed with the statement, while 18.3% (55 participants) remained neutral.

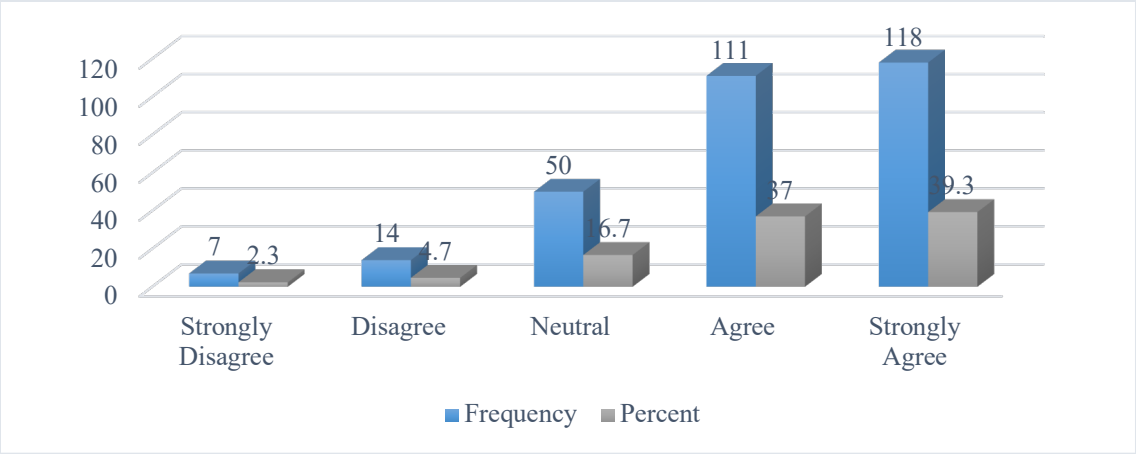

Figure 4.29: AI may optimize energy use and minimize waste in the manufacturing process.

The majority of respondents (76.3%) believe that AI may optimize energy use and minimize waste in the manufacturing process, with 39.3% strongly agreeing and 37% agreeing. On the other hand, 7% of participants (2.3% strongly disagreeing and 4.7% disagreeing) do not agree with this statement, while 16.7% (50 respondents) remained neutral.

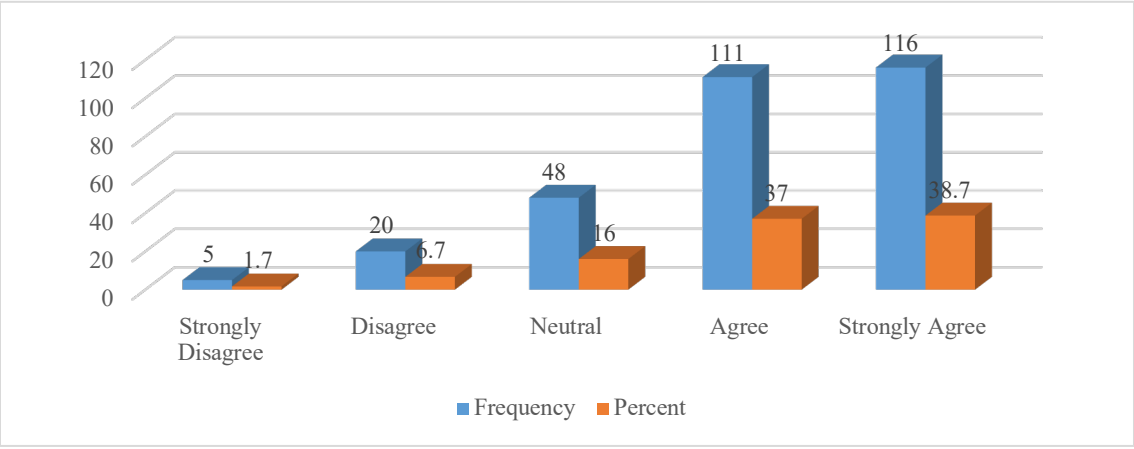

Figure 4.30: AI can help companies better adhere to regulatory requirements.

A large portion of respondents (75.7%) believe that AI can help companies better adhere to regulatory requirements, with 38.7% strongly agreeing and 37% agreeing. However, a small minority, 8.4% (1.7% strongly disagreeing and 6.7% disagreeing), disagreed with the statement, while 16% (48 participants) remained neutral.

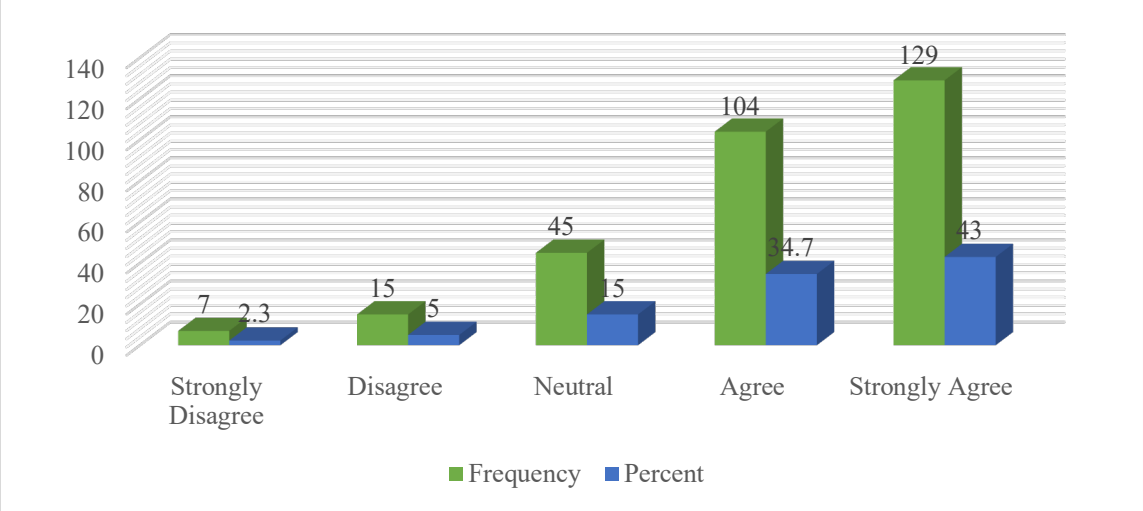

Figure 4.31: AI systems may simplify the process of compliance monitoring and reporting.

A significant majority of respondents (77.7%) believe that AI systems may simplify the process of compliance monitoring and reporting, with 43% strongly agreeing and 34.7% agreeing. However, a smaller proportion, 7.3% (2.3% strongly disagreeing and 5% disagreeing), disagreed with the statement, while 15% (45 participants) remained neutral.

4.3 Crosstabs

*Table 4.6: Regulatory Challenges*Implementation of AI in Pharmaceutical Manufacturing Crosstabulation*

Count						
	Implementation of AI in Pharmaceutical Manufacturing					Total
	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	

Regulatory Challenges	Strongly Disagree	2	0	1	2	17	22
	Disagree	1	2	2	13	27	45
	Neutral	0	1	21	28	49	99
	Agree	0	1	8	35	44	88
	Strongly Agree	0	1	3	9	33	46
Total		3	5	35	87	170	300

The table presents responses regarding the implementation of AI in pharmaceutical manufacturing, particularly focusing on regulatory challenges. A majority of respondents strongly agree (170 out of 300) that regulatory challenges impact AI implementation, followed by 87 agreeing and 35 neutral responses. The least agreement comes from those who disagree (45) or strongly disagree (22). This indicates that most participants recognize regulatory challenges as a significant barrier to the adoption of AI in the pharmaceutical industry.

*Table 4.7: Data Management Challenges*Implementation of AI in Pharmaceutical Manufacturing Crosstabulation*

Count							
		Implementation of AI in Pharmaceutical Manufacturing					Total
		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	
Data Management Challenges	Strongly Disagree	2	0	2	0	6	10
	Disagree	1	0	4	6	8	19
	Neutral	0	4	19	20	57	100
	Agree	0	0	7	45	58	110

	Strongly Agree	0	1	3	16	41	61
Total		3	5	35	87	170	300

The table highlights responses regarding data management challenges in implementing AI in pharmaceutical manufacturing. A significant portion of respondents (170 out of 300) strongly agree that data management challenges are an issue, while 110 agree. A smaller group (100) remain neutral, and only 8 disagree or strongly disagree. This indicates that data management is perceived as a considerable challenge in the implementation of AI within the pharmaceutical industry, with strong consensus on its importance.

*Table 4.8: Integration Challenges*Implementation of AI in Pharmaceutical Manufacturing Crosstabulation*

Count							
		Implementation of AI in Pharmaceutical Manufacturing					Total
		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	
Integration Challenges	Strongly Disagree	3	0	2	0	5	10
	Disagree	0	3	1	11	27	42
	Neutral	0	1	22	37	75	135
	Agree	0	0	10	33	38	81
	Strongly Agree	0	1	0	6	25	32
Total		3	5	35	87	170	300

The table reflects responses regarding integration challenges in enactment of AI in pharmaceutical manufacturing. The largest group of respondents (135 out of 300) remain

neutral, while 81 agree and 32 strongly agree that integration challenges are significant. A smaller group (42) disagree, and only 10 strongly disagree. This suggests that while integration challenges are acknowledged, there is a varied perception, with many participants uncertain about their impact or feeling that they are not a major concern.

*Table 4.9: Cost and Investment Challenges*Implementation of AI in Pharmaceutical Manufacturing Crosstabulation*

Count							
		Implementation of AI in Pharmaceutical Manufacturing					Total
		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	
Cost and Investment Challenges	Strongly Disagree	3	0	0	2	2	7
	Disagree	0	3	8	11	8	30
	Neutral	0	0	22	30	27	79
	Agree	0	1	4	37	62	104
	Strongly Agree	0	1	1	7	71	80
Total		3	5	35	87	170	300

The table presents responses regarding cost and investment challenges in executing AI in pharmaceutical manufacturing. A significant portion of respondents (170 out of 300) strongly agree that cost and investment are challenges, followed by 104 agreeing. A smaller group (79) remain neutral, and only 37 participants disagree or strongly disagree. This suggests that cost and investment concerns are recognized as important barriers to the adoption of AI in the pharmaceutical industry, with strong consensus on their significance.

*Table 4.10: Technological Challenges*Implementation of AI in Pharmaceutical Manufacturing Crosstabulation*

Count							
		Implementation of AI in Pharmaceutical Manufacturing					Total
		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	
Technological Challenges	Strongly Disagree	2	0	3	0	8	13
	Disagree	0	1	3	3	9	16
	Neutral	0	2	14	26	55	97
	Agree	0	1	7	31	50	89
	Strongly Agree	1	1	8	27	48	85
Total		3	5	35	87	170	300

The table illustrates responses regarding technological challenges in enactment of AI in pharmaceutical manufacturing. A notable proportion of respondents (170 out of 300) strongly agree that technological challenges are a significant barrier, with 89 agreeing. Additionally, 97 participants remain neutral, while only 16 disagree or strongly disagree. This indicates that technological challenges are widely recognized as a key obstacle to AI implementation, with a strong consensus on their importance in the pharmaceutical industry.

*Table 4.11: Perceptions of the Influence of AI on Key Aspects of Pharmaceutical Manufacturing * Implementation of AI in Pharmaceutical Manufacturing Crosstabulation*

Count

		Implementation of AI in Pharmaceutical Manufacturing					Total
		Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	
Perceptions of the Impact of AI on Key Aspects of Pharmaceutical Manufacturing	Strongly Disagree	3	0	0	0	0	3
	Disagree	0	3	2	0	0	5
	Neutral	0	2	29	12	1	44
	Agree	0	0	4	64	23	91
	Strongly Agree	0	0	0	11	146	157
Total		3	5	35	87	170	300

The table presents responses regarding perceptions of the impact of AI on key aspects of pharmaceutical manufacturing. A majority of respondents (170 out of 300) strongly agree that AI has a significant impact on these aspects, followed by 91 agreeing. A smaller group (44) remains neutral, while only 8 participants disagree or strongly disagree. This indicates that most respondents perceive AI as having a substantial positive effect on pharmaceutical manufacturing, with a strong consensus supporting its transformative potential.

4.4 Descriptive

Table 4.12: Descriptive Statistics

	N	Mean		Std. Deviation
	Statistic	Statistic	Std. Error	Statistic
Regulatory Challenges	300	3.3033	.06486	1.12348
Data Management Challenges	300	3.6433	.05675	.98286

Integration Challenges	300	3.2767	.05466	.94681
Cost and Investment Challenges	300	3.7333	.05979	1.03560
Technological Challenges	300	3.7233	.06157	1.06642
Implementation of AI in Pharmaceutical Manufacturing	300	4.3867	.04806	.83235
Perceptions of the Impact of AI on Key Aspects of Pharmaceutical Manufacturing	300	4.3133	.04936	.85494

The table presents descriptive statistics for various challenges in the implementation of AI in pharmaceutical manufacturing. Among the challenges, "Cost and Investment Challenges" (mean = 3.7333) and "Technological Challenges" (mean = 3.7233) have the highest means, indicating significant concerns in these areas. "Regulatory Challenges" (mean = 3.3033) and "Integration Challenges" (mean = 3.2767) are perceived as slightly less critical but still notable. The implementation of AI in pharmaceutical manufacturing and its perceived impact on key aspects show higher mean values (4.3867 and 4.3133, respectively), reflecting a generally positive outlook.

4.5 Hypothesis Testing

Hypothesis 1

- **H0:** There is no significant impact of Challenges in the Implementation of AI in Pharmaceutical Manufacturing.
- **H1:** There is a significant impact of Challenges in the Implementation of AI in Pharmaceutical Manufacturing.

Table 4.13: Model Fitting Information

Model	-2 Log Likelihood	Chi-Square	df	Sig.
Intercept Only	551.722			
Final	465.500	86.221	5	.000
Link function: Logit.				

A logistic regression analysis's results are shown in the table. The fit of the baseline model is indicated by -2 Log Likelihood for intercept-only model, which is 551.722. The final model, with an updated set of predictors, has a -2 Log Likelihood of 465.500. The statistical significance of the Chi-Square value (86.221) with 5 degrees of freedom ($p < .001$) indicates that in terms of fit, the finished model performs better than the intercept-only model. The model is suitable for making predictions with binary outcomes, as shown by the use of the logit link function.

Table 4.14: Goodness-of-Fit

	Chi-Square	df	Sig.
Pearson	1066.749	823	.000
Deviance	410.493	823	1.000
Link function: Logit.			

The Pearson Chi-Square test gives a significant result ($p < .001$), suggesting that model fits the data well. The Deviance Chi-Square is not significant ($p = 1.000$), suggesting no issue with model fit. The logit link function is used for binary predictions.

Table 4.15: Pseudo R-Square

Cox and Snell	.250
Nagelkerke	.285
McFadden	.137
Link function: Logit.	

The model explains a moderate amount of variance, with Cox and Snell R^2 at 0.250, Nagelkerke R^2 at 0.285, and McFadden R^2 at 0.137, indicating a modest fit.

Table 4.16: Parameter Estimates

		Estimate	Std. Error	Wald	Df	Sig.	95% Confidence Interval	
							Lower Bound	Upper Bound
Threshold	[I_AI_PM = 1.00]	-.683	.832	.673	1	.412	-2.313	.948
	[I_AI_PM = 2.00]	.411	.714	.331	1	.565	-.988	1.809
	[I_AI_PM = 3.00]	2.456	.694	12.515	1	.000	1.095	3.816
	[I_AI_PM = 4.00]	4.353	.732	35.381	1	.000	2.919	5.787
Location	CI_RC	-.236	.138	2.919	1	.088	-.507	.035
	CI_DMC	.341	.157	4.696	1	.030	.033	.649
	CI_IC	-.113	.153	.540	1	.462	-.413	.188
	CI_CIC	1.135	.139	66.338	1	.000	.862	1.409
	CI_TC	.081	.126	.417	1	.519	-.166	.329
Link function: Logit.								

The logistic regression model indicates the influence of different factors on the likelihood of being in specific categories of dependent variable, with thresholds for categories 1 through 4 provided. The significant results show that, compared to the baseline category, being in category 3 (I_AI_PM = 3.00) has significantly higher log-odds (Estimate = 2.456,

p = 0.000) of the outcome, as does being in category 4 (I_AI_PM = 4.00) with an even higher log-odds (Estimate = 4.353, p = 0.000). For the location variables, CI_RC has a marginally non-significant negative effect (p = 0.088), while CI_DMC has a significant positive effect (Estimate = 0.341, p = 0.030), suggesting a higher likelihood of the outcome in this location. CI_CIC has a strong positive effect (Estimate = 1.135, p = 0.000), while CI_IC and CI_TC show no significant effects (p > 0.05). Overall, the model indicates that certain locations, particularly CI_DMC and CI_CIC, significantly increase the odds of being in higher outcome categories, while other variables have minimal impact. Since the majority of significance value in the dependent variable is greater than 0.05 hence, alternate hypothesis states that "There is a significant impact of Challenges in Enactment of AI in Pharmaceutical Manufacturing." is rejected in favour of null hypothesis.

Hypothesis 2

- **H0:** There is no significant relationship between perceptions of the influence of AI on key aspects of pharmaceutical manufacturing and the implementation of AI in pharmaceutical manufacturing processes.
- **H1:** There is a significant association between perceptions of the influence of AI on key aspects of pharmaceutical manufacturing and the implementation of AI in pharmaceutical manufacturing processes.

Table 4.17: Correlations

			Implementation of AI in Pharmaceutical Manufacturing	Perceptions of the Impact of AI on Key Aspects of Pharmaceutical Manufacturing
Spearman's rho		Correlation Coefficient	1.000	.828**

	Implementation of AI in Pharmaceutical Manufacturing	Sig. (2-tailed)	.	.000
		N	300	300
	Perceptions of the Impact of AI on Key Aspects of Pharmaceutical Manufacturing	Correlation Coefficient	.828**	1.000
		Sig. (2-tailed)	.000	.
		N	300	300
**. Correlation is significant at the 0.01 level (2-tailed).				

The outcomes of Spearman's rho correlation indicate a strong positive association between implementation of AI in pharmaceutical manufacturing and perceptions of its impact on key aspects of the industry, with a connection coefficient of 0.828 ($p < 0.00$). This suggests that as AI is increasingly implemented in pharmaceutical manufacturing, the perceptions regarding its impact on various key aspects of the industry are likely to improve. This study's data from 300 participants supports the alternate hypothesis, which states that "There is a significant association between perceptions of influence of AI on key aspects of pharmaceutical manufacturing and implementation of AI in pharmaceutical manufacturing processes." The correlation is highly significant at the 0.01 level, representing a robust association between two variables.

4.6 Summary of Findings

This study examined the application of AI in pharmaceutical manufacturing, identifying major challenges and evaluating its impact on industry outcomes. Issues raised as obstacles include cost and investment issues, and technology factors as the main hurdles that make the implementation of AI difficult. Likewise, regulatory compliance, data

management, and integration remain as other barriers but are rated as less serious than cost and technology factors.

However, the surveyed individuals have fairly optimistic perceptions of the effects that AI will have on pharmaceutical manufacturing. The findings also indicate that applying AI leads to better drug quality and production, decrease in manufacturing costs, compliance with the sustainability objectives and fuels the production to maintain compliance with regulations. There is a high positive relationship between the degree of automation and the perceptions towards AI on the industrial impact, which implies that as the degree of automation increases, then the perceived positive impact of AI also increases.

Therefore, the study reveals an important need to work out effective ways and recommendations to address the major barriers with special emphasis on cost issues and technology integration. Recommendations include increasing investment in data infrastructure, streamlining regulatory frameworks, and raising awareness about AI's potential advantages. These strategies could facilitate smoother AI integration, allowing the pharmaceutical industry to fully leverage AI’s capabilities for enhanced production and overall efficiency.

4.7 Conclusion

In conclusion, this study reveals the prospects and the risks that follow the application of AI in manufacturing of drugs. For instance, AI has the opportunities of enhancing drug quality and manufacturing productivity, as well as the costs of production, sustainability, and regulatory compliance. The challenges of using AI, however, they are costly, technically challenging, have regulatory constraints and may require large data volumes. From among them, cost, and technological factors can be distinguished as being more dominant, thus requiring corresponding investments and enhancement of the infrastructural base.

That the correlation between the implementation of AI and the perception industry held tends to increase with the optimism industry hold in the benefits of AI as the implementation unfolds. By conventional efforts, AI cannot be fully harnessed hence the need to employ targeted efforts in relation to the above identified barriers through upgrading technology, data and regulation. These actions will assist the pharmaceutical industry in properly applying AI, and progress towards developments that seek to advance the industry and many of its processes.

CHAPTER V:
DISCUSSION

5.1 Discussion of Results

The findings of this research provide a basic perspective in respect of the complications of interest concerning the achievement of artificial intelligence on pharmaceutical production facilities. These are the regulatory issues, data management issues, integration issues, cost issues, issues of investments, and technology issues of this discussion. In addition, it analyses how the perceived benefits of AI in improving the quality and productivity of manufacturing, as well as compliance to regulation because of the challenges affecting the industry, but culminating to the adoption of the technology.

This research examines the applications of AI in pharmaceutical production, the issues this technology experiences, and the advantages it offers. This study establishes that there are benefits, which come with the use of AI in drug manufacturing, efficiency, and compliance to regulatory guidelines; however, there is a challenge when it comes to cost, technology, regulation, and data management. Industry technical workers envision a better future with AI where performances would be optimised, mistakes minimised and sustainability achieved. But the problems arise when many organisations do not have adequate financial and technical capacity to do AI well. In the course of the study, the researchers also discovered that while the level of AI implementation rises, so does the impression regarding the positive impact of the technology. To fully unlock AI's potential, companies need to invest in better technology, streamline regulations, and improve data management systems. Addressing these challenges will help the pharmaceutical industry use AI more effectively, leading to safer, faster, and more cost-efficient drug manufacturing.

The study defines regulatory issues as one of the significant problems that slow the use of AI in the pharmaceutical production process. Justifiably, regulatory compliance in the marketplace is stringent due to customer safety and product quality concerns in the pharmaceutical industry, hence a protracted undertaking. Most of the participants highly endorsed the observation that regulatory concerns affect the implementation of AI, as evidenced in the current body of knowledge, with pharmaceutical firms considered to exert high regulatory compliance. Policies and legal frameworks are sometimes slow to develop to keep up with advances in technology, therefore confusing as to whether an organization can use certain AI-based processes. Furthermore, punitive regulatory measures in drug production require a trace of all procedures, which is automation-laden as AI units are dynamic and modify automatically. The promise of decision support systems driven by AI to improve clinical processes, aid in diagnosis, and make personalised therapy a reality is becoming more apparent by the day. However, the implementation of these innovative technologies raises many unique issues in practice and health care contexts that require a comprehensive discussion of the ethical, legal, and regulatory aspects (Mennella et al., 2024).

Another core challenge highlighted in the study is data management; a large number of respondents said that data challenges affect AI implementation. Through systematic compilation of the current progress, issues, and opportunities of AI application in the pharmaceutical field, this review provides timely and useful information for analysing the current and future trend of drug development and regulatory policies in AI era (Huanbutta et al., 2024). Moreover, pharmaceutical data is often considered as confidential and is subject to strict privacy policies which enlarge the challenges of data management (Filkins et al., 2016). Deficiencies in information quality like incomplete, noisy or inconsistent information can lower the effectiveness of AI, which means that data

management approaches play a crucial function in AI usefulness that has to be utilised to achieve favourable organisational results. Problems with the algorithms are that they need perfect, correct or balanced data to initially input so according to Sowjanya S et al. (2024) If there is weak data or even very partial data it affects the whole AI system. The use of AI and data analytics is more advantageous for businesses to work and get more competitive for improving the business value. The findings are in line with literature that has time and again highlighted a need to have a strong data structure to support AI-related processes within the pharmaceutical industry.

Integration challenges also came out as another factor influencing AI implementation processes in the pharma sector. Many respondents viewed the difficulty of integrating AI with existing legacy systems as a significant issue. Pharmaceutical companies often rely on traditional manufacturing processes, which can be incompatible with AI technologies, requiring costly upgrades or adaptations. Research into drug pharmacokinetics and pharmacodynamics using conventional experimental methods has mixed results; some studies have found that these approaches are ineffective, costly, and time-consuming (Mager, Woo and Jusko, 2009; Tuntland *et al.*, 2014). Furthermore, integration requires that the AI is considered within existing working patterns, and employees are trained to work with the AI system, which disrupts working operations and generates negative attitudes among the staff. Integration challenges, therefore, call for a framework transition plan to ensure that the existing applications are gradually transformed as they prepare to adopt AI solutions.

The study also elaborates on cost and investment as key issues about cost, participants expressed a strong concern that funds constrain the use of AI in pharmaceutical manufacturing. AI has the potential to optimise R&D processes, which in turn can help reduce development costs. The pharmacokinetics and toxicity of potential drugs can be

predicted with the help of machine learning algorithms, which also aid in the design of experiments. With this capability, lead compounds can be optimised and prioritised without resorting to expensive and time-consuming animal testing. AI algorithms can analyse real-world patient data to support personalised medicine approaches. This can lead to better treatment outcomes and increased patient adherence. (Vora et al., 2023). It especially poses a problem to small firms as they may not afford to invest in complex AI systems.

Some of the participants also note that other challenges that emanate from technologies that are limiting are also a factor that hinders AI adoption utilizes special factors and a highly skilled human staff: the latter being a limited resource in pharmaceutical companies (Zuhair et al., 2024). In addition, unlike limitations of AI technology where the key challenge is often how to implement AI effectively in hospital routine practice. To achieve comprehensive adoption, AI systems must be approved by the regulatory authorities, follow standard operating procedures that assure standardized performance, clinicians must be trained for using them, necessary funding must be cascaded by the public and private payers and, AI supervision must face repeated iterations. These adoption challenges will one day be overcome but more time when the technologies themselves take time to mature. This is in line with the literature where it is established that while the implementation of AI technologies requires capital investment, it also requires technology updates in organizations (Mennella et al., 2024).

The participants generally perceived the use of AI as having positive topographical features where its application in pharma production is wrought on quality, cost, and regulatory aspects. They said that AI solutions such as predictive and process optimization can actually enhance drug manufacturing since they can reduce the intricate process and seldom mistakes. Furthermore, the efficient fine of AI ensures that an organization in compliance management, particularly regarding regulations and tracking its activities

throughout the manufacturing process, given that the pharmaceutical industry is one of the industries where essential regulation norms must be adhered to.

The increase in perceived benefits of implementing AI also supports the hypothesis that as companies try implementing AI, the more they will believe in the technology. Studies show that as organisations start referring benefits derived from AI implementation they are likely to extend the types of applications in the organisation, making adoption a cycle that benefits both users and implementers (Dwivedi et al., 2023). The results also support the view from the related literature that the potential for AI to deliver significant long-term benefits may beajar of existence when the organizations overcome the starting obstacles.

The findings of this study align with and expand on existing research regarding the adoption of AI in pharmaceutical manufacturing. Several studies affirm that AI plays a transformative role in enhancing quality control, productivity, and regulatory compliance in pharmaceutical production (Saha *et al.*, 2023; Sumedh M Bodade *et al.*, 2023). However, as identified in this research, AI adoption is constrained by regulatory challenges, data management issues, integration difficulties, high costs, and technological barriers—a recurring theme in contemporary literature (Kulkov, 2021; Lodhi *et al.*, 2022; Kimta and Dogra, 2024).

The regulatory constraints highlighted in this study align with earlier research that points to the extent that legacy regulatory frameworks from times of 'typical' manufacturing do not equally well cope with AI-powered automation and analysis (Arden *et al.*, 2021; Patil, Kulkarni and Gaikwad, 2023). It is not a discovery that AI improves compliance processes and increases data quality (Wei and Nurhaliza, 2024), but firms remain slow to obtain approval for AI systems and adjust to new compliance standards. It

for this reason that there is a need for international conventions and the formulation of best practices and policies on AI that foster it use.

The results identified in the present study regarding cost and investment barriers add up to the results of previous research. In AI implementation, business owners have to invest a considerate amount of capital in infrastructure costs, internal training, and system incorporation which poses a high entry barrier, especially for SMEs (Guo, 2023; Mehta *et al.*, 2023). Some literature points that due to efficiency, proper resource management, and minimizing errors AI has lower operational expense in the long term (Singh et al., 2023; Yadav et al., 2024), yet this was not an issue witnessed where this study established that many firms face challenges in covering initial costs as identified by Reinhardt et al. (2020). Such analysis indicates that government incentives and industrial collaborations can significantly support AI introduction and reduce the financial load on businesses.

Data management issues are still a significant issue, which agrees with the literature, where data accessibility, accuracy, and compatibility are viewed as the key barriers to applying AI (Dangeti, Bynagari and Vydani, 2023; Vora *et al.*, 2023). Though AI loves big data for prediction and decision making, there are issues of data inconsistency, data security and lack of standard structures on its use. As Karimian et al. (2022), have pointed out, there are also secondary ethical issues that may potentially slow the implementation of AI tools in pharmaceutics: the distinct question of data privacy. This study affirms such concerns holding that proper data governance frameworks and AI-appropriate data validation mechanisms can address such barriers.

However, the study established the fact that there is a growing acceptance of AI across the industry with appreciating sentiments about the role of AI in enhancing the quality of the drugs, efficiency of the systems and compliance with regulatory requirements. Past studies show that AI enhances supply chain, monitoring and

maintenance process, and medicine precision. (Boniolo *et al.*, 2021; Sampene and Nyirenda, 2024). However, this study adds to the literature by demonstrating that AI's full potential is contingent on overcoming integration hurdles and workforce skill gaps. The lack of skilled personnel remains a major challenge M. Sharma et al. (2022), suggesting that investments in AI training programs, interdisciplinary collaboration, and knowledge-sharing initiatives are crucial for accelerating adoption.

This study's recommendation sills show that there is a need for strategic interventions towards dealing with these implementation problems. Thus, the research aimed at the investigation of the tendencies of AI applications in manufacturing industry as a way to contribute comprehensive view of how and what AI applications are changing production and make To address this problem, regulatory processes should also be rationalised, and AI-suitable policies should be established, which is in line with the demands of researchers who urge regulatory authorities to catch up with advances that have already occurred. Also, problems of integration can be aggravated, as it has been pointed out by different authors, by employees' resistance that can be overcome by training sessions and other awareness-raising activities to spread acceptance of AI. Thus, the study shows that it becomes a symbolic product AI turns into a new cultural means that alters decision-making and impacts the core of the firms (Al Samman, 2024). By addressing these obstacles, pharmaceutical companies can fully leverage AI's potential to enhance productivity, reduce costs, and ensure quality in drug manufacturing.

Therefore, the present work advances the knowledge of the disparate problems and opportunities connected with AI in pharmaceutical production. It is stressed that regulation, data, integration, and cost/technology issues are important while quality, compliance, and cost benefits are the reasons why people turn to AI. If these barriers are to be addressed by

high-level strategies, the pharmaceutical industry can improve the status of AI integration and make good use of its potential.

In conclusion, this study strengthens existing discourse by providing empirical evidence of AI's benefits and challenges in pharmaceutical manufacturing. It highlights the critical need for regulatory modernization, strategic investments, improved data management, and workforce training to ensure AI's successful integration. Addressing these concerns will enable the pharmaceutical industry to harness AI's full capabilities, leading to higher efficiency, cost reductions, and enhanced drug quality.

5.2 Discussion of Research Question One

RQ1: What is the Current situation of AI applications in Pharmaceutical Manufacturing?

The study found that AI is being used in quality control, production optimization, regulatory compliance, and supply chain management. A significant proportion of respondents believe AI improves drug quality, manufacturing efficiency, and sustainability. However, adoption remains fragmented, with larger pharmaceutical companies implementing AI more effectively than smaller firms. This suggests that while AI has gained traction, its full potential is not yet realized across the industry. Implication: Policymakers and industry leaders must support AI adoption through funding incentives, training programs, and industry collaborations to ensure wider accessibility and implementation.

The research shows that AI use in the production of pharmaceutical products is gradually improving, mainly in increasing productivity and reducing costs and improving product quality. Today, AI technologies are applied in quality assurance, maintenance, prediction, accurate manufacturing and so on to enhance outputs. These applications assist

manufacturers in cutting costs and time and minimising mistakes, which are good signs toward embracing Artificial Intelligence in manufacturing companies.

However, several pertinent problems affect the diffusion of AI in a comprehensive manner. There are various external barriers as well, including cost and technology it is pivotal to note that here, the costs needed to build the structure for an AI program and AI-skilled human resources are still high. Again, integration problems remain rife, especially given that new manufacturing structures struggle to implement new sophisticated AI-enhanced frameworks in their current legacy structures. Another source of additional difficulties – is regulations: existing legislation was not always designed or adopted with AI in mind, and may be outdated as those technologies are advanced quickly; these risks make compliance yet another issue for manufacturers. Decision-making is also another mentioned challenge, as the industry often must address large volumes of data securely and effectively.

As a result of these challenges, however, there remains optimism that AI will remain a force of change in the pharma manufacturing industry. With a rise in the implementation of AI, there have been presentations of clearer production speed, quality and regulatory compliance that are expected to be brought by innovations. With proper investments, IT implementation and appropriate regulatory framework, these primary Industry challenges may be solved to unlock the full potential of AI, moving the pharmaceutical Industry to a higher level of efficiency and perhaps quality output.

The study's findings align with existing literature, highlighting that AI is progressively enhancing productivity, reducing costs, and improving product quality in pharmaceutical manufacturing. AI applications in quality assurance, maintenance, predictive analytics, and precise manufacturing have been instrumental in achieving these improvements (Varol, 2024).

However, this study points out key issues that limit the utilisation of AI; high implementation costs, technological complications, and regulatory constraints. The foregoing challenges are evident in the literature, pointing to the fact that there is a need to invest much in AI capital and human capital. (Blanco-González *et al.*, 2023).

Nevertheless, there are a lot of concerns about such changes and AI can be seen as bringing a deeply positive change in the pharmaceutical market. The study proposes that, if right investments are made technological changes occur and, and right policies that support the adoption of AI are put in place, the take up of AI will cause the attainment of higher inefficiencies as well as better product quality.

Overall, this research demonstrates proposals of how one could overcome challenges that already exist to realize AI enhanced pharmaceutical manufacturing. This resonates with the current literature encouraging stakeholders to make smart investments and regulatory enhancement for the incorporation of AI in the industry.

5.3 Discussion of Research Question Two

RQ2: What are the Key Challenges Associated with AI Implementation in the manufacturing process of the pharmaceutical industry?

According to the results of the study the greatest concerns are the cost and investment, technological integration, regulatory issues, and data handling. Expenditures constrain numerous organisations to provide in the AI system; furthermore, technology's challenges its implementation and human capital's inadequate expertise hinders the integration process. Regulation is also a significant pressure since AI technologies have to pass through multiple compliance processes before going live. Implication: Tackling all these issues entails the rationalisation of the guidelines, funds towards acquisition of Artificial Intelligence and the training of human capital to meet the demand. Compared to

the above efforts, AI adoption will remain slow which hinders the delivery of its positive impacts.

There are significant challenges that pose from this study concerning the use of AI in production of drugs and medicines in the pharma manufacturing industry; The main one being as follows: Major challenges affecting the adoption of AI are in aspects such as Product pricing pressures (cost), problems implementing the technology, regulatory compliance and data management.

The issues of cost and investment are particularly important because the introduction of artificial intelligence involves considerable expenses for purchasing sophisticated technologies, creating required facilities, and rearing up staff. This cost implication can make companies shy away from adopting AI especially when they are struggling to meet the competitive product pricing and meets the regulatory standards.

All in all, the implementation of technology is associated with significant challenges. The usage of AI means redesign of primary structure of technology use, marrying different infrastructures, and months of physical security. These implementation challenges may also be challenges accompanied by some compatibility issues such as the compatibility of the new AI systems with the older systems utilized in the manufacturing processes; not only do these produce costs that may be hard to meet but they also offer technical hitches. Other essential component is that the law must be observed. It is a highly regulated industry with different regulation that impacts on the quality and security of its drugs and the information that it publicizes. AI systems need to do this and this requires more validation steps, clearly defined audit trails, and high data privacy compliance.

Data management is also a core issue also as organizations move from one form of technology to another or redesign their data management architectures. AI systems in pharmaceutical manufacturing rely on large as well as accurate data to run the processes.

The collection, storage, analysis, and secure handling of this information calls for huge logistical possibilities, on top of privacy and legal issues.

Taken together, these results underscore the imperative for effective problem-solving of prescient issues, including augmented investments in infrastructure, contextually-specific rules and regulations, and sound IT infrastructures to facilitate AI integration, ultimately to optimize productivity in the production of pharmaceuticals.

The challenges that have been identified in this study as affecting the implementation of AI in pharmaceutical manufacturing namely; cost and investment, technology integration, regulatory constraints, and data management are valid as supported by existing literature. The proprieties of the AI infrastructure, the expensive cost, and the qualities of human resources required to manage AI programs remain a major demerit. For example, Medivant Health invested in semi-automatic vial inspection systems, which cost even ten times more than the human staff to accomplish the same work, which proves the material investments needed for employing artificial intelligence(Kaplan, 2023). Technological integration brings added challenges because using AI in industrial processes requires important investments in new technologies and in the construction of suitable structures to integrate them in the current manufacturing systems. AI adoption can, therefore, be complicated by this level of complexity.

Regulation is still a serious threat as long as it is a key concern related to investment in emerging economies. AI technologies are to be validated and to provide clear audit trails and, thus, the requirements necessary for the pharmaceuticals industry can only be met by well-regulated technologies. This regulatory environment allows for the slowing of AI implementation and the addition of implementation costs (Higgins and Johner, 2023).

Another big problem involves how to store and make sense of all the data collected. AI means large amounts of accurate data and the work with these data has organizational

and structural problems, as well as with questions of privacy and legal points. To achieve successful manufacture of medicines through the effective use of AI technologies, the data used must be protected from compromise as well as its credibility ascertained as stated by(Blanco-González *et al.*, 2023).

Solving these problems requires a complex of measures: simplification of legislation governing AI, adequate financing of infrastructure development, and the provision of training for a new generation of employees. Otherwise, potential benefits of using AI in the pharmaceutical manufacturing process will continue to be restrained to a minimal level. (Varol, 2024).

5.4 Discussion of Research Question Three

RQ3: How do the AI Implementation influence the Pharmaceutical Manufacturing?

The current research revealed a highly significant link between the implementation of artificial intelligence and the enhancement in drug quality, production, and costs as well as compliance to regulatory agencies' standards. People expect that AI lowers the chances of mistakes, improves comparisons and efficiency, and equals resource use. Nonetheless, integration problems remain as such problems cause disturbances in some firms, making it clear that AI integration is sensitive to the firm's planning and adjustment. Implication: Organizations are required to come up with well-organized AI integration techniques that would enhance flow and reduced interferences. This includes the process of pilot implementing AI solutions, construction of data environment, and nature of approach between the AI creators and pharma employees.

From this study, it would be clear that the use of AI is instrumental in shifting dynamics of pharma manufacturing along efficiency, output and process discipline. By applying the principles of Big data and machine learning procedures, AI technologies are capable of improving management within the process of production thereby delivering

enhanced quality of drugs and minimizing on errors. This resonates with existing automation theories on industrial production where AI's capacity to ingest large data sets and perform elaborate calculations, then sustain coherency in production schedule.

In addition, AI enables better optimization of resources' usage and, ultimately, their cost since it reduces wastage. The prediction of maintenance and optimization of the performance of a machine are other ways through which AI systems help to reduce operating costs and increase production efficiency. Such efficiency is critical to meeting the industry's need for cost-cutting while at the same time promoting the use of resources more sustainably.

AI is also essential in the aspect of regulation and compliance. Chemical production remains a strictly controlled area, and the fact that AI is capable of constant supervision of production parameters as well as recording and analysis in real-time makes it easier for companies in the sector to adhere to the required standards. Since chasing traceability and reporting, these AI systems allow compliance with the required regulatory rules and this is critical in a very regulated sector.

Finally, the attitudes toward AI's influence are optimistic, and the rise in automatization contributes to enhancing the assessment of the construction industry's AI prospects. Hence, the results presented here highlight the affirmative change brought by AI in the advancement and optimisation of standards in pharmaceutical manufacturing.

The findings of this study align with the broader literature on the transformative role of AI in industrial and pharmaceutical production. For instance, prior research emphasizes that AI technologies, particularly machine learning and big data analytics, offer unprecedented potential to enhance quality control, operational efficiency, and compliance in manufacturing settings. Studies such as those by Martinez *et al.*, (2018) and Suriyaamporn *et al.*, (2024) highlight similar trends, where AI has been shown to optimize

processes and reduce costs through predictive maintenance, waste reduction, and resource allocation. The consistency between this study's findings and existing research underscores the growing consensus around AI's benefits in the pharmaceutical sector.

AI implementation and drug quality share a direct positive relationship with the literature on precision manufacturing. The capability of performing large data analysis and making timely changes as noted by Nimmagadda, (2024), explains that AI quality assurance eradicates flaws and improves product standardization. It also provides back to theories actually present in the world of quality management and establishing the implication that the concept of an improvement in quality necessitates a constant reinvention of quality management systems.

The AI as found in the study enhance resources utilization and cost minimization is in support with automation discourses discussed by authors such as (Keleko *et al.*, 2022). Their work showed how AI for Predictive Maintenance reduces time a machine spends off – from this, enhancing effectiveness and lowering expenses. This research confirms the need for pharma AI application to balance the twin drivers of cost and sustainability in the industry.

AI remains beneficial in the pharmaceutical company because no company can afford to ignore regulations in the industry. Syed and Kousar, (2024) elaborate on how real-time data analytics as well as smarter recount ability isolation arrangements make compliance easy by eradicating paperwork and monitoring. In line with such knowledge, this study shows how AI makes it easy to follow relevant rules and regulations, essential for the pharma business's integrity and effectiveness.

However, the study recognizes that integration has some difficulties that include interference by those that are poorly managed and planned. Previous research for instance the one by Agrawal et al., (2023) also establish this problem and call for increased

development of sound AI plans that will entail use of pilot testing and incorporating stakeholders. The findings presented here extend this line of discussion by presenting the following practical conclusions: enhancing data support and developing collaborations between AI designers and drug specialists.

5.5 Discussion of Research Question Four

RQ4: What are the actionable recommendations to overcome the identified challenges, facilitating the successful integration and utilization of AI technologies in pharmaceutical manufacturing?

The study suggests several key recommendations: The priority areas include: (1) enhance the development of AI infrastructure, (2) encourage AI-friendly regulations, (3) enhance the skills in AI technologies of the workforce, and (4) enhance data management. The following actions can assist overcome the financial factors, regulatory barriers, and technical as mentioned in the study. Implication: Companies and regulatory bodies must work together to create an AI-friendly environment, ensuring that AI solutions are affordable, compliant, and easily integrated into existing pharmaceutical processes. By addressing these challenges, the industry can fully leverage AI's potential to drive innovation and efficiency in drug manufacturing.

This research revealed antecedents that arguably conceptualise theoretical challenges of AI application within the manufacturing context of the pharmaceutical industry particularly on Regulatory Compliance, Data Management, Integration, Cost and Technological factors. Many of these challenges are weighty since the pharmaceutical industry has many strict regulatory standards for safety and quality, which puts constraints on the ability to integrate novel AI solutions. Policies about applications are still in a state of flux, and there are high regulatory barriers that must be cleared to enable the general application of any manifestation of AI; this manner of regulation poses quite a rigid context

that might stifle the growth and advancement of AI within this sector. This is in line with regulatory compliance theories as regards the need to sustain innovation amidst the stringencies of set rules since risk management forms the core of such jurisdictions.

Problems with data management only add to these concerns, as AI cannot perform seamlessly unless smoothly fed with quality integrated data. According to data governance theories, a lack of proper structures for dealing with data, such as poor quality, compatibility, and data security, hampers AI execution. Likewise, integration issues highlight difficulties in synthesizing new AI systems with existing manufacturing structures and applications, consistent with theoretical accounts of technology adoption in complex and safety-sensitive settings. Moreover, costs and technology barriers also emphasize the deficiencies of economic theories of capital-intensive structures and implements where high capital investment is required for AI technologies and networks to instantly deploy.

Based on these challenges, the study proposes the following practical recommendations. First, the flexibility of the regulation domain is an important aspect; continuous work of the pharmaceutical companies and the regulatory organizations to develop a set of new general rules and regulations for AI use in the pharmaceutical companies, compliant enough to prevent the industry from the misuse of AI but open enough to allow the progress. Second, improvement of data environment is crucial to developing AI through bridging the quality, organization and safety gaps of data accessible to AI models. Third, encouraging the uptake of technological solutions based on modular AI systems that can be connected to currently implemented solutions may also help to solve the problem and reduce disruption.

CHAPTER VI:
SUMMARY, IMPLICATIONS, AND RECOMMENDATIONS

6.1 Summary

This study explores the application of artificial intelligence in pharmaceutical manufacturing, focusing on current uses, challenges, and potential solutions to improve AI implementation in the industry. AI is used daily in the manufacturing of drugs to forecast the future demand, monitor the quality of products, improve the process, and manage the supply chain. These applications bring sizeable advantages such as increased throughput, precision and effectiveness in manufacturing, decreased cost and reliability on quality that allow delivering effective and safe drugs to the patients much quicker.

Nevertheless, the implementation of AI in pharmaceutical manufacturing has some significant challenges. These challenges include data quality and availability, the nature of AI models, and the security of the connected systems. Regulatory and compliance concerns also pose significant challenges, given the strict guidelines for pharmaceutical products and processes. Other strategic barriers include high implementation costs, and an unavailability of the skilled workforce to support AI. Some of these aspects can slow down the growth of AI to the optimal level of development in industry and bring out innovation or changes in the production methods and line.

The study also explores the impact of AI in the pharma business as a way of improving operational performance and developing the concept of personalized medicine. In order to counter the termed challenges, the study offers practical advice such as enhancing the data management framework, developing a talent pool, strengthening partnerships with the regulatory authorities, and enhancing IT security infrastructure.

Specifically, it is critical to recognise that, despite all the opportunities that AI offers to pharmaceutical manufacturing, the former obstacles need to be addressed to

ensure the successful adoption of the latter. Solving these problems may pave the way to more efficient, progressive and secure manufacture of medications that will be in the good interest of the pharmaceutical business and the general population.

6.2 Implications

From this study, there are practical implications for the pharmaceutical manufacturing firms, policy makers, equipment manufacturers and researchers; whereby the insights on how to incorporate AI are wide-ranging. This study has brought into focus how AI, or Artificial Intelligence, could help pharmaceutical manufacturers become more efficient and economically beneficial, including helping increase drug quality while reducing potential costs in areas such as maintenance, quality control and supply chain management, among others. Enhancing manufacturing processes by reducing people's mistakes create more accurate production, which can satisfy the continuously high demand for affordable drugs. But effectively, manufacturers face crucial struggles like data security, deployment or development of staff utilizing AI technology, and regulatory compliance. The management of AI has to be orderly, at least through the pilot approach and the involvement of AI developers in a project to avoid significant disturbances during implementation.

Based on the study's conclusions, policymakers should understand and work on developing new flexible rules that are suitable for the current market regulations that apply to the application of AI in the making of drugs. Of course, these guidelines should be designed in a way that both will maintain safety and AI conformity with the industry standards, and, at the same time, will encourage further technological developments. Policy makers should also look at the development of frameworks that will encompass ethical issues, security and responsibility of artificial intelligence AI. In this way they can bolster

safer and more orthodox AI configurations which points toward the credibility and stability of the industry they are representing.

In conclusion, for researchers, this study points to the future research direction such as: the emergence of higher-level algorithms for pharmaceutical applications; approaches to solving compliance and integration issues; and the role of AI for sustainable operation of the drug production line. The authors also call for more studies on how academics, technology suppliers, policymakers and manufacturers can work together to foster the application of AI that is appropriate to address the diverse needs of the pharmaceutical industry. This research concludes with prospective discussions for future work that will help improve the intelligent manufacturing solutions for the pharmaceutical industry and offer global gains for businesses and patients alike.

6.3 Recommendations for Future Research

Future research on this kind of domain should focus on the following areas to advance understanding and enhance practical application:

1. **Data Quality and Integration**: More studies ought to be directed towards methods that would improve data quality and the degree of integration of different information systems used in the production of pharmaceuticals. AI is under development on data frameworks that formalise the processes for managing and integrating data in line with quality assurance for making genuine predictions to optimise operation and regulation compliance.
2. **Cybersecurity and Privacy**: Since the subject of pharmaceuticals is highly confidential, the subsequent investigations should focus on more complex methods of information security to prevent AI from being breached. Investigations into modern methods of data encryption, the secure way of sharing information and AI applications in security can be useful. The need to understand the relationship

between information availability for the AI algorithms and privacy in the secure deployment of AI is also important.

3. **Human-AI Collaboration and Workforce Adaptation**: Further studies into behaviours of humans and Artificial Intelligence in manufacturing environments need to be conducted. Research could look at how AI might complement or scale human decision-making and review the training initiatives that can orient staff members to new artificial intelligence-led practices. This research can help in achieving ways to work with AI without compromising existing positions that will help create a society with an AI-ready workforce.
4. **Scalability and Cost-Efficiency**: Further research could also find out if there are AI solutions suitable for medium and small pharma companies that can be scaled up appropriately, economizing on costs. Research that investigates the more versatile and scalable solutions aimed at AI infrastructure may contribute to decentralization of the practice. Cost and benefits analyses of implementing AI can also be used by scholars in doing research to assist the company in deciding on where to invest most of its resources to get the best out of the AI investment.

By addressing these areas, future research can contribute to a more robust and responsible integration of AI in pharmaceutical manufacturing, overcoming current limitations and promoting innovation and efficiency in drug production.

6.4 Conclusion

AI implementation in pharmaceutical processing shows promising change to positively impact effectiveness, accuracy, as well as innovation throughout the pharmaceutical industry. This study has discussed the situation of using artificial intelligence at present, with a focus on how it has impacted the drug products manufacturing industry with regard to production, quality assurance and the supply chain.

Manufacturing is also made easier by the use of artificial intelligence together with automation and predictive analysis means that responses and results are faster, human errors are avoided and there is improved quality of drug products. However, significant challenges persist, including data quality issues, regulatory constraints, cybersecurity risks, costing and workforce adaptability.

These issues need comprehensive strategies, including setting up proper data management measures, governing rules and regulations in cooperation with AI developers, improving cybersecurity measures, and promoting implementation of AI in pharmaceutical industries. The role of the pharmaceutical industry, policy makers, pharmaceutical equipment manufacturer is to drive and guide the role of AI in pharma manufacturing and layout the ethical frameworks required for the correct usage of an impactful technology.

Further research addressing the issues of data management, an appropriate ethical approach, security considerations, collaboration between humans and AI, model interpretability, and creating AI solutions that could be implemented at an industrial scale will be important to harness AI in the context of pharmaceutical manufacturing. In conclusion, the pharmaceutical industry might solve these challenges, letting AI achieve innovative high-quality products at lower costs, and faster time to reach lifesaving drugs to the patients around the globe.

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APPENDIX:

DATASET

	A	B	C	D	E	F	G	H	I	J	K	L	M	N
1	What is you	What is yo	What is your	What is your	How many yea	Regulatory gui	The approval p	Data quality iss	The quality of	Integration of A	Technical supp	The initial invest	Our organization	AI technologies are
2	1	3	2	2	5	5	2	3	4	2	5	5	4	2
3	1	3	2	3	5	5	5	5	5	5	5	5	5	5
4	1	3	3	2	5	3	5	5	5	4	2	2	2	5
5	1	3	3	5	4	1	2	5	5	5	2	5	3	2
6	1	3	2	3	5	5	1	1	1	1	5	5	5	5
7	1	5	1	5	5	3	2	3	4	2	3	4	1	2
8	1	4	3	3	5	2	3	5	5	2	3	4	4	5
9	1	3	2	2	5	3	1	5	3	5	3	5	3	3
10	1	3	2	2	4	4	4	5	5	5	5	3	2	5
11	1	4	2	2	5	1	4	3	5	2	4	4	3	5
12	1	4	2	2	5	3	4	5	3	3	3	2	3	5
13	1	3	3	3	5	3	4	3	4	4	2	3	4	4
14	1	3	3	2	5	3	5	4	5	3	5	5	5	2
15	1	3	2	2	5	3	4	4	4	5	4	3	4	3
16	1	4	3	5	5	2	2	1	4	1	2	4	3	3
17	1	3	3	1	5	3	4	4	4	2	3	4	4	4
18	1	4	2	2	5	1	3	2	3	2	3	2	1	2
19	1	3	3	1	4	4	5	3	5	3	4	4	3	5
20	1	3	4	5	5	4	2	3	4	2	3	4	2	3
21	1	2	3	3	3	5	3	1	5	1	5	5	5	1
22	1	3	2	2	5	3	5	4	4	3	4	4	4	3
23	1	3	3	2	3	5	2	2	5	2	5	4	5	4
24	1	3	3	2	4	4	3	3	3	3	4	4	4	4
25	1	4	2	2	5	5	2	2	5	5	5	4	3	3
26	1	3	2	2	5	3	4	4	5	1	3	5	3	2

	O	P	Q	R	S	T	U	V	W	X	Y	Z
1	Lack of skilled pe	AI may signific	The implement	AI technolog	Regulatory com	The integration	AI may play a cruc	AI has the poten	AI may help to rec	AI implementation ma	AI can streamline manu	AI may reduce overall
2	4	5	5	5	5	5	5	5	5	5	4	5
3	5	5	5	5	5	5	5	5	5	5	5	5
4	5	2	4	4	2	4	4	4	2	2	2	2
5	5	4	5	4	5	5	5	4	5	5	4	4
6	5	5	5	5	5	5	5	3	2	5	5	5
7	3	3	4	4	4	5	5	5	5	3	4	4
8	5	5	5	5	5	5	5	5	5	5	5	5
9	5	5	5	5	5	5	5	5	5	5	5	5
10	5	3	3	3	5	4	5	1	4	3	3	3
11	5	4	5	4	4	3	5	4	4	4	4	4
12	4	3	2	4	2	3	4	4	4	3	3	2
13	5	5	5	4	4	4	4	4	4	5	5	5
14	1	5	5	5	5	5	5	5	5	5	5	5
15	5	3	5	5	4	5	5	4	4	4	4	5
16	3	4	4	4	4	4	4	4	4	4	4	4
17	4	2	3	3	4	3	2	2	3	3	3	3
18	4	5	5	5	5	5	5	4	5	5	5	3
19	5	5	3	3	4	3	4	4	5	4	4	4
20	3	4	4	4	4	4	4	4	4	4	4	4
21	4	5	5	5	5	5	5	5	5	5	5	5
22	3	3	4	3	3	3	4	3	4	3	4	4
23	4	5	5	5	5	5	5	5	5	5	5	4
24	2	4	4	4	4	4	3	4	4	3	3	3
25	1	5	5	4	5	3	3	4	4	5	5	5
26	3	5	4	5	5	5	5	4	4	5	4	4

AA	AB	AC	AD	AE
AI might help in cutti	AI implementation ma	AI may optimize ene	AI can help companies be	AI systems may simpli
5	4	5	5	5
5	5	5	5	5
5	4	4	3	4
3	4	4	5	5
5	5	5	5	5
5	5	4	4	4
5	5	5	5	5
5	5	5	5	5
2	3	3	5	4
2	2	3	3	2
2	3	3	3	4
4	4	4	4	4
5	5	5	5	5
5	4	5	4	4
4	4	4	4	4
4	2	3	3	3
4	5	5	4	4
3	4	4	4	4
4	4	4	4	4
5	5	5	5	5
4	4	4	3	4
4	5	5	5	5
3	3	4	4	4
5	5	5	5	5
3	5	5	4	4