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The Impact of AI (Machine Learning and Automation) on Biopharmaceutical Manufacturing industry

A thesis submitted in partial fulfilment of the requirements for

MSc in Digital Transformation (Life Science)

Griffith College Dublin – Innopharma

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[redacted]

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CANDIDATE DECLARATION

Candidate Name: Ruchi Sayal

I declare that this thesis, titled "The Impact of AI (Machine Learning and Automation) on Biopharmaceutical Manufacturing Industry," represents my original work. This work is submitted in partial fulfilment of the requirements for the MSc in Digital Transformation (Life Science). I have conducted this research ethically, adhering to academic standards and acknowledging all sources used.

Candidate Signature:

Date: 18th May 2024

Supervisor Name: André Maiocchi

Supervisor Signature:

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LIST OF ABBREVIATIONS

ABBREVIATION	FULL FORM
AI	Artificial Intelligence
CAGR	Compound Annual Growth Rate
GAN	Generative Adversarial Network
GDPR	General Data Protection Regulation
GSK	GlaxoSmithKline
IBM	International Business Machines
MES	Manufacturing Execution System
ML	Machine Learning
NLP	Natural Language Processing
PAT	Process Analytical Technology
QC	Quality Control
ROI	Return on Investment
RPA	Robotic Process Automation
SVM	Support Vector Machine
TA	Thematic Analysis
USD	United States Dollar
XAI	Explainable Artificial Intelligence

ABSTRACT

This research investigates the transformative effects of artificial intelligence (AI), machine learning (ML), and automation on the biopharmaceutical manufacturing industry. The study provides a comprehensive analysis of how these advanced technologies are revolutionizing manufacturing processes. Through an extensive literature review and detailed survey analysis, the research examines how these technologies address challenges such as data quality and complex biological systems, emphasizing their role in overcoming regulatory hurdles and improving manufacturing efficiency. The study explores key trends and drivers behind the escalating adoption of AI, including the need for process optimization, advancements in drug discovery, and enhanced quality control.

Furthermore, the research assesses the impact of AI on traditional biopharmaceutical manufacturing models. It illustrates how AI disrupts conventional processes by enabling real-time issue identification, enhancing quality control, and boosting productivity. The introduction of new methodologies such as personalized medication production, AI-powered robotics, and AI-assisted drug discovery showcases the transformative potential of these technologies.

In conclusion, the study reveals that AI adoption in the biopharmaceutical industry is rapidly advancing, driven by its transformative potential in enhancing efficiency, innovation, and competitiveness. Addressing challenges and ensuring responsible adoption will be pivotal in realizing the full benefits of AI-enabled technologies in biopharmaceutical manufacturing. The research provides valuable insights for industry stakeholders, guiding strategic decision-making and fostering a more informed approach to integrating AI technologies, ultimately contributing to the growth and advancement of the biopharmaceutical sector.

Key Words: *Artificial Intelligence, Machine Learning, Automation, Biopharmaceutical Manufacturing, Process Optimization, Robotic Process Automation, Real-Time Monitoring.*

1 INTRODUCTION

1.1 Overview

The biopharmaceutical manufacturing sector is undergoing an important change, driven by the increasing adoption of artificial intelligence (AI), machine learning (ML), and automation technologies. This dissertation examines the effects of this technological shift, aiming to understand AI's widespread impact on several aspects of the industry. In short, the study aims to understand how the use of AI, particularly machine learning and automation, is transforming the field of biopharmaceutical manufacturing.

As the manufacturing industry faces new challenges and opportunities, understanding the effects of these advanced technologies is important. This study seeks to explain the interactions between AI and biopharmaceutical manufacturing, focusing on how these technologies could possibly reduce manufacturing costs, improve operational efficiency, and improve quality control procedures. This research also aims to provide a thorough understanding of the potential transformational impact of artificial intelligence for the biopharmaceutical manufacturing sector through studying adoption trends, driving factors, and specific benefits. This study will provide important insights into the role of AI in determining the future of biopharmaceutical manufacturing.

Title: The Impact of AI (Machine Learning and Automation) on Biopharmaceutical Manufacturing industry.

Module the topic is linked to

- Advanced Manufacturing in the Smart Factory

Purpose and Aim

The overall objective of this research is to provide insight into the transformative effects of artificial intelligence (AI), machine learning (ML), and automation on the biopharmaceutical manufacturing industry through thorough research and analysis. The study aims to provide an understanding of how the introduction of these intelligent technologies is transforming manufacturing processes. Finally, the research intends to provide meaningful insights into the overall influence of AI on the biopharmaceutical manufacturing industry, guiding stakeholders and industry professionals towards a more informed and strategic approach to integrating technologies.

1.2 Background

The introduction of Artificial Intelligence (AI), including Machine Learning and Automation, has transformed the biopharmaceutical manufacturing industry in recent years. This innovative technology has the potential to transform how medications are manufactured, improving efficiency, quality, and overall production. As the industry aims for improvements, understanding the implications of AI on biopharmaceutical manufacturing becomes more and more essential. This research aims to explore the background and issues related to using AI, automation, and machine learning in biopharmaceutical manufacturing. It also aims to analyze the current situation, future possibilities, and implications of these technologies.

Justification for the research

The study focuses on understanding the changes that are taking place in the biopharma manufacturing sector. AI technologies are becoming more important in manufacturing, offering both benefits and challenges. This study will look into how AI, primarily machine learning and automation, affects production costs, operational efficiency, and quality control in the sector. By bridging gaps in the study, this research will contribute to academic and industrial understanding of AI's current state and future potential in biopharmaceutical manufacturing. The findings of this study will help both researchers and industry professionals by guiding them on how to incorporate AI technologies for improved outcomes in biopharmaceutical manufacturing.

1.3 Research objectives

The application of AI (Automation & Machine Learning) in the biopharmaceutical manufacturing industry holds immense potential for transforming the sector and enhancing its efficiency, productivity, and overall impact. To fully understand the implications of this technological revolution, this research will focus on the following research objectives:

- **Identify and characterize the current state of AI adoption in the biopharmaceutical industry, including the specific AI techniques- machine learning, and automation tools that are being used.**

  The objective of researching the current state of AI adoption in the biopharmaceutical industry is to understand how artificial intelligence techniques, particularly machine learning and automation tools, are being used to enhance various aspects of manufacturing processes. This objective aims to provide insights into specific AI applications, their effectiveness, challenges encountered, and potential future directions. This will be achieved through an extensive literature review of academic papers, data analysis, and case studies highlighting successful AI implementations in the biopharmaceutical sector.

- **Assess the trends and factors driving the increasing adoption of AI, machine learning (ML), and RPA in the biopharmaceutical industry, exploring the factors that have contributed to this growth in recent years.**

  The research objective aims to evaluate the growing adoption of AI, machine learning (ML), and robotic process automation (RPA) in the biopharmaceutical industry. This aims to better understand the reasons and trends behind this increase, as well as the factors that increase adoption. This research takes an in-depth approach, using literature reviews to find a theoretical basis, data analysis to acquire quantitative insights, and case studies to demonstrate real-world applicability.

- **Examine the transformative impact of AI on the biopharmaceutical model, particularly in the manufacturing sector, analysing how AI has disrupted traditional processes and introduced new methodologies.**

  The research objective is to look into the fundamental changes that AI has brought to the biopharmaceutical sector, with particular focus on its impact on manufacturing processes. By examining how AI disrupts traditional methods and introduces new methods, this research seeks to understand the transformative effects on efficiency, quality, and innovation within the biopharmaceutical sector. This research will be carried out through a thorough study that will include a literature review, data analysis to find trends and patterns, and case studies that show the practical applications and effects of AI in biopharmaceutical manufacturing.

- **Assess the specific benefits that AI-enabled technologies have brought to the biopharmaceutical industry, encompassing efficiency improvements, productivity gains, and cost reduction opportunities.**

  The purpose of this objective is to look at the benefits that AI-enabled technologies have brought to the biopharmaceutical sector. By looking into existing literature, analysing relevant findings, and reviewing real-world examples, the study seeks to identify particular benefits such as greater efficiency, productivity, and reduced costs as a result of artificial intelligence integration. The objective is to fully explore the transformative impact of AI on biopharmaceutical processes.

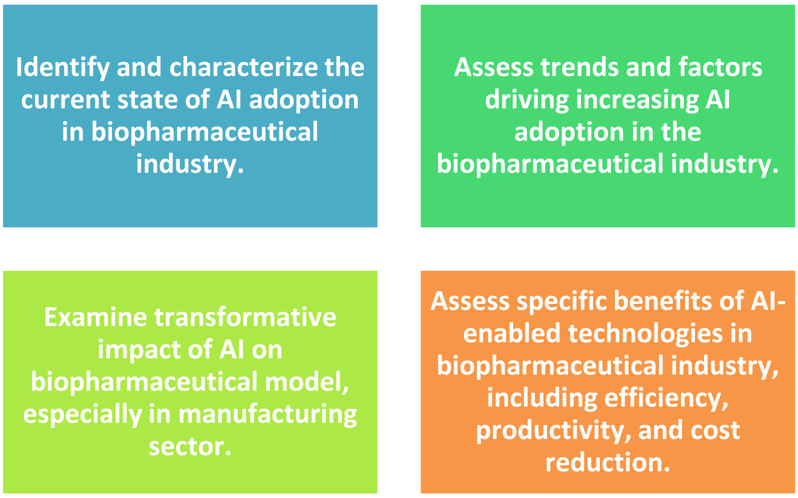

Figure 1 Objectives of the study

1.4 Research Questions

In the rapidly changing field of biopharmaceutical manufacturing, the integration of artificial intelligence (AI), machine learning (ML), and robotic process automation (RPA) is becoming increasingly important. In order to begin research to understand the complex relationships between technology and biopharmaceutical processes, four key research questions will eventually contribute to the study. The research questions listed below will act as a signal, resulting in the research we do to not only understand the current condition but also provide insight into the path forward in the collaboration between AI and the biopharmaceutical industry.

1. What artificial intelligence (AI) techniques are now in use in the biopharmaceutical industry, and which will be employed in the future?
2. How has the adoption of AI, machine learning (ML) & RPA in biopharmaceutical industry increased in recent years?
3. How has AI changed the biopharmaceutical model, especially in manufacturing sector?
4. What specific benefits and challenges have AI-enabled technologies brought to the biopharmaceutical industry?

1.5 Structure of the study

The structure of the study consists of five chapters, each serving a specific purpose in the research process. The first chapter serves as the study's foundation, providing a comprehensive overview. This chapter describes the research purpose and aims, research objectives and questions, justification for the research, and hypothesis. By laying the foundation, it will provide an outline for understanding the content of the chapters that follow as well as the study's overall significance.

In the second chapter, the focus shifts to an in-depth review of relevant literature on the implementation of AI in the biopharmaceutical sector. This chapter aims to synthesise the existing information by covering topics such as an overview of AI in biopharmaceutical manufacturing, the evolution of AI adoption, current AI adoption characterization, machine learning, robotic process automation, challenges, and trends. It concludes with a summary of key findings and identifies gaps in the research, laying the foundation for the following chapters.

In the third chapter, the research methodology is discussed in detail. This chapter focuses on a mixed-methods approach, covering a philosophical basis, a research approach, and a strategy for gathering primary data. The use of qualitative and quantitative research methodologies, such as interviews and surveys with industry professionals, ensures a complete and reliable methodology for data collection in the biopharmaceutical manufacturing sector.

The observations, analysis, interpretation, and conclusions drawn from the data gathered are discussed in Chapter four, which constitutes the research's main section. This chapter thoroughly examines the data acquired from interviews and surveys, providing insights into the influence of AI on biopharmaceutical companies.

The concluding section, fifth chapter, summarises the research journey, providing a brief summary of major results and insights gained. Furthermore, it makes recommendations and suggestions for future studies in this field. This final chapter serves as a conclusion, ensuring that the study contributes meaningfully to the overall understanding of AI's impact on the biopharmaceutical manufacturing sector while also laying the path for future research and development in this area.

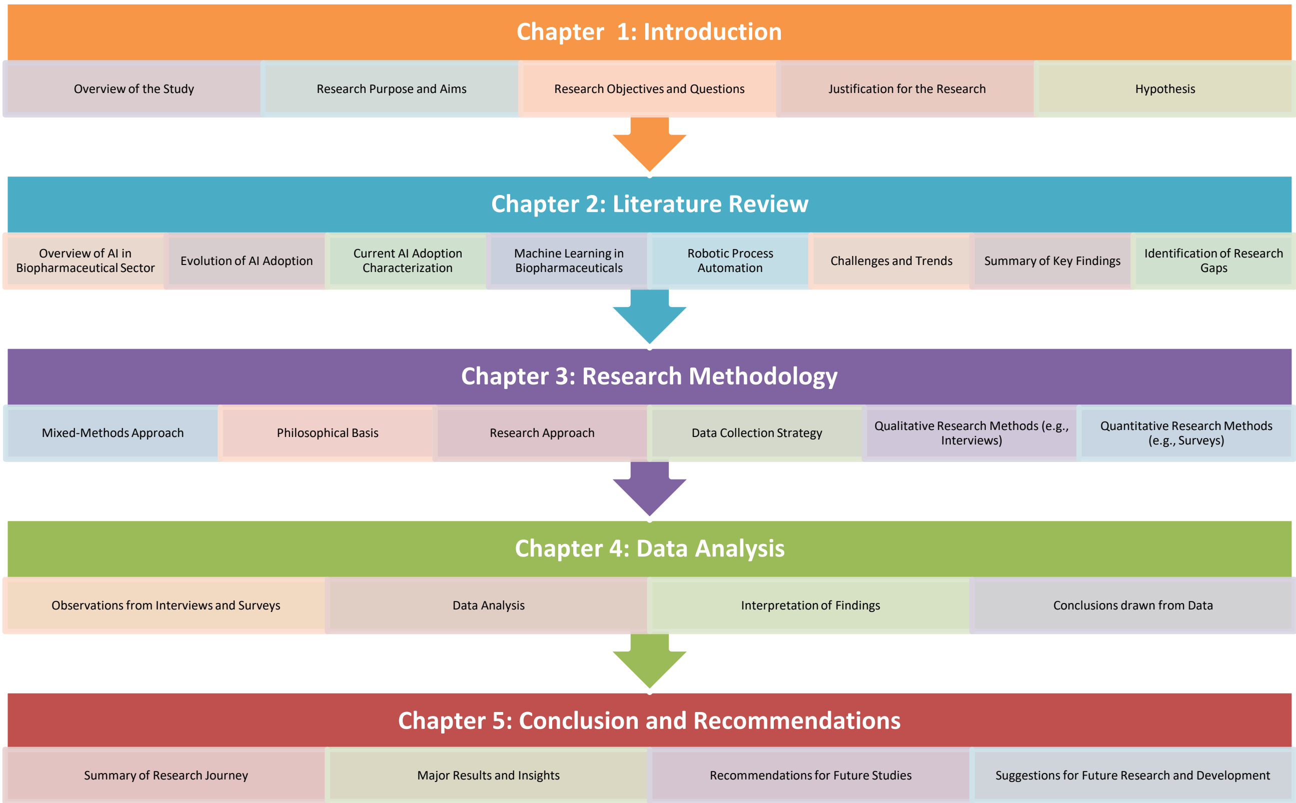

Figure 2 Research framework

2 LITERATURE REVIEW

2.1 Overview

This chapter provides a review of the literature and a number of publications that focus on the concept of the impact of AI (machine learning and automation) on the biopharmaceutical manufacturing industry, a topic that explores how artificial intelligence technologies can impact the biopharmaceutical manufacturing sector. This literature review aims to look at the ways that artificial intelligence (AI), specifically machine learning and automation, has transformed different areas of biopharmaceutical manufacturing processes. Artificial intelligence has evolved into a powerful technology that uses human-like abilities to solve complex problems quickly. In recent years, the integration of AI technologies in the biopharmaceutical sector has shown huge potential for increasing efficiency, productivity, and quality control (Vora et al., 2023).

AI can analyse a huge amount of data generated across the various stages of biopharmaceutical manufacture using machine learning methods. This analysis allows manufacturers and researchers to identify patterns, optimise manufacturing processes, predict results, and make data-driven decisions. (Paul et al., 2021). AI technologies can reduce human error and improve overall accuracy by automating repetitive tasks such as data entry or quality assurance checks. Furthermore, AI technologies have the potential to improve drug development and research processes using virtual compound screening, predicting drug-target interactions, optimising formulation design, and speeding up clinical trial recruitment (Raza et al., 2022). These innovations not only save time but also help to reduce costs in R&D.

However, it is critical to overcome potential problems when integrating AI in biopharmaceutical manufacturing. To ensure regulatory compliance, ethical factors such as patient privacy and data security must be carefully considered. In addition, workforce training programmes should be created to provide professionals with the skills required for effectively utilising AI tools. In conclusion, this literature review will consider the impact of AI (machine learning and automation) on the biopharmaceutical manufacturing industry. By reviewing existing literature and research findings in this area, the study aims to provide significant insights into how these technologies have changed numerous aspects of biopharmaceutical manufacturing processes.

2.2 Artificial Intelligence: An introduction

2.2.1 What is Artificial Intelligence?

Artificial intelligence (AI) is a cutting-edge technology that aims to replicate human intelligence in machines. By programming machines to think and learn like humans, AI can perform tasks such as reasoning, problem-solving, perception, and language understanding (Xu et al., 2021). There are different types of AI, including reactive machines, limited memory machines, theories of mind, and self-awareness (IBM, 2022). AI has a wide range of applications in fields like healthcare, finance, transportation, and entertainment. However, it has the potential to revolutionize industries and enhance the quality of life (Bodra, 2022).

Moreover, there are ethical concerns surrounding its development. Privacy issues and worries about job displacement are also raised by the rapid advancement of AI technology. In conclusion, AI is a powerful tool with immense potential for positive change. Therefore, it is crucial to address the challenges associated with its implementation in order to ensure a responsible and ethical use of this ground-breaking technology (Davenport & Kalakota, 2019).

2.2.2 Introduction to subsets of AI: Machine Learning and Automation

Machine learning, as a branch of artificial intelligence, has revolutionized the field of pharmaceuticals. However, its primary contribution lies in enabling computers to learn from data and make predictions or decisions without explicit programming, as noted by Kolluri et al. (2022). This technology has played a crucial role in various aspects such as drug discovery, personalized medicine, disease diagnosis, and treatment optimization.

One of the key strengths of machine learning in pharmaceuticals is its ability to analyze large amounts of data quickly and accurately. Moreover, as highlighted by Vora et al. (2023), this capability allows researchers to identify patterns and trends that may not be apparent through traditional methods. Pharmaceutical companies can use machine learning algorithms and models to streamline drug discovery, develop personalised treatments for patients based on their genetic makeup, diagnose diseases more effectively, and optimise treatment plans for better outcomes.

According to Somareddy et al. (2020), automation in the pharmaceutical industry involves employing different control technologies to execute tasks with minimal human intervention, thereby optimising processes, increasing efficiency, and ensuring adherence to regulatory requirements.

Automation is very important in pharmaceutical manufacturing because it helps with tasks like packaging, labelling, filling, and sealing. These tasks are done more efficiently and accurately by robots and automation tools compared to humans. Automation tools can track actions, create data records, and remind users to enter credentials and note important times and dates to follow data integrity standards. (Bhattamisra et al., 2023).

Additionally, using automation in pharmaceutical manufacturing can greatly increase return on investment (ROI) by providing cost-effective solutions for routine tasks. This not only enhances operational efficiency but also lowers the chances of errors in important processes such as packaging, labelling, and data management. Automation tools are not only cheaper than employing human labour for tasks like packaging, labelling, and inventory management, but they also help streamline the overall pharmaceutical manufacturing process, making it more cost-effective (Somareddy et al., 2020).

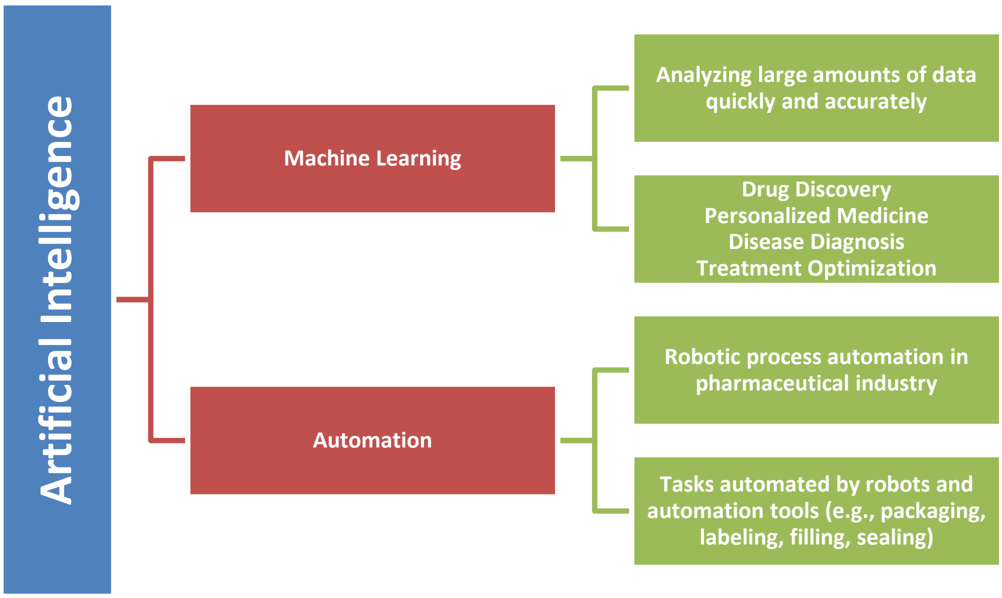

Figure 3 Subsets of AI

This diagram represents the subsets of AI i.e., Machine Learning and Automation. Under Machine Learning, it has a ability to analyse large amounts of data quickly and accurately, leading to advancements in drug discovery, personalized medicine, disease diagnosis, and treatment optimization. Under Automation, the focus is on its role in pharmaceutical manufacturing, specifically in automating tasks such as packaging, labelling, filling, and sealing, leading to increased efficiency, cost-effectiveness, and adherence to regulatory requirements.

In conclusion, the use of machine learning and automation has led to major advancements in the pharmaceutical industry. Machine learning helps researchers find crucial details in abundant data making advances in finding drugs, personalized medication, and disease detection. Automation transforms the drug production process, improving quality and compliance with regulations. Together, these technologies create opportunities for a future where pharmaceutical companies can develop safer and more effective drugs while improving manufacturing procedures and improving patient outcomes.

2.3 Introduction to AI Adoption in the Biopharmaceutical Industry

2.3.1 Overview of AI in the biopharmaceutical manufacturing

The adoption of artificial intelligence (AI) into biopharmaceutical manufacturing has transformed the industry, enabling improvements in a variety of fields. This section gives an overview of AI applications in biopharmaceutical manufacturing, drawing on insights from several research articles. AI plays a vital role in process optimisation in biopharmaceutical manufacturing. Machine learning algorithms analyse large amount of data gathered at various stages of manufacturing, enabling real-time monitoring, quality control enhancements, predictive maintenance, and supply chain optimisation (Vora et al., 2023). One study by Rathore et al. (2023) summarises the most widely used AI-ML algorithms in biopharmaceutical manufacturing. These methods include multivariate data analysis, support vector machines (SVM), random forests, and neural networks. Manufacturers can use these algorithms to analyse complex datasets collected at various stages of manufacturing to enhance efficiency and optimise procedures.

2.3.2 Evolution of AI adoption in biopharmaceutical manufacturing

AI has played an important role in optimising manufacturing processes in the biopharmaceutical sector. To improve efficiency and quality assurance, real-time monitoring and control systems were developed using machine learning algorithms. These systems analyse huge amounts of data collected at various phases of production to identify patterns, identify problems, and make informed decisions regarding process optimisation (Rathore et al., 2023). In addition, predictive maintenance facilitated by AI has become a critical component of biopharmaceutical manufacturing. Potential problems or irregularities can be identified early by continuously monitoring equipment and analysing sensor data with AI algorithms. This proactive approach allows timely maintenance interventions, which reduce downtime and increase overall productivity (Aswal et al., 2022). Additionally, a report from Precedence Research, 2023 predicts an era of opportunity for AI in the biopharmaceutical sector. The artificial intelligence in pharmaceuticals industry is expected to be valued around USD 14.07 billion by the year 2032, with a CAGR (compound annual growth rate) around 32.3% from 2023. This indicates the industry's growing confidence and investment in artificial intelligence technologies. (Precedence Research, 2023).

2.4 Introduction to AI Adoption in the Biopharmaceutical Industry

2.4.1 Identification and characterization of current AI adoption

AI has shown significant potential in transforming approaches to pathway or target identification for disease treatment. Pharmaceutical manufacturers can use AI algorithms to analyse data and receive feedback, resulting in more consistent and efficient manufacturing processes (Vora et al., 2023). AI in drug discovery has also been recognised as a game changer, providing increased efficiency, accuracy, and speed (Blanco-González et al., 2023).

In biopharmaceutical manufacturing, AI techniques like machine learning (ML) are gaining popularity. ML algorithms are used to improve production processes by analyzing large datasets and finding patterns that can enhance quality control (Vora et al., 2023). These algorithms can also predict drug interactions and help identify potential targets for drug discovery (Aswal et al., 2022).

The current use of AI in biopharmaceutical manufacturing suggests its potential to transform various industry aspects. From optimizing production through ML algorithms to streamlining operations with RPA, AI provides opportunities for increased efficiency, accuracy, and innovation in the field (Vora et al., 2023).

Table 1: AI adoption in Pharmaceutical Industry

S.No.	Pharmaceutical Company	AI technology used	Collaboration scope	Reference
1	Pfizer	IBM Watson for Drug Discovery	Collaborated to discover new drugs and improve drug discovery process	(Pfizer Press Release, 2016)
2	Merck	Palantir Technologies for data analysis	Collaborated to improve data analysis and decision making	(Merck KGaA, 2023)
3	Sanofi	GSK and Google's Verily Life Sciences for R&D	Collaborated to accelerate R&D and improve drug discovery	(Sanofi, 2019)
4	Novartis	Microsoft for AI-powered lab automation	Collaborated to automate lab processes and improve efficiency	(Microsoft News Center, 2019)
5	AstraZeneca	BenevolentAI for drug discovery	Collaborated to discover new drugs and improve drug discovery process	(BenevolentAI Press Release, 2019)
6	Roche	Flatiron Health for real-world data analysis	Collaborated to improve real-world data analysis and decision making	(Roche Article, 2018)

7	Johnson & Johnson	Verily Life Sciences for R&D	Collaborated to accelerate R&D and improve drug discovery	(J&J Announcements, 2015)
8	Gilead Sciences	Insitro for drug discovery	Collaborated to discover new drugs and improve drug discovery process	(Gilead, 2019)
9	Amgen	Generate Biomedicines for drug discovery	Collaborated on protein-based drugs for five targets in several therapeutic areas	(Amgen, 2022)
10	Eli Lilly	Atomwise for drug discovery	Collaborated to discover new drugs and improve drug discovery process	(Tirumalaraju, 2019)

The table provides an overview of 10 pharmaceutical and biopharmaceutical companies that have collaborated with AI technology companies to improve drug discovery, R&D, and decision making. The scope of collaboration varies between companies, but the overall goal is to improve the efficiency and effectiveness of the drug discovery process.

2.5 AI techniques in use: Machine Learning and Robotic Process Automation

Robotic Process Automation (RPA) and Machine Learning (ML) are extensively researched and used in different industries, including biopharmaceutical manufacturing. Rathore et al. (2023) provided an overview of AI-ML applications in biopharmaceutical manufacturing, emphasizing widely used algorithms like multivariate data analysis. Additionally, a review in the Journal of Advanced Manufacturing and highlights AI and ML as promising technologies for enhancing manufacturing processes, particularly in biopharmaceutical manufacturing Process (Plathottam et al., 2023).

2.5.1 Machine Learning in the Biopharmaceutical Industry

Machine learning is increasingly used in various industries, including biopharmaceutical manufacturing. Recent successful case studies highlight its implementation in this field. One study, discussed in a review article, focuses on using machine learning for drug discovery, emphasizing its application in every stage, from target identification to lead optimization (Dara et al., 2021). This showcases the potential of machine learning to enhance efficiency and accuracy in biopharmaceutical manufacturing.

Recognizing the challenges of innovation implementation in bioprocess development, machine learning has become a valuable tool. It addresses these challenges by optimizing bioprocessing parameters and improving overall efficiency (Guerra & Glassey, 2020). Through data analysis and predictive modelling, machine learning algorithms assist in optimizing production processes, leading to increased productivity and reduced costs.

2.5.2 The Impact of Robotic Process Automation (RPA) on Biopharmaceutical Industry

Robotic process automation (RPA) significantly improves efficiency and workflow optimization in biopharmaceutical manufacturing. RPA software interfaces with computer applications to perform repetitive, rule-based tasks, calculations, and decision execution (Andruszkiewicz, 2023).

Despite its benefits, implementing RPA in biopharmaceutical manufacturing comes with challenges and limitations. These include the complexity and variability of biological systems, the necessity for meticulous planning, validation, and compliance with regulatory requirements, and the potential for job losses due to automation (Hafke, 2023) (Bremme et al., 2020).

2.6 Challenges and limitations in implementing ML

Implementing machine learning in biopharmaceutical manufacturing faces challenges that require addressing for successful integration. One key challenge is the need for a substantial amount of high-quality data. Machine learning models depend on extensive datasets for accurate training and predictions, but obtaining representative and comprehensive datasets in the biopharmaceutical industry proves challenging. The industry's lack of accessible and standardized data hampers the development of robust machine learning models (Guerra & Glassey, 2020).

Another hurdle involves the complexity and variability of biological systems in biopharmaceutical manufacturing. The intricate biological processes are influenced by factors such as cell lines, culture conditions, and environmental variables. These complexities hinder the creation of generalized machine learning models capable of effectively capturing all the nuances of these systems (Khuat et al., 2023).

Despite these challenges, ongoing efforts aim to overcome limitations in implementing machine learning in biopharmaceutical manufacturing. Researchers are actively working on strategies to address data availability issues through collaborations and data-sharing initiatives (Guerra & Glassey, 2020).

2.7 Trends and Drivers of AI, ML, and RPA Adoption

Recent research shows that the growth of artificial intelligence (AI) in biopharmaceutical manufacturing is influenced by factors such as process optimization, drug discovery, and testing. AI and machine learning technologies play a crucial role in analyzing process data, predicting challenges, and detecting quality control problems. This results in enhanced efficiency and more reliable manufacturing systems, as highlighted by Stucky in 2023.

AI facilitates the rapid identification of promising compounds and targets, reducing the need for time-consuming and costly trials. However, implementing AI in biopharma research requires a careful balance between developing internal capabilities and collaborating with AI-enabled drug discovery platforms, as pointed out by Devereson et al. in 2022.

The use of AI in biopharmaceutical manufacturing is expected to greatly impact clinical trials and the development of cell and gene therapies. It has the potential to automate manual processes, leading to more personalized medicine and improved treatment effectiveness. The growing adoption of AI in biopharmaceutical manufacturing is motivated by its ability to enhance efficiency, productivity, and the overall drug development process (Stucky., 2023).

A 2021 Deloitte survey revealed that 75% of life sciences leaders in the manufacturing sector consider AI a top investment priority for the next five years. The increasing adoption of AI, ML, and RPA in biopharma manufacturing is driven by their potential to boost efficiency, productivity, and streamline the drug development process (Kudumala et al., 2023).

2.8 Transformative Impact of AI on the Biopharmaceutical Model

2.8.1 AI's disruption of traditional processes in the biopharmaceutical sector

AI is set to make a big difference in traditional biopharmaceutical manufacturing. Advanced machine learning models are being used to find issues in real time. This allows for quick corrective actions to maintain the product's quality. (Hafke, 2023). Artificial intelligence (AI) and machine learning algorithms are important for improving various aspects of biopharmaceutical manufacturing. These technologies help streamline processes, predict and address future manufacturing issues, and maintain high quality control standards. (Stucky, 2023).

According to Wong et al. (2023), the use of AI in Pharma 4.0 is expected to result in stronger and more adaptable manufacturing processes, increased productivity, and enhanced connectivity in the pharmaceutical supply chain. To fully adopt artificial intelligence in the pharmaceutical industry, Paul et al. (2021) highlight the importance of ensuring data reliability and quality, addressing budget constraints for smaller organisations, and reducing concerns about potential job losses and lack of transparency in AI systems.

2.8.2 Introduction of new methodologies and practices

Extensive research has been conducted on the integration of artificial intelligence (AI), machine learning (ML), and automation in pharmaceutical manufacturing. These innovative methodologies and practices have shown great potential to bring about significant advancements and revolutionize the pharmaceutical industry (Dashpute et al., 2023). AI has had a significant impact on the of personalized medications. By integrating AI into pharmaceutical manufacturing processes, it becomes possible to create medications that are specifically tailored to individual patients. This includes precise dosage requirements, release parameters, and other necessary specifications. The incorporation of AI not only speeds up the production time but also improves the quality and safety of the products (Paul et al., 2021).

Furthermore, AI is being utilized across various domains within pharmaceutical manufacturing. It plays a important role in drug discovery by assisting in identifying potential drug candidates through data analysis. Additionally, AI aids in process optimization, drug delivery dosage form designs, and testing. These applications enable quick prototyping and optimize the drug release profiles, geometries and dosage strengths (Vora et al., 2023). The impact of AI on pharmaceutical manufacturing is further evident through the integration of AI-powered robotics and automation. This integration streamlines manufacturing processes while ensuring heightened quality control measures and improved efficiency (Chi Cheng, 2023).

2.9 Recent Applications of AI, ML, and Automation in Biopharmaceutical Manufacturing

Recent use cases of AI, machine learning (ML), and automation in biopharmaceutical manufacturing include:

Figure 4 Recent Applications of AI, ML, and Automation in Biopharmaceutical Manufacturing

- **Streamlining Lab Processes:** AI-driven automation in the biopharma sector streamlines lab processes, reducing the need for manual data analysis and management. This has led to enhanced operational efficiency and improved productivity in the industry (Hafke, 2023).

- **Enhancing Efficiency and Safety:** AI in biopharma manufacturing plays a crucial role in analysing process data to generate insights for greater efficiency and safety. By predicting potential roadblocks, identifying quality control issues, and creating better, more reliable systems, AI is revolutionising the way biopharma companies operate (Stucky., 2023).

- **Automating Manufacturing Processes:** With advancements in technology, AI is increasingly being used to automate processes like continuous fermentation, with the goal of achieving substantial automation within the next decade. This automation not only increases efficiency and productivity but also leads to more personalised medicine, allowing for the treatment of a wider range of diseases and a larger population (Stucky., 2023).

- **Improving Quality Control:** Intelligent automation solutions are being implemented in quality control processes within the pharmaceutical industry. These solutions are able to detect defects and inconsistencies in real-time, improving product quality and reducing the risk of recalls. By utilising AI to automate manufacturing processes and enhance quality control measures, pharmaceutical companies can ensure that their products meet high standards while also increasing their overall competitiveness in the market. (Hafke, 2023)

- **Transforming Supply Chain Management:** The smart automation implementation is transforming the way the pharma industry is managing its supply chain by optimising inventory levels, tracking products, vendor management, and streamlining transportation management to make it more efficient and productive (Rathore et al., 2023).

- **Optimising Manufacturing Processes:** The utilisation of machine learning algorithms has become essential in optimising manufacturing processes. By analysing vast amounts of data, these algorithms can identify ways to improve efficiency and quality while reducing costs. Through simulations and virtual models, different scenarios can be tested to find the most effective solutions (Hafke, 2023).

- **Enhancing Customer Service**: Customer service within the pharmaceutical industry is being transformed by AI technology. Chatbots, virtual assistants, personalised communications, predictive analytics, and feedback analysis are all being used to provide customers with a more personalised and efficient experience (Hafke, 2023).

2.10 AI's Influence on Efficiency, Productivity, and Cost Reduction

AI in the biopharmaceutical manufacturing industry offers several specific benefits, including:

- **Drug Discovery and Development:**
  Artificial intelligence is employed to develop new proteins, peptides, nucleic acid biologics, and immunotherapeutic, as well as to find potential compounds and targets throughout the entire process (Paul et al., 2021).
- **Process Optimization:**
  Artificial Intelligence (AI) plays a crucial role by helping to predicting and addressing potential difficulties in the manufacturing process. It works to optimize the printing parameters and ensures that quality is maintained. Additionally, AI enables quick and efficient prototyping, optimizing aspects such as drug release patterns, dosage strengths, and geometries for improved outcomes (Vora et al., 2023).
- **Quality Control and Safety:**
  Using AI in making personalized medications not only makes the production faster but also enhances the quality of the medicines and ensures the safety of the entire production process (Paul et al., 2021).
- **Efficiency and Productivity:**
  The use of AI in drug development can make the process more effective and goal-focused. This enhances overall productivity and efficiency in the pharmaceutical industry by providing advanced and objective-oriented approaches (Devereson et al., 2022).
- **Cost Reduction opportunities:**
  AI allows quick creation of prototypes and predictions, helping to overcome manufacturing challenges and reducing costs. (Kolluri et al., 2022). Using AI can make supply chain management decisions better, help create new biologics, and make product development more efficient, ultimately lowering costs (Vora et al., 2023)

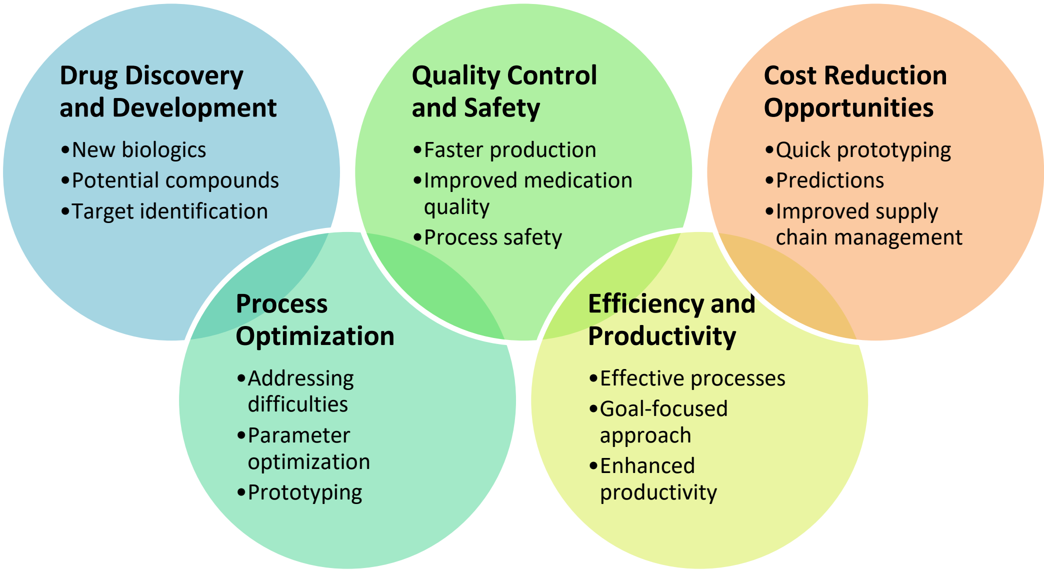

Figure 5 AI's Influence on Efficiency, Productivity, and Cost Reduction

2.11 Conclusion

2.11.1 Summary of key findings from the literature

This section will have a summary of key findings related to the four objectives:

i. The literature looks at how AI, especially machine learning, is used in the biopharmaceutical industry for drug discovery and making production more efficient. It mentions challenges like data quality and complex biological systems when using machine learning. The review also talks about the benefits of using Robotic Process Automation (RPA) in biopharmaceutical manufacturing. It emphasizes that overcoming challenges like data availability and meeting regulatory requirements is important for successful AI use. Overall, the findings highlight how AI, particularly machine learning and RPA, can greatly improve biopharmaceutical processes which helps establish the first objective of identifying and describing how AI is currently being used in the biopharmaceutical industry, including the specific techniques like machine learning and automation.

ii. The literature review highlights key trends and drivers behind the escalating adoption of AI, ML, and RPA in the biopharmaceutical industry. Factors such as process optimisation, drug discovery, and testing contribute to this growth. The role of AI and ML in analysing process data, predicting challenges, and improving quality control is emphasized. Insights from recent studies underscore the potential for AI to enhance clinical trials, cell and gene therapies, and overall drug development processes, reflecting a significant industry shift towards increased efficiency and productivity, which helps establish the second objective of assessing the trends and factors driving the increasing adoption of AI, machine learning (ML), and RPA in the biopharmaceutical industry and exploring the factors that have contributed to this growth in recent years.

iii. The study highlights the impact of AI on the biopharmaceutical model, particularly in manufacturing. AI disrupts traditional processes by quickly identifying issues in real-time, enhancing quality control, and boosting productivity. It introduces new methodologies like personalised medication production, drug discovery assistance, and AI-powered robotics for streamlined processes and improved efficiency. This is the focus of the third objective, which is to look at how AI is transforming the biopharmaceutical model, especially in manufacturing, and to see how it's changing traditional ways and bringing in new methods.

iv. Finally, the foundation for the fourth objective is to evaluate how AI technologies have positively impacted the biopharmaceutical industry by improving efficiency, increasing productivity, and reducing costs. The literature highlights the specific benefits of AI-enabled technologies in the biopharmaceutical industry, such as improved efficiency, productivity, and cost reduction. Key findings indicate AI's role in drug discovery, process optimization, quality control, and safety. These advancements lead to enhanced productivity, streamlined manufacturing processes, and significant cost-saving opportunities, ultimately benefiting the biopharmaceutical sector.

2.11.2 Gaps in the Literature

The literature gives a detailed look at how AI, especially machine learning and automation, affects the biopharmaceutical manufacturing industry. But there are some important gaps and opportunities for more research in this area.

I. The literature emphasises the need of regulatory compliance while also addressing ethical concerns like as patient privacy and data security. However, a more thorough understanding of the specific regulatory challenges, guidelines, and ethical frameworks associated with AI use in biopharmaceutical manufacturing is required.

II. The literature highlights the value of workforce development initiatives in preparing professionals to use AI tools efficiently. More research could delve into the specific skills and abilities needed, potential gaps in the existing workforce, and effective ways for up skilling workers in the biopharmaceutical manufacturing industry.

III. The complexity and variability of biological systems in biopharmaceutical manufacturing pose significant challenges for implementing machine learning. Further research could explore advanced modelling techniques, such as incorporating domain-specific knowledge or leveraging advanced algorithms capable of handling intricate biological processes.

Table 2 Summary of literature review

Objectives	Summary of Literature Review	Relation to Objective	Related Research Gaps
Identify and characterize the current state of AI adoption in the biopharmaceutical industry	- AI, especially machine learning, is used for drug discovery and enhancing production efficiency. - Challenges include data quality and complex biological systems. - Robotic Process Automation (RPA) benefits biopharmaceutical manufacturing.	Establishes current usage of AI, ML, and RPA in biopharmaceutical industry.	Need for a better understanding of regulatory challenges and ethical frameworks in AI implementation.
Assess the trends and factors driving the increasing adoption of AI, ML, and RPA in the	- Trends include process optimization, drug discovery, and testing. - AI and ML improve quality control and enhance efficiency. - Shift towards increased efficiency and productivity.	Highlights factors driving AI, ML, and RPA adoption in biopharmaceutical industry.	- More research needed on regulatory compliance and workforce development initiatives.

biopharmaceutical industry			
Examine the transformative impact of AI on the biopharmaceutical model	- AI disrupts traditional processes, improves quality control, and boosts productivity. - Introduces new methodologies like personalized medication production and AI-powered robotics.	Examines how AI transforms traditional biopharmaceutical model, especially in manufacturing.	- Exploration of advanced modelling techniques to handle complex biological systems.
Assess the specific benefits that AI-enabled technologies have brought to the biopharmaceutical industry	- AI benefits include drug discovery, process optimization, quality control, and safety improvements. - Enhanced productivity, streamlined processes, and cost-saving opportunities.	Evaluates positive impacts of AI technologies in biopharmaceutical industry.	- Further understanding of workforce development initiatives and skills needed for AI implementation.

2.11.3 Conceptual Framework

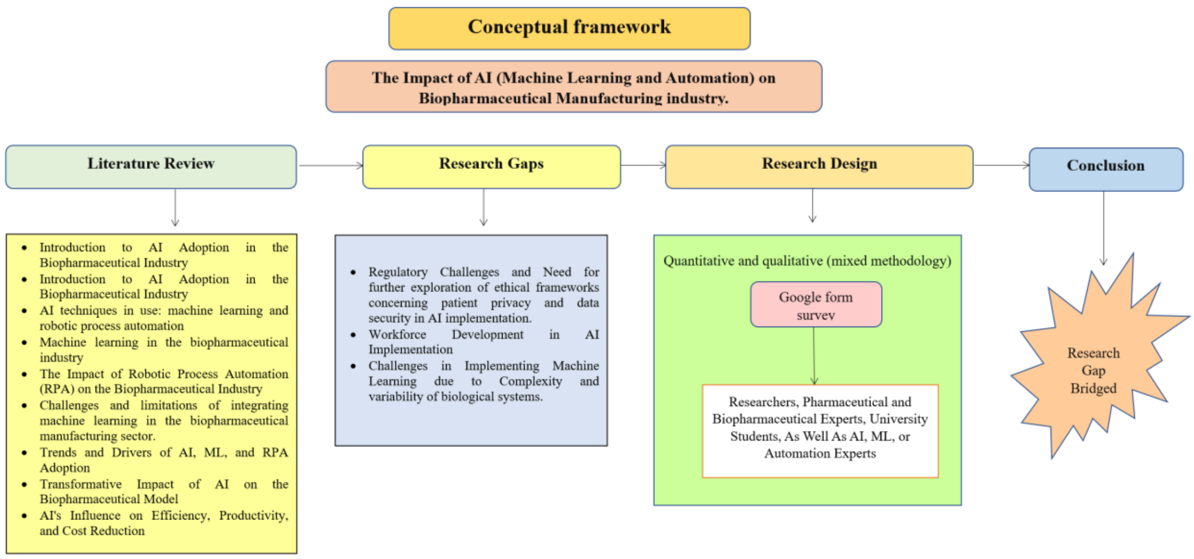

Figure 6 Conceptual Framework

This conceptual framework focuses on the influence of artificial intelligence (AI), particularly machine learning and automation, in the biopharmaceutical manufacturing sector. It describes a research journey that begins with identifying AI's role and the particular techniques used. The framework then goes into the various ways that machine learning and robotic process automation (RPA) are impacting this industry. It acknowledges challenges like regulatory hurdles and ethical considerations around patient privacy and data security. The framework explores the driving forces behind AI adoption and how it's transforming the biopharmaceutical model altogether, with a focus on efficiency, productivity, and cost reduction. Finally, it details the research methodology used, including a literature review, the identification of research gaps, the chosen research design, and the conclusions drawn. The framework highlights the gaps this study bridges and identifies its target audience, encompassing researchers, industry professionals, students, and AI/machine learning/automation experts.

3 RESEARCH METHODOLOGY

3.1 Overview

According to Dawson (2019), a research methodology serves as the primary guiding principle for research. It outlines the overall approach for studying a topic and determines the specific methods used for data collection. It's important to distinguish between a research methodology and research methods, as the former sets the framework while the latter are the tools utilized for gathering data (Dawson, 2019). The following chapter will describe why the research philosophy, design, and methods employed in this study were chosen. The justifications for these decisions will be thoroughly explained. Furthermore, the reasons for selecting a specific research philosophy, research design and methodology will be discussed, highlighting how it aligns with the research objectives and the desired outcomes.

3.2 Research Onion Framework

The research onion model, which was developed by the group of Saunders, Lewis and Thornhill, is a framework that shows the different stages of the research methodology. It comprises six stages that start from the outermost layer and move to the innermost layer with each stage representing a more detailed step in the research process (Okesina, 2020) (Saunders et al., 2019).

The outermost layer stands for the research philosophy, which is the first step in the research process that determines the research approach and is the basis for the second layer. The research approach can be either deductive or inductive (Melnikovas, 2018). The next layer is the research strategy that describes the particular techniques of data collecting and analysing. Research approaches may include experiments, surveys, case studies and action research (Saunders et al., 2016).

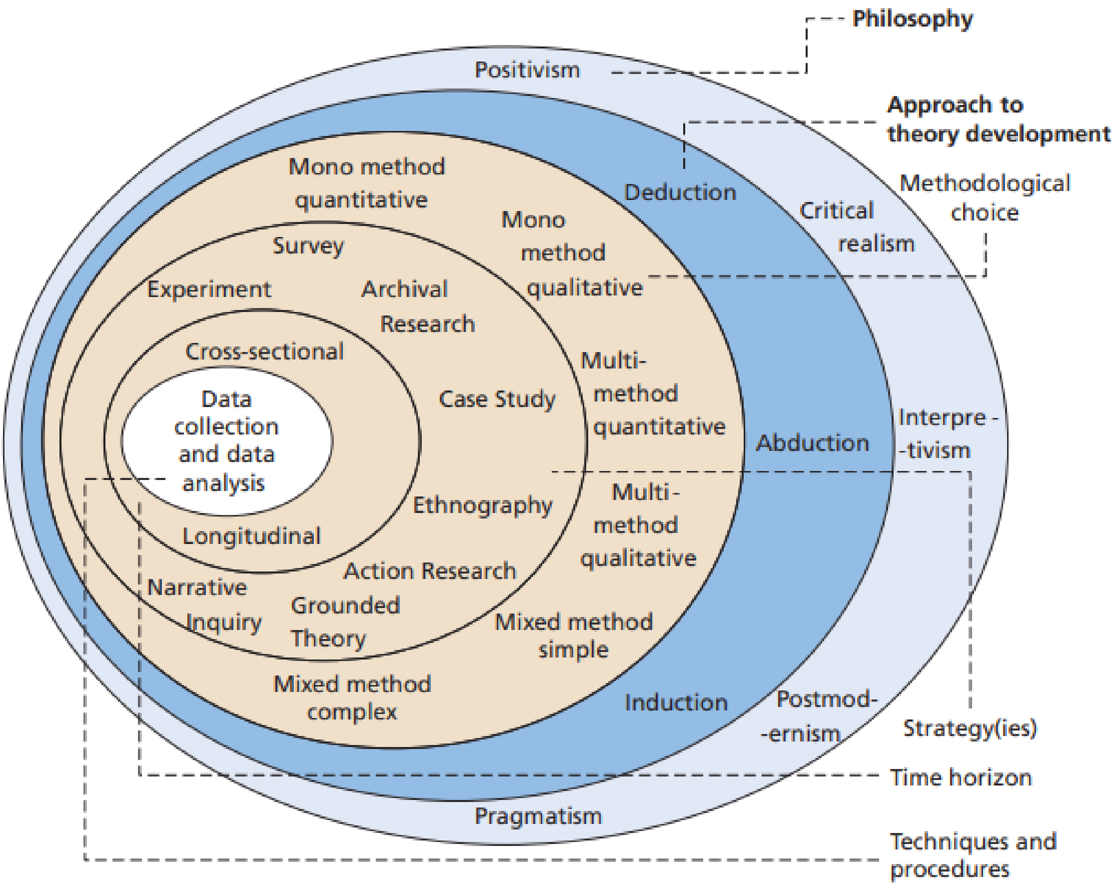

Figure 7 The Research Onion (Saunders et al., 2019)

The research methodology is highlighted on the fourth layer, wherein the choices of a mixed-method (which combines quantitative and qualitative data collection techniques), a mono-method (which combines different data collection techniques and procedures but is restricted to either a quantitative or qualitative design), or a multi-method (which combines both techniques) are made (Saunders et al., 2019).

The time horizon, which can be longitudinal or cross-sectional, forms up the fifth layer. While longitudinal research examines changes and developments over time, cross-sectional research concentrates on a particular occurrence at a certain period. Within the innermost layer are techniques and procedures, which include methods such as how data is collected and analysed. Such consists of carefully selected research instruments, sampling procedures, and data analysis techniques (Saunders et al., 2019).

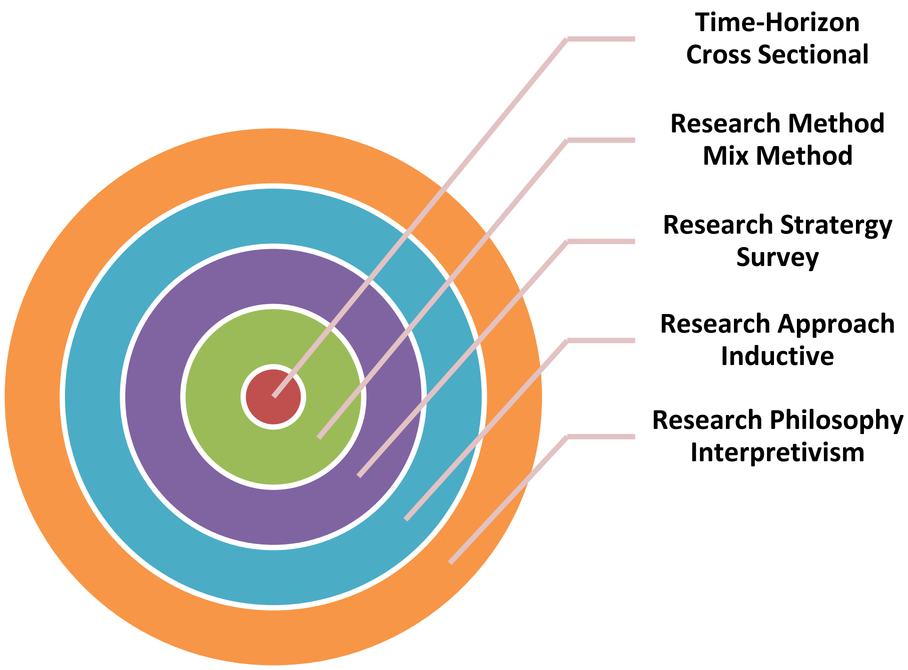

Figure 8 Research Onion overview of choices (Saunders et al., 2019)

3.2.1 Research Philosophy

Philosophy of research, according to the research onion model, is at the top layer of the research process and serves as the base for the entire research methodology (Saunders et al., 2019). It is related to the beliefs and assumptions about the methods of data collection, analysis, and usage about a certain phenomenon. The research philosophy is the expression of the author's significant assumptions and it is the foundation of the research (Moroi, 2020). The main philosophical research paradigms that constitute the basis of research processes are positivism, interpretivism, critical realism, postmodernism and pragmatism (Saunders et al., 2019).

The research based on the interpretivist approach because of its emphasis on the understanding of the subjective experiences and interpretations of biopharmaceutical professionals on the impact of AI on their industry. Interpretivism stresses the significance of context, meaning and the personal views of the individuals in the creation of social phenomena (Puglisi, 2008). Through this method, the research intends to closely examine the subtle opinions of specialists in the biopharmaceutical industry, which will enable a thorough investigation of the way AI is perceived, understood and experienced in this particular industry.

3.2.2 Research Approach

According to the research onion model, the research approach includes the methodology that a researcher adopts, which can be broadly categorised as either deductive, inductive, or abductive (Saunders et al., 2019).

An inductive research approach is employed in this study on the impact of AI, machine learning, and automation on the biopharmaceutical manufacturing industry because of its exploratory nature, this study uses an inductive research approach to study the impact of AI, machine learning, and automation on the biopharmaceutical manufacturing sector. Firstly, it poses a general question: how is artificial intelligence affecting biopharmaceutical manufacturing? There is no predefined hypothesis on the impact. Second, it collects data (via a survey of professionals) to detect trends and patterns in AI use in the industry. On the other hand, deductive reasoning starts with a general theory or hypothesis and draws on specific observations (Saunders et al., 2019). However, that approach may not be suitable here, as the aim is to discover the present situation and the influence of AI in the industry while there is no hypothesis to be tested. In addition, abduction, which represents the process of inferring the best explanation for observed phenomena (Saunders et al., 2019), too is not the prime focus of the experiment given that the emphasis is on the new insights obtained from the collected data rather than explaining existing phenomena.

3.2.3 Research Method

This layer covers different options: mono method (a single data collection technique and corresponding analysis procedures), multi-method (more than one data collection technique with analysis procedures, which belong either to the quantitative or qualitative technique), or mixed methods (an intermix of quantitative and qualitative data collection techniques and analysis procedures) (Saunders et al., 2019).

The data collection strategy involves sending a survey to biopharmaceutical professionals with a variety of questions, including multiple choice, Likert scale, and open-ended questions. With the use of this mix of question types, it is possible to collect both qualitative and quantitative data, leading to an in-depth understanding of the state, trends, and effects of AI in the industry. The systematic analysis of survey findings, along with qualitative analysis of open-ended responses, allows for a more in-depth exploration of the research objectives. This methodology provides an in-depth understanding of the complex dynamics of AI in biopharmaceutical manufacturing by integrating quantitative and qualitative methodologies, providing significant information about its role and implications. Hence, a mixed methodological approach is used in the research.

3.2.4 Research Strategy

Saunders et al. (2019) describe the research strategy in their model, known as the research onion, as the approach by which the researcher plans to conduct the study. This strategy outlines the methods and procedures that will be employed to achieve the research objectives. It includes various approaches such as experiment, survey, case study, action research, grounded theory, ethnography, and archival research (Saunders et al., 2019).

The main data collection method applied is a survey distributed among biopharmaceutical industry professionals. This method enables the collection of both qualitative and quantitative data, involving various types of questions, including multiple choice, Likert scale, and open-ended questions. Multiple choice and Likert scale questions provide structured data that is analysed in order to identify trends and patterns in AI adoption and its benefits, while open-ended questions offer valuable insights into the participants' views and experiences.

In addition, a systematic literature review was carried out to gain a thorough understanding of existing research and theories on the subject. This required a thorough search, critical evaluation, and synthesis of relevant academic journals, reports, and other scholarly sources. The literature review additionally provides insights on the various approaches, methodologies, and findings from previous studies, resulting in a thorough understanding of the research topic. Furthermore, by combining findings from primary survey data and secondary literature sources, the research aimed to improve the validity and reliability of its findings while also contributing to the advancement of knowledge in the field.

3.2.5 Time Horizon

This layer is about the fact that the research can focus on a particular moment in time (cross-sectional) or presents the events during a given duration (longitudinal) (Saunders et al., 2019). This research uses a cross-sectional time horizon, which means that it collects data at a single point in time. Because the research must be completed within a restricted timeframe, the proposed approach enables the collection of comprehensive data from a varied pool of biopharmaceutical industry participants.

3.2.6 Data Sourcing, Collection and Data Analysis

The fourth layer of the Research Onion model concerns "tactics," which is a broader concept referring to the techniques used in data collection and data analysis. This level is very important because it will direct and help researchers to focus on the various aspects of developing research methodology. It includes not only data collection ways but also their analysis approaches and ethical concerns (Saunders et al., 2019).

Primary research data collection is an essential method used to gather first-hand information on a specific topic (McMillan and Gogia, 2014). The research aims to understand how AI, including machine learning and automation, impacts biopharmaceutical manufacturing. To achieve this comprehensive understanding, different methods will be employed. Firstly, a careful examination of existing literature and information about AI's influence on biopharmaceutical manufacturing will be conducted. Furthermore, Google surveys will be utilised to gather a broader range of opinions on AI's impact in this industry. These surveys will incorporate both multiple-choice and open-ended questions, thus allowing for the collection of diverse insights. Consequently, by using a combination of methods like literature reviews and surveys, a more holistic understanding of AI's effects on biopharmaceutical manufacturing can be gained. This research is essential, as it sheds light on the potential benefits and challenges associated with incorporating AI technologies into this sector.

This research is based on online survey method with the data that was gathered through the Google Forms Application. The form was mainly distributed via LinkedIn and WhatsApp, with professionals like researchers, pharmaceutical and biopharmaceutical developers, and AI, ML or automation experts as the primary targets. The goal was to gain comprehensive insights into their experiences and perspectives regarding the subject matter.

To ensure the accuracy and validity of data, primarily, the researcher used LinkedIn to get participation from possible respondents. The online questionnaire's survey included 21 questions that were developed with the particular aim and objectives of this study in mind.

An introduction was made at the beginning of the survey in a brief and straightforward manner that explained the research's objectives and possible outcomes. This introduction aimed to help participants understand the study's objectives and encourage their participation. Additionally, an initial question was added so that the participants would have an option to determine whether or not to participate in the survey. This was an important step to make sure that the ethical considerations were taken into account and sustained for the integrity of the research study. Consequently, this primary research data collection technique allowed for a streamlined, focused approach to gathering valuable insights from targeted professionals in the field.

In the study on "The Impact of AI (Machine Learning and Automation) on the Biopharmaceutical Manufacturing Industry," various types of questions were presented to participants:

(i) Likert scale questions were utilized to assess participants' opinions on the importance of AI, ML, and automation in the future success of the biopharmaceutical industry, as well as the necessity for biopharmaceutical companies to invest in AI technologies for manufacturing. Likert scales provided a quantitative assessment of subjective opinions, allowing for numerical data representation (Gunderman and Chan, 2013).

(ii) Closed-ended questions were used to collect factual information regarding participants' experiences with AI integration in the biopharmaceutical manufacturing industry. This approach simplified the response process for participants and typically yielded a higher response rate (Rosala, 2023).

(iii) Open-ended questions were included to draw out some additional insights from participants. These questions invited participants to share any other AI techniques they had encountered in biopharmaceutical manufacturing and to speculate on emerging AI techniques that they believed would be important in the future of the industry. Open-ended questions allowed participants to express their opinions freely, without being constrained by predetermined response options, thereby providing a richer understanding of their perspectives (Husain et al., 2012).

An "Other" choice was also included for certain questions to offer participants an extra chance to offer alternative perspectives or insights related to the question asked.

The questions depicted in the table below were formulated to enable participants to provide in-depth information and share their experiences regarding the Impact of AI (Machine Learning and Automation) on the Biopharmaceutical Manufacturing industry. Additionally, the table demonstrates how each question is aligned with the research objective.

Table 3 Mapping Survey Questions to Research Goals

Research objectives	**Glimpse of Survey question (Refer to "Appendix A – Survey" for the full survey questionnaire)**
Identify and characterize the current state of AI adoption in the biopharmaceutical industry, including the specific AI techniques- machine learning, and automation tools that are being used.	• Current use of AI • Specific AI techniques used • Prevalence of AI in biopharma manufacturing
Assess the trends and factors driving the increasing adoption of AI, machine learning (ML), and RPA in the biopharmaceutical industry, exploring the factors that have contributed to this growth in recent years.	• Adoption timeline of AI/ML/RPA • Importance of AI/ML/RPA for future success • Investment criticality in AI for manufacturing • Future potential of AI in biopharma manufacturing
Examine the transformative impact of AI on the biopharmaceutical model, particularly in the manufacturing sector, analyzing how AI has disrupted traditional processes and introduced new methodologies.	• Challenges in adopting AI in biopharma • Areas impacted by AI in biopharma manufacturing • Impact of AI on efficiency • Other AI techniques encountered • Most impactful future AI techniques • Emerging AI techniques for the future

	• Changes in AI use over the past 5 years • Challenges hindering wider AI adoption
Assess the specific benefits that AI-enabled technologies have brought to the biopharmaceutical industry, encompassing efficiency improvements, productivity gains, and cost reduction opportunities.	• Specific benefits of AI in biopharma manufacturing • Effectiveness of AI in improving processes • Overall benefit vs. challenge of AI • Impact of AI on productivity • Effectiveness of AI in cost reduction

Data Analysis

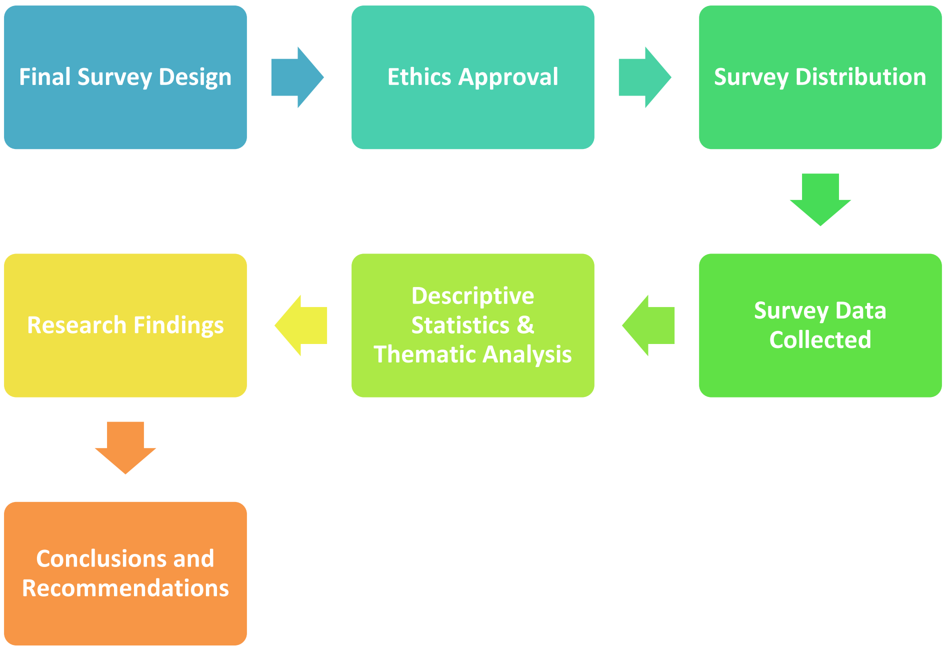

Figure 9 Methodology and Data Analysis Flowchart

A survey was distributed among biopharmaceutical professionals to gain a comprehensive understanding of the impact of AI (Machine Learning and Automation) on the biopharmaceutical manufacturing industry. This approach aimed to gather valuable data on current practices and perspectives. The data analysis began with a thorough review and cleaning in order to ensure its accuracy, consistency, completeness, and structure. This was done to prepare it for further analysis.

The survey incorporated a variety of question types to collect some important insights:

- **Multiple choice and Likert scale questions:** These questions provided a structured format to assess the prevalence of AI adoption, industry trends driving its use, and the perceived benefits experienced by professionals. Data from these questions were analysed using descriptive statistics. This analysis enabled the creation of visualizations like pie charts and bar charts to clearly represent trends in AI usage and perceived benefits.
- **Open-ended questions:** These questions encouraged participants to share their experiences and detailed perspectives on AI's impact. Thematic analysis (TA) was used to analyse this qualitative data. TA is a rigorous method for identifying recurring themes and patterns within the open-ended responses. This analysis provided deeper insights into the nuances of AI's influence on biopharmaceutical manufacturing.

By using both quantitative and qualitative data analysis methods, this research provided a comprehensive view of how AI is being used in the biopharma industry. It explored how AI is changing manufacturing processes and its potential for the future.

3.3 Ethical Considerations

The survey conducted was carefully designed with participant privacy as the top priority. Each question was carefully chosen to be relevant to the study while avoiding request for personal contact details. The questions were written in clear and simple English to ensure that all participants could easily understand them. Before beginning the survey, informed consent was obtained from each participant. This included an explanation of the research objectives and how the findings would be utilized. Participants were reassured that their responses would be kept confidential, following the General Data Protection Regulation (GDPR) guidelines. Participation in the survey was entirely voluntary, with participants understanding that all collected data would be submitted to Griffith College as part of a thesis project. The data would then be retained by the college for a maximum of two years, in case it proves valuable for further research. After this period, Griffith College will have the authority to decide how the data is disposed of. In conclusion, this survey was conducted with utmost care and respect for participant privacy and confidentiality.

4 FINDINGS AND ANALYSIS

4.1 Overview

This chapter explores the key insights obtained from the survey conducted for the research titled "The Impact of AI (Machine Learning and Automation) on the Biopharmaceutical Manufacturing Industry." The survey utilised a variety of question formats to capture a comprehensive understanding of AI's influence within this sector.

Two primary methods were employed to analyse the collected data. Descriptive statistics will be used to analyse the results of multiple-choice and Likert scale questions. This analysis aimed to provide a clear picture of the prevalence of AI adoption, the trends driving its use, and the perceived benefits and challenges experienced by biopharmaceutical professionals. The results will then be presented visually using charts and graphs to enhance understanding.

Furthermore, thematic analysis will be employed to explore the open-ended questions within the survey. This method will allow for the identification of recurring themes and patterns within the participants' detailed responses. As a result, this analysis will provide more detailed insights into how AI is affecting biopharmaceutical manufacturing. Through this combined analysis, this chapter unveils the true impact of AI on this vital industry.

4.2 Survey Engagement and Outreach

A research survey examined the viewpoints of professionals within the biopharmaceutical and pharmaceutical industries. The survey specifically targeted individuals with prior industry experience. The data collection period spanned from mid-April 2024 to the first week of May 2024. During this time, estimated 95–100 surveys were distributed primarily through LinkedIn, with additional distribution via WhatsApp. To encourage participation, reminder messages were sent throughout the data collection period via direct messages on LinkedIn and WhatsApp.

These efforts to improve response rates proved successful. Following the implementation of follow-up communication strategies, a significant increase in participation was observed. Ultimately, 44 professionals chose to participate in the survey. The survey itself began with a brief introduction that provided information about the research for the participants.

Additionally, an initial question allowed the respondents to make an informed decision about their participation, encouraging a sense of autonomy and respect for their preferences. This approach resulted in a satisfactory response rate of 46.31%, indicating a strong level of engagement from the targeted professional community.

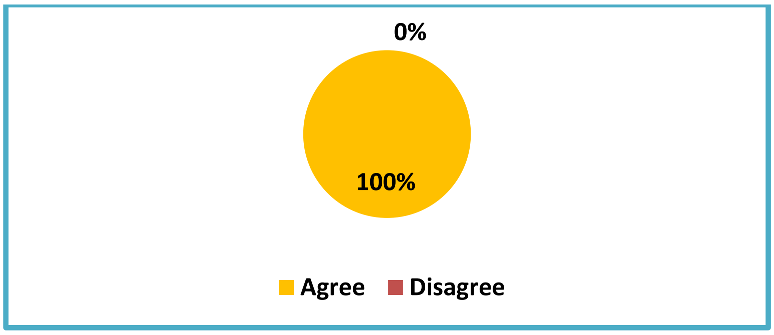

Figure 10 Chart on Participant Consent

4.3 Survey Responses and Analysis

AI Adoption in R&D and Manufacturing at Respondent Companies

A survey question 1 investigated the current use of artificial intelligence (AI) within the biopharmaceutical industry, specifically focusing on its application in research and development (R&D) and manufacturing processes. A total of 44 industry professionals responded to the question.

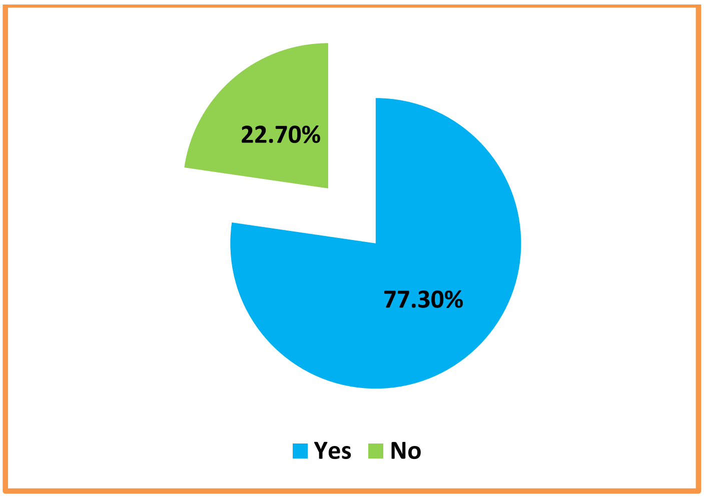

Figure 11 Q 1- Chart on AI Adoption in R&D and Manufacturing at Respondent Companies

The results revealed a significant trend towards AI adoption. 77.3% (33 respondents) indicated that their companies currently utilize AI in R&D or manufacturing. This suggests that AI is becoming increasingly integrated within the biopharmaceutical sector. However, a notable minority (22.7% or 10 respondents) said their companies do not currently employ AI in these areas as shown in figure 11.

This distribution indicates a prevalent trend towards AI adoption within the biopharmaceutical industry, with a notable minority yet to integrate such technologies into their operations. The high adoption rate suggests that AI is playing an increasingly important role in biopharmaceutical research and development. However, there is also a segment of the industry that has not yet begun to leverage this technology.

Duration of AI, ML, and Automation Implementation in Respondent Companies

The pie chart shown in figure 12 breaks down how long companies have been utilizing AI, ML, and automation technologies, based on responses of 44 participants. The largest slice of the pie, representing 34.1% or 15 respondents, reveals that these technologies have been implemented within the last 1-2 years at their companies. This suggests a recent surge in adoption.

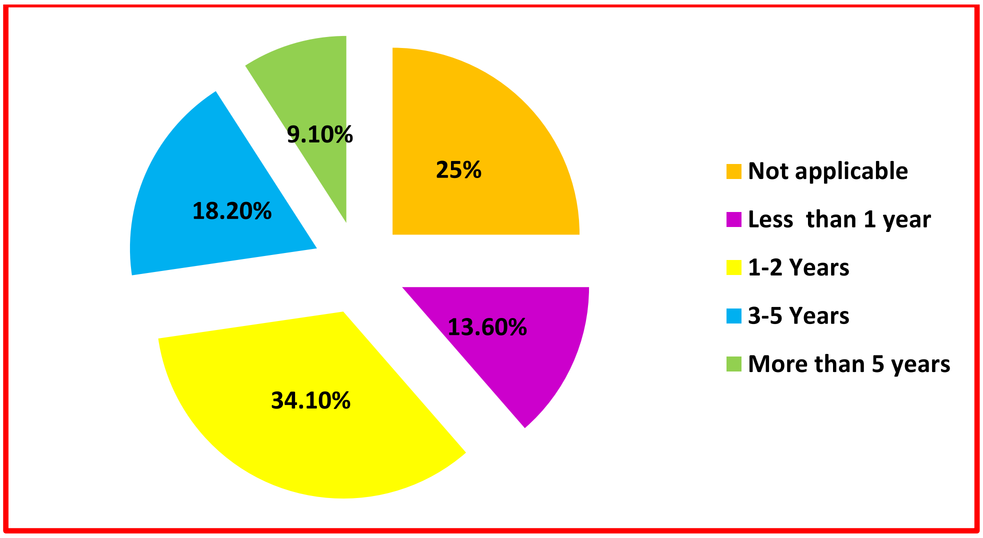

Figure 12 Q2- Chart on Duration of AI, ML, and Automation Implementation in Respondent Companies

Following closely behind is the group whose companies have been using these technologies for 3-5 years, accounting for 18.2% (8 respondents). There's also a segment (13.6%, or 6 respondents) where adoption is very new, having begun less than a year ago. While a smaller portion (9.1%, or 4 respondents) reflects companies that have been leveraging these technologies for over 5 years, it indicates some early adopters. Interestingly, a sizable portion, nearly a quarter (25%, or 11 respondents) of the surveyed companies haven't begun using AI, ML, and automation technologies at all. In conclusion, while the survey results show a promising rise in AI, ML, and automation adoption, with a focus on recent implementations, there are also a sizable number of companies yet to embark on this technological journey.

Current Utilization of AI Techniques within Organizations

Question 3 investigated the specific AI techniques that organizations are currently utilizing. A total of 44 respondents participated, and a majority (65.9%, or 29 people) indicated that they use machine learning. This suggests that machine learning is the most prevalent AI technique among the surveyed organizations.

Following machine learning, robotic process automation (RPA) (25%, or 11 people), natural language processing (NLP), and computer vision (20.5%, or 9 people each) were the next most popular choices. Deep learning, a more advanced subset of machine learning, was used by 13.6% (6 people) of the respondents. Interestingly, 6 respondents (13.6%) indicated that none of the listed options applied to their organization. One respondent even mentioned a technique not included in the survey, MES (Manufacturing Execution System), which could represent a specialized use case. – see Figure 13.

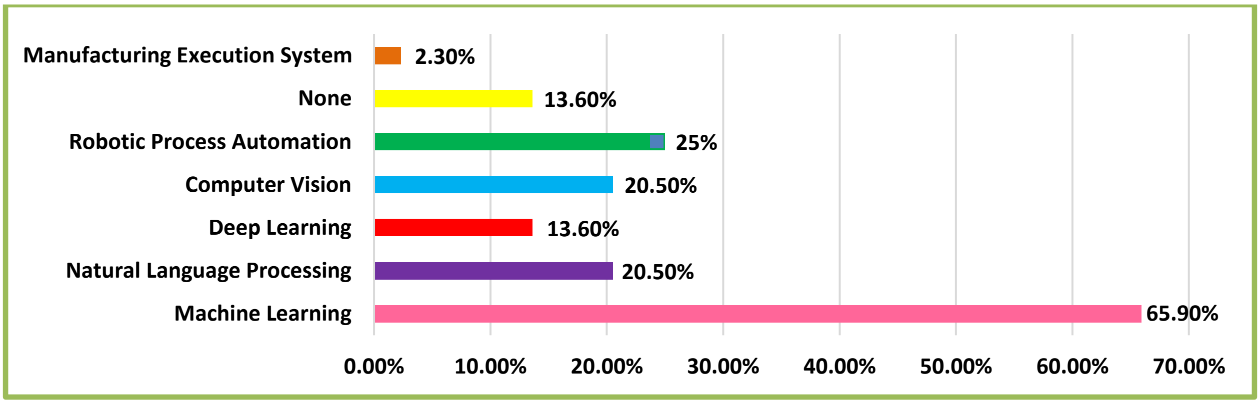

Figure 13 Q-3 Bar graph representing current utilization of AI techniques within organizations

These findings suggest that machine learning is a foundational AI technique that many organizations have already adopted. Techniques like RPA, NLP, and computer vision, which can address specific tasks and data types, are also gaining traction. Deep learning, while promising, might require more advanced technical expertise or specific use cases for implementation. The fact that some organizations haven't adopted any AI techniques yet indicates a potential gap in awareness, resources, or the need for a suitable AI application. The mention of MES highlights the diverse set of AI techniques that might be used in various industries.

Key Challenges in Integrating AI within the Biopharmaceutical Industry

Question 4 investigated the key hurdles biopharma companies face when implementing artificial intelligence (AI). A total of 44 respondents participated, with the majority highlighting two main challenges. – see Figure 14.

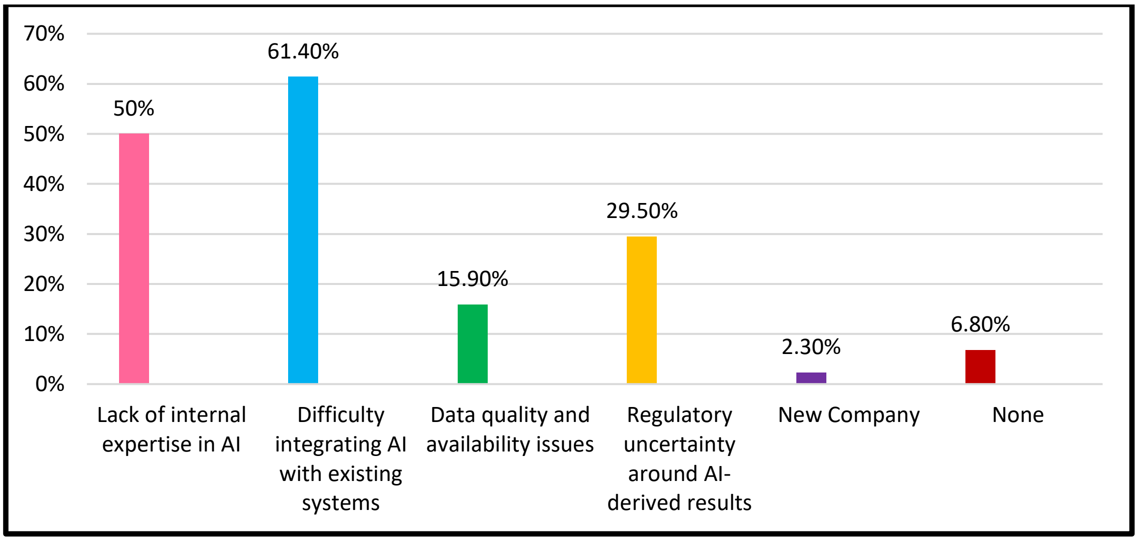

Figure 14 Q4- Key Challenges in Integrating AI within the Biopharmaceutical Industry

- The biggest challenge, selected by over 60% of respondents (27 out of 44), was integrating AI with existing systems. This suggests that biopharmaceutical companies already possess valuable data and processes but struggle to seamlessly connect them with new AI technologies. This can be due to outdated infrastructure, incompatible data formats, or a lack of technical expertise in bridging the gap.

- 50% of the respondents (22 out of 44) identified a lack of internal AI expertise as a significant barrier. This indicates a need for biopharma companies to invest in training or recruitment to build a workforce capable of understanding, developing, and utilizing AI effectively.
- Data quality and availability issues were a concern for 15.9% of respondents (7 out of 44), highlighting the importance of clean and accessible data for successful AI implementation. Additionally, regulatory uncertainty surrounding the use of AI-derived results was a factor for nearly 29.5% (13 out of 44), suggesting a need for clearer guidelines from regulatory bodies.
- A small percentage (6.8%) of respondents indicated no major challenges, potentially representing early adopters who have already addressed these hurdles or the respondents whose companies are not implementing AI. One respondent (2.3%) mentioned "new company" in the "other" category, suggesting a potential difference in challenges faced by startups compared to established companies.

In conclusion, integrating AI with existing systems and a lack of internal AI expertise emerged as the biggest roadblocks for biopharma companies looking to leverage AI's potential. Addressing these challenges through targeted investments in infrastructure, training, and data management will be crucial for successful AI adoption in the biopharma industry.

The Future Impact of AI, ML, and Automation on the Biopharmaceutical Industry

As seen in Figure 15, Question 5 analysed industry professionals' opinions on the significance of artificial intelligence (AI), machine learning (ML), and automation to the biopharmaceutical industry's future success. Participants responded on a Likert scale, with 1 indicating "not important" and 5 signifying "very important." The results were overwhelmingly positive, with a clear preference for options, indicating high importance.

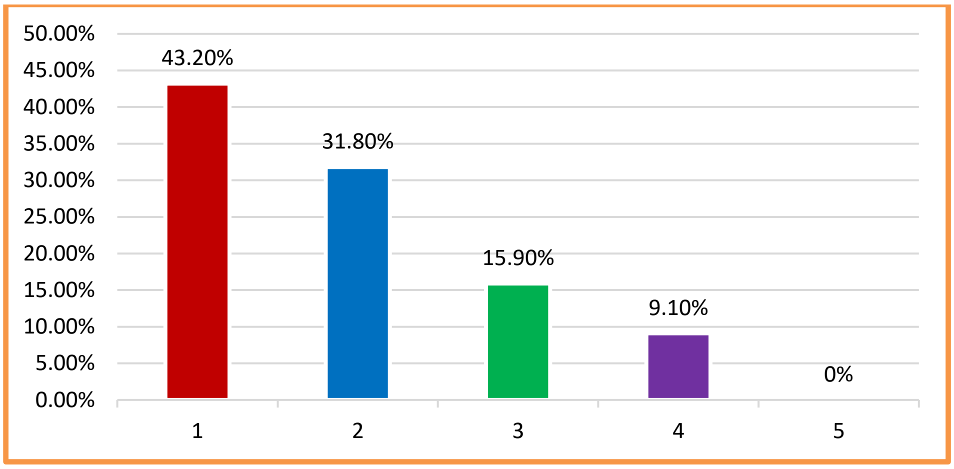

Figure 15 Q5- The Future Impact of AI, ML, and Automation on the Biopharmaceutical Industry

- Nearly half (43.2%) of the 44 respondents selected the strongest option (5), signifying that they believe AI, ML, and automation will be "very important" for the industry's future success.
- This opinion was further supported by 31.8% of those who chose option 4 ("important").
- A combined 77% of participants (43.2% + 31.8%) placed high importance on these technologies.
- Only a small minority (9.1%) felt these advancements would be of moderate importance (option 3), and none considered them not important (option 1) or somewhat least important (option 2).

The data leans heavily towards a strong belief (over 77%) that AI, ML, and automation hold immense importance for the biopharmaceutical industry's future. The complete absence of responses in the "not important" category (option 1) further strengthens this conclusion. These results suggest a widespread recognition within the biopharmaceutical industry of the transformative potential of AI, ML, and automation. These technologies are likely to be seen as crucial tools for accelerating drug discovery, optimizing manufacturing processes, and ultimately delivering better healthcare solutions.

Impact of AI Technology on Various Areas within Biopharmaceutical Manufacturing

Question 6 explored the specific areas within biopharmaceutical manufacturing that have been impacted by artificial intelligence (AI) technology. Participants were allowed to select multiple options, offering an in-depth understanding of AI's current impact.

The survey results reveal a strong focus on AI for core manufacturing processes. A significant majority of respondents (70.5%) indicated that AI is being utilized for process optimization. This is closely followed by quality control (61.4%), highlighting the industry's emphasis on ensuring product quality and efficiency. Over half of the participants (56.8% and 52.3%) reported AI's involvement in batch monitoring and predictive maintenance, respectively. These findings showcase the growing adoption of AI for real-time monitoring and predictive maintenance practices. The results of the data are presented in the table 4 and figure 16 below.

Table 4: Data distribution of participant responses on Impact of AI Technology on Various Areas within Biopharmaceutical Manufacturing

Area	Frequency	Percentage
Process optimization	31	70.50%
Quality control	27	61.40%
Batch monitoring and control	25	56.80%
Predictive maintenance	23	52.30%
Supply chain management	19	43.20%
Regulatory compliance	10	22.70%
Other	2	4.50%

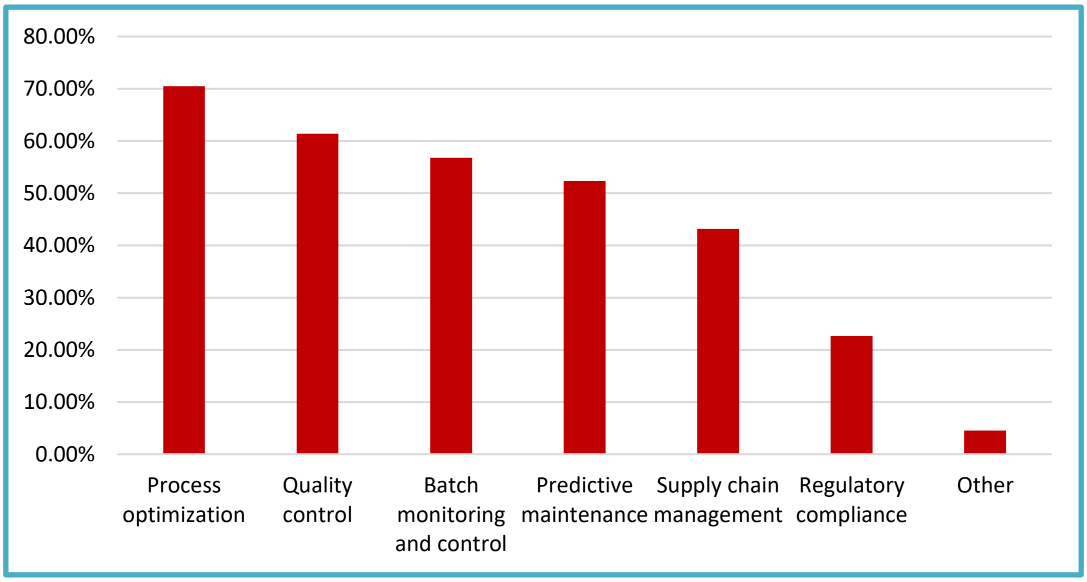

Figure 16 Q6- Impact of AI Technology on Various Areas within Biopharmaceutical Manufacturing

While a smaller percentage of respondents selected regulatory compliance (22.7%) and supply chain management (43.2%), it's important to note that these areas are still under exploration. The addition of "other" as an option, with one participant mentioning visual inspection, suggests that AI could have future applications. This highlights the ongoing exploration and development of AI applications within the biopharmaceutical industry.

Exploring the Benefits of AI in Biopharmaceutical Manufacturing

The next question looked at industry professionals' opinions on the specific benefits of artificial intelligence (AI) in biopharmaceutical manufacturing. The question allowed for multiple selections, and the results revealed that AI is seen as a major driver of increased efficiency, with 81.8% of respondents selecting this benefit. Faster time to market was another key area highlighted by 61.4% of participants. Improving product quality (59.1%) and cost reduction (43.2%) were also viewed as important advantages of AI. Interestingly, enhanced safety and compliance, while still important, were selected by a comparatively smaller group (45.5%). These findings suggest that AI is a beneficial tool for streamlining production processes, accelerating drug development timelines, and potentially reducing costs in the biopharmaceutical industry. However, for some, safety and compliance considerations may require further exploration alongside AI implementation. - See figure 17.

Figure 17 Exploring the Benefits of AI in Biopharmaceutical Manufacturing

Personal Experiences and Observations in Implementing AI Technologies in Biopharmaceutical Manufacturing

This survey question investigated the prevalence of exposure to AI technologies within the biopharmaceutical manufacturing sector. Participants were asked whether they had personally been involved in or witnessed the implementation of AI.

Table 5 Data distribution of participant responses on Personal Experiences and Observations in Implementing AI Technologies in Biopharmaceutical Manufacturing

AI Experience	Frequency (n)	Frequency Percentage (%)
Yes	24	54.5
No	20	45.5
Total	44	100

- Over half of the participants (54.5%, n = 24) indicated having personal experience with AI implementation in biopharmaceutical manufacturing.
- The remaining participants (45.5%, n = 20) reported no such experience.

The results suggest a moderate level of AI adoption within the biopharmaceutical manufacturing industry, with slightly more than half of the participants having encountered AI technologies in this setting. It is important to note that this is a relatively small sample size, but it is clear that a significant portion of professionals in this industry have already been exposed to AI implementation.

Evaluating the Effectiveness of AI in Enhancing Manufacturing Processes

This survey question asked participants to evaluate the effectiveness of artificial intelligence (AI) in improving manufacturing processes within the biopharmaceutical industry. Respondents were given three answer choices: "very effective," "somewhat effective," and "not effective."

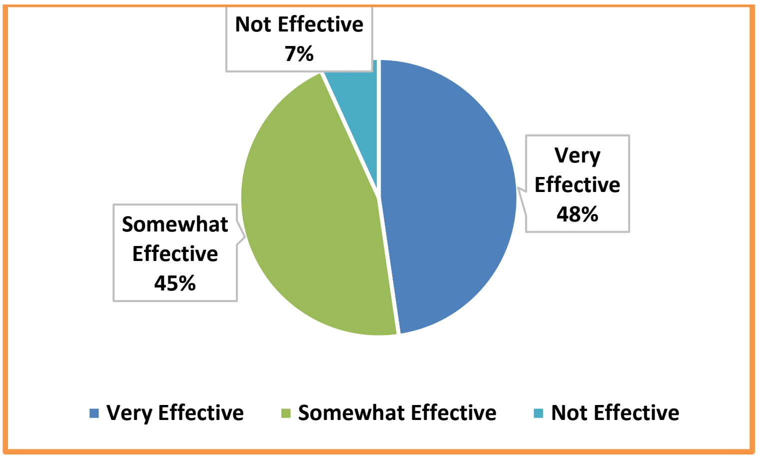

Figure 18 Q9- Evaluating the Effectiveness of AI in Enhancing Manufacturing Processes

- Almost half (47.7%) of the respondents held a highly favourable view of AI's impact, indicating its potential to significantly improve manufacturing.
- A significant portion (45.5%) acknowledged a positive influence, suggesting AI offers some level of improvement.
- A small percentage (6.8%) expressed a negative view, indicating some skepticism or challenges in utilizing AI effectively.

Overall, the results suggest that AI is viewed favourably for its potential to improve biopharmaceutical manufacturing processes. – see Figure 18.

Assessing the Importance of AI Investment in Biopharmaceutical Manufacturing

This question investigated the perceived importance of AI investment in manufacturing for biopharmaceutical companies. Respondents rated their opinion on a 5-point scale, with 1 signifying "not critical at all" and 5 representing "extremely critical."

A significant majority (69.9%, combining responses 4 and 5) believe AI holds high importance in biopharmaceutical manufacturing. Nearly half (47.7%) rated it "extremely critical" (5), highlighting a strong emphasis on AI's potential. A smaller portion (18.2%) viewed it as "somewhat critical" (3), suggesting cautious optimism. Only a minority (11.4%) considered it "not critical" (1 or 2), indicating a low barrier to AI adoption in the industry.

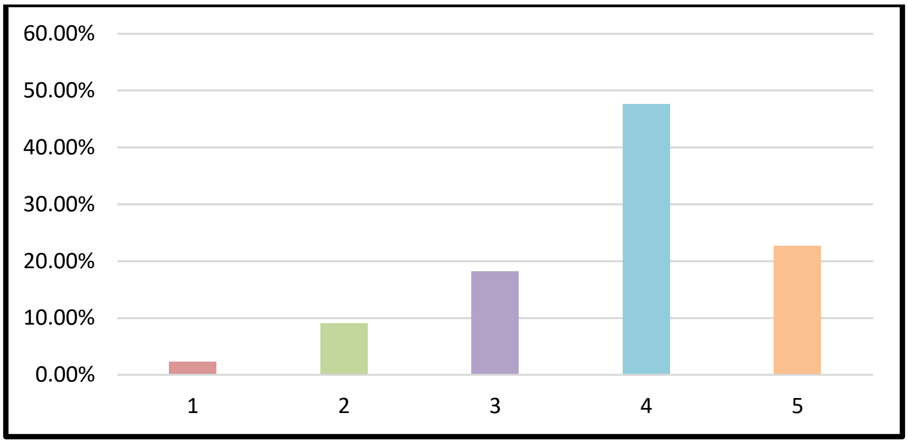

Figure 19 Assessing the Importance of AI Investment in Biopharmaceutical Manufacturing

Based on this data, it can be inferred that biopharmaceutical companies recognize the significant potential of AI technologies in their manufacturing processes. The overwhelming majority of respondents see AI as a critical area for investment, suggesting a belief that AI can lead to substantial improvements in efficiency, quality, and other key metrics.

AI's Impact on Biopharmaceutical Manufacturing Efficiency

This survey investigated how biopharmaceutical professionals perceive the impact of artificial intelligence (AI) on manufacturing efficiency. The majority of respondents (63.6%, or 28 people) indicated that AI has significantly reduced process times and streamlined production. This suggests a strong positive perception of AI's role in the industry.

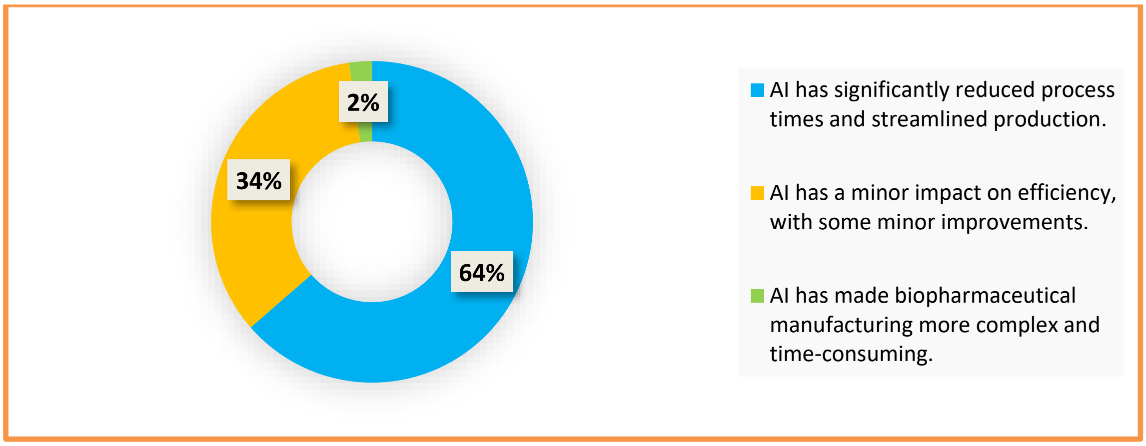

Figure 20 Q11- AI's Impact on Biopharmaceutical Manufacturing Efficiency

A smaller portion (34.1%, or 15 people) reported a minor impact on efficiency with some improvements. This indicates that AI may not be universally impactful yet, or its benefits might not be fully realized in all areas. Interestingly, only a minimal percentage (2.3%, or 1 person) believed AI had made manufacturing more complex and time-consuming. – See Figure 20.

The data suggests that AI is having a significant positive impact on biopharmaceutical manufacturing efficiency. However, there is also room for further optimization and integration to ensure all participants experience its benefits.

AI's Influence on Productivity in Biopharmaceutical Manufacturing

This survey investigated the impact of artificial intelligence (AI) on productivity within biopharmaceutical manufacturing. The results revealed a mixed perspective among respondents.

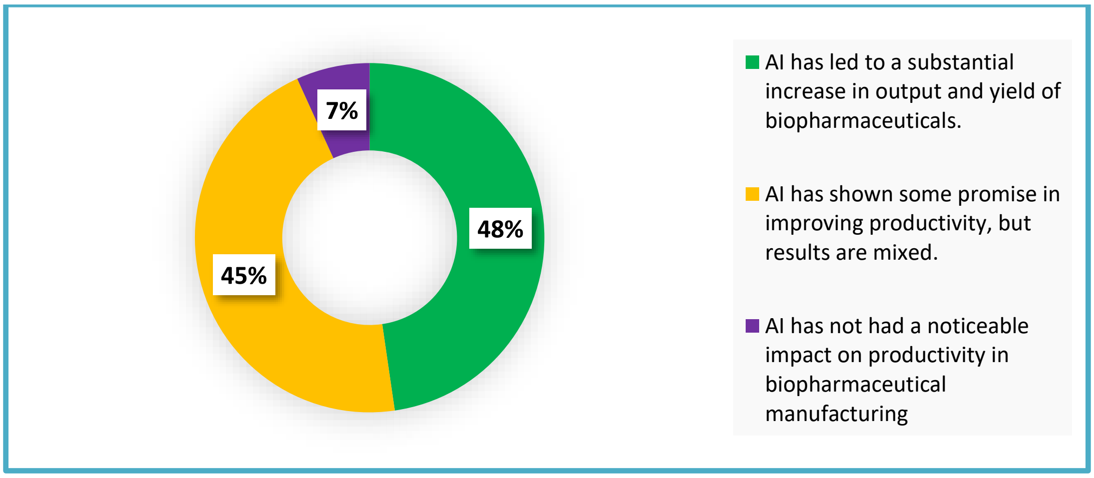

Figure 21 Q12- AI's Influence on Productivity in Biopharmaceutical Manufacturing

- Nearly half (47.7%) of respondents, representing 21 individuals, believe AI has led to a significant boost in both output and yield of biopharmaceuticals. This statistically significant result suggests a strong positive perception of AI's contribution.
- Another significant portion (45.5%, or 20 participants) acknowledged AI's potential for improvement but indicated the effects are not yet clear-cut. This suggests a cautious optimism, with a need for more definitive data.
- A small minority (6.8%, or 3 respondents) felt AI hasn't noticeably impacted productivity. This could indicate a lack of awareness about AI applications, limited implementation in their specific workplaces, or a skepticism towards their effectiveness.

Overall, the survey reveals a positive outlook on AI's potential for biopharmaceutical manufacturing. However, a sizeable group recognizes the need for further evaluation to strengthen its impact.

Cost-Reduction Impact of AI in Biopharmaceutical Manufacturing

Question 13 investigated industry perspectives on the cost-saving potential of artificial intelligence (AI) in biopharmaceutical manufacturing. The results revealed a mixed view.

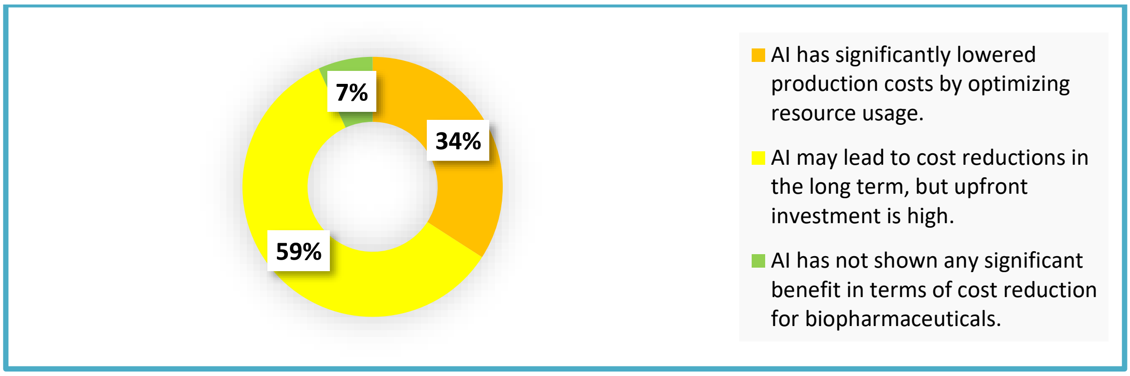

Figure 22 Q13- Cost-Reduction Impact of AI in Biopharmaceutical Manufacturing

- The majority (59.1%, or 26 participants) believe AI has the potential to reduce costs in the long term. However, they acknowledge a significant hurdle: a high upfront investment may be hindering wider adoption.
- A significant portion (34.1%, or 15 participants) are already experiencing cost reductions through AI. This suggests AI can optimize resource usage, leading to immediate financial benefits.
- A small minority (6.8%, or 3 participants) observed no significant cost reduction with AI. This indicates that for some, the current implementation may not be delivering on its cost-saving promises.

These findings suggest that AI is gaining traction in biopharmaceutical manufacturing, with many recognizing its long-term potential for cost reduction. However, high upfront investment costs might be a barrier for some companies.

The Future Potential of AI in Biopharmaceutical Manufacturing

This survey question investigated the opinions surrounding the potential of artificial intelligence (AI) to revolutionize biopharmaceutical manufacturing. It presented participants with three answer choices, allowing them to gauge their level of optimism.

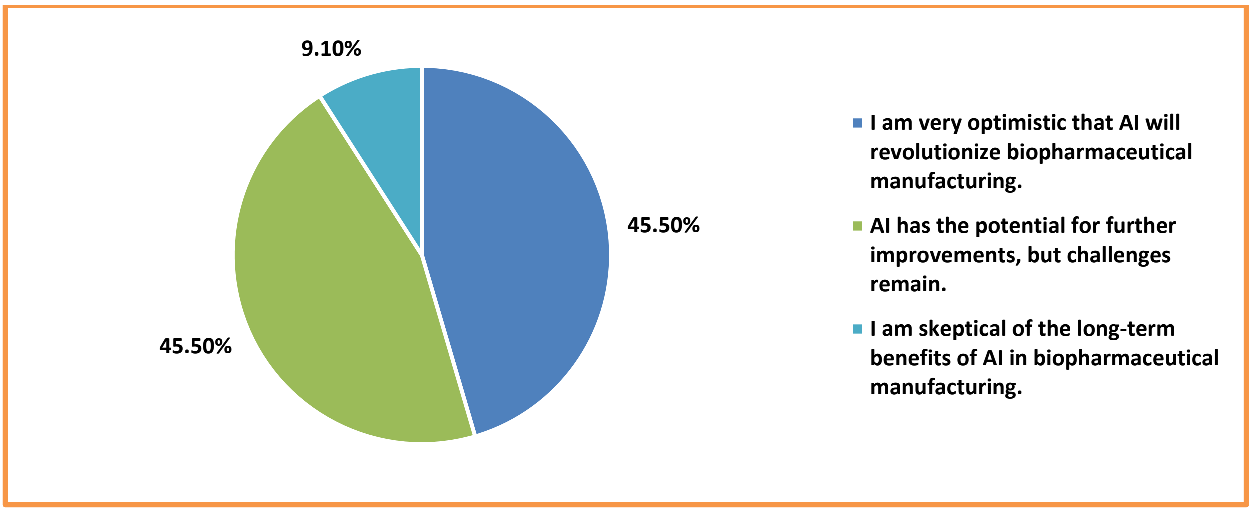

Figure 23 Q14- The Future Potential of AI in Biopharmaceutical Manufacturing

A descriptive analysis reveals a near-even split between those who are "very optimistic" (45.5%, 20 people) and those who believe "AI has the potential for further improvements, but challenges remain" (45.5%, 20 people). This suggests a cautious optimism within the group, with a significant portion recognizing the transformative potential of AI while acknowledging existing hurdles.

A small minority (9.1%, 4 people) expressed uncertainty about the long-term benefits of AI in biopharmaceutical manufacturing. This indicates that a large majority of the participants (over 90%) see AI as a positive force for the future of the industry. – see Figure 23.

Exploring the Current Landscape: The Role of Artificial Intelligence in Biopharmaceutical Manufacturing

The survey question asked participants to share their experience with the prevalence of artificial intelligence (AI) in biopharmaceutical manufacturing today. Respondents were presented with four answer choices reflecting a range of AI usage: not prevalent at all, used in niche applications, moderately used across various functions, and widely adopted as a standard practice.

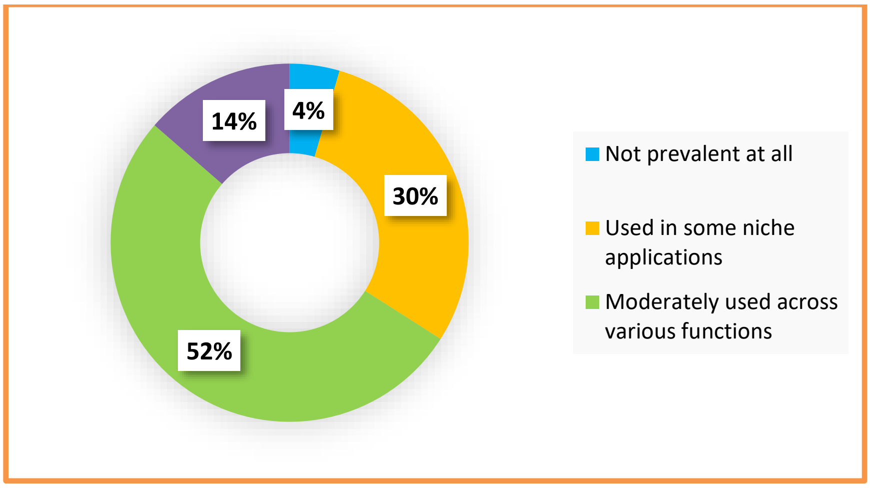

Figure 24 Q15- Exploring the Current Landscape: The Role of Artificial Intelligence in Biopharmaceutical Manufacturing

- A majority (52.3%, or 23 participants) indicated AI is moderately used across various functions. This suggests AI is making inroads but hasn't become ubiquitous.
- Nearly a third (29.5%, or 13 participants) felt AI was only used in some niche applications, implying limited implementation.

- A relatively small group (13.6%, or 6 participants) viewed AI as widely adopted, indicating it hasn't become the standard yet.
- Only a small portion (4.5%, or 2 participants) believed AI was not prevalent at all, suggesting AI is not prevalent at all, indicating some may not yet see its influence.

Based on these findings, AI appears to be in a growth phase within biopharmaceutical manufacturing. While not yet commonplace, a significant portion recognizes its usage across various functions.

Exploring additional AI techniques

Table 6 Thematic Analysis on Exploring additional AI techniques

S.No.	Themes	Responses	Count	Percentage Responses
1	**Modelling**	Bioprocess modelling and simulation	3	12.5%
		Molecular modelling		
		Deep learning models		

2	**Robotics**	Robotics	2	8.33%
		Robotic process automation		
3	**Software**	AGS software	1	4.17%
4	**Medicine**	Human genome mapping	1	4.17%
5	**Systems**	Ambr systems	1	4.17%
6	**ML**	Machine Learning	4	16.67%
		Pattern recognition and Machine learning		
		Real-time monitoring with AI algorithm		
7	**Assistance**	Voice-activated lab assistance by Labtwin	1	4.17%
8	**Processing**	Natural Language Processing (NLP)	1	4.17%
9	**AI**	Process Analytical Technology (PAT)	1	4.17%
10	**Not Applicable**	N/A	9	37.5%
Total Responses			24	

The thematic analysis of responses to an open-ended question 16 involved data from 44 participants, with 24 responses ultimately included after data cleaning, representing a participation rate of 54.5%. Ten common themes emerged from the analysis. Modelling was mentioned by 12.5% of participants, encompassing various techniques such as bioprocess modelling and molecular modelling. Robotics, covering general robotics and robotic process automation, was mentioned by 8.33% of respondents. One response, accounting for 4.17%, focused on AGS software specifically. Similarly, Medicine, Systems, Assistance, Processing, and AI (Process Analytical Technology) each gained 4.17% of responses, highlighting topics such as human genome mapping, Ambr systems, voice-activated lab assistance by Labtwin, Natural Language Processing, and the utilization of AI for process analysis, respectively. Machine learning was discussed by 16.67% of participants, including general machine learning and pattern recognition. Notably, 37.5% of responses were categorized as "not applicable," indicating they either didn't directly address the question or deviated from its intended scope.

Evaluating the future impact of AI techniques in biopharmaceutical manufacturing

This question investigated participant beliefs on the most impactful AI techniques for the future of biopharmaceutical manufacturing. A significant portion, nearly 39%, believed all of the above techniques would be transformative. This suggests a strong recognition of the multifaceted potential of AI in this industry.

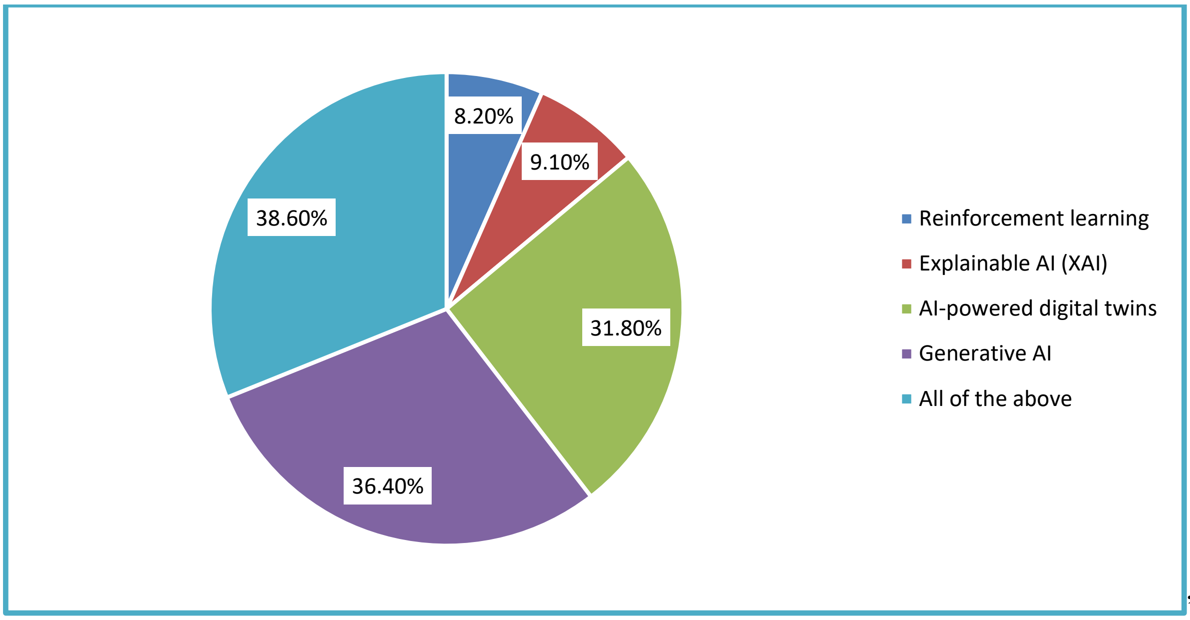

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Figure 25 Q17- Evaluating the future impact of AI technique

- Generative AI (36.4%) emerged as the most popular individual choice. This technique utilizes AI algorithms to accelerate drug discovery and design, potentially leading to faster development of new treatments. This aligns with the constant drive for innovation in the biopharmaceutical sector.
- AI-powered digital twins (31.8%) were closely followed. This technology creates virtual replicas of manufacturing processes, enabling real-time simulation and prediction. This highlights the industry's focus on optimizing production efficiency and proactively addressing potential issues.
- Reinforcement learning (18.2%) received a moderate level of support. This technique allows AI to learn from trial and error, potentially optimizing complex manufacturing processes.
- Explainable AI (XAI) (9.1%) received the fewest individual votes. XAI focuses on making AI decision-making processes transparent. While crucial for building trust and regulatory compliance, it might be viewed as an underlying necessity rather than a standalone, impactful technique.

These results suggest that the biopharmaceutical industry sees AI as a holistic solution, encompassing various techniques to improve multiple aspects of the manufacturing process.

While real-time process optimization and generative AI received the most individual attention, a significant portion recognized the combined value of all the presented techniques.

Emerging AI techniques shaping the future of biopharmaceutical manufacturing

Table 7 Participant Response Data Arranged Under a Common Theme: Subsets of AI

S.NO.	THEME-SUBSET OF AI	COMMON RESPONSES	COUNT	PERCENTAGE RESPONSES
1	**Digital Twins**	- Digital Twins	2	10%
2	**Machine Learning**	- Machine learning - Generative Adversarial Networks (GANs) - Process optimization with AI	1 1	5%
3	**Explainable AI (XAI)**	- Explainable AI (XAI)	1	5%
4	**Ambr Technology**	- Ambr technology	1	5%
5	**Robotics Process Automation**	- Robotics process automation	1	5%
6	**Reactive Machines**	- Reactive Machines	1	5%
7	**Process Monitoring and Optimization**	- Process Monitoring and optimization	2	10%
8	**Generative AI and Reinforcement Learning**	- Generative AI - Reinforcement learning	2	10%
9	**Predictive Analytics and Maintenance**	- Predictive maintenance - Predictive Analytics	2	10%
10	**Computer Vision and Image Analysis**	- Computer vision - Image analysis in QC	3	15%
11	**Other**	- Not Applicable	3	15%
	Total Responses		**20**	

This survey question explored the future of biopharmaceutical manufacturing by asking participants to share their thoughts on emerging AI techniques with significant potential. An open-ended survey question was answered by 20 participants (out of 44 participants), who provided relevant responses (45.45% participation rate). Thematic analysis revealed a focus on various AI subsets.

A common theme emerged from the responses, focusing on various subsets of AI. Notably, 10% of respondents each mentioned digital twins, process monitoring and optimization, generative AI, and reinforcement learning as important techniques. Predictive analytics and maintenance also gained 10% each. Interestingly, only 5% of participants identified core AI techniques like machine learning, explainable AI (XAI), Ambr technology, and robotics process automation (RPA) as crucial for the future. Similarly, 5% mentioned reactive machines, suggesting a focus on more specialized AI applications. Notably, 15% of responses fell under the category of computer vision and image analysis, indicating a strong emphasis on these areas. Finally, 15% of responses were either irrelevant or unclear (categorized as "other").

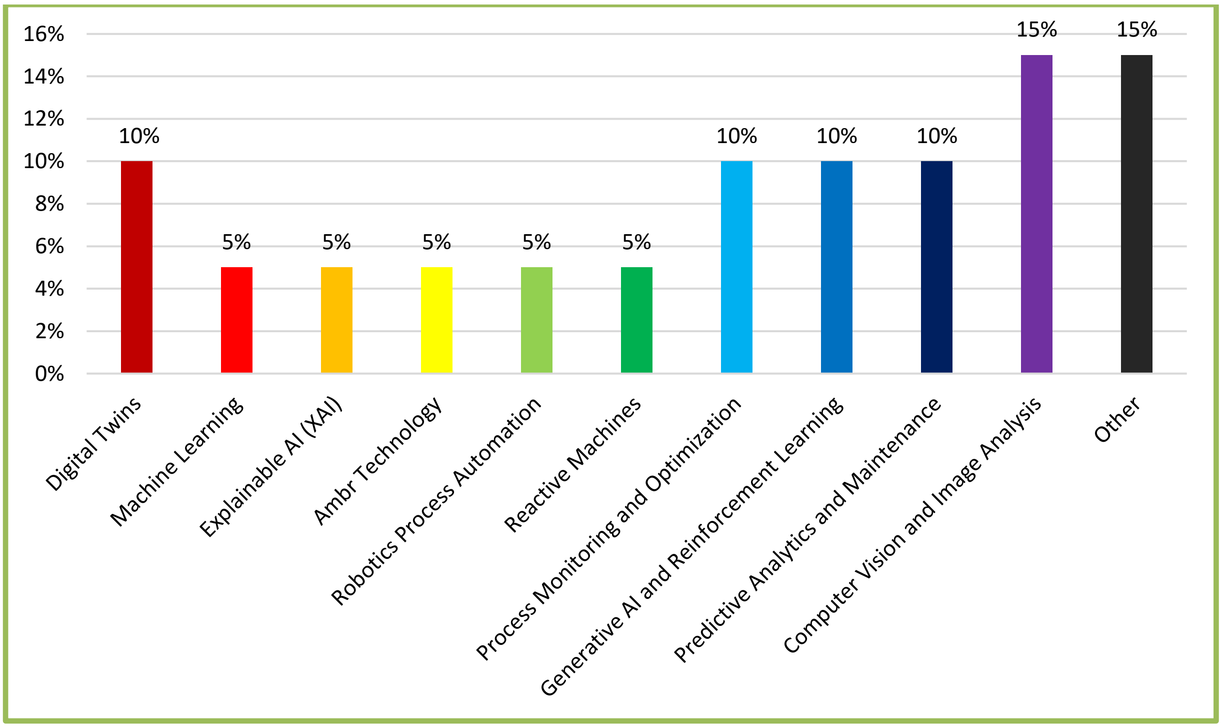

Figure 26 Q18- Emerging AI techniques shaping the future of biopharmaceutical manufacturing

This analysis provides valuable insights into expert opinions on the future of AI in biopharmaceutical manufacturing. The data suggests a potential shift towards more specialized and application-focused AI tools. Overall, the results reveal a diverse landscape of emerging AI techniques believed to be important for the future of biopharmaceutical manufacturing. While specific techniques like digital twins and process optimization received significant interest.

Evolution of AI, ML, and automation technologies in biopharmaceutical manufacturing over the past 5 years

Question 19 investigated the perceived changes in the adoption of artificial intelligence (AI), machine learning (ML), and automation technologies within biopharmaceutical manufacturing over the past five years. The results reveal a positive trend, with a majority (50%, n = 22) of participants indicating a moderate increase in adoption. This is followed by 40.9% (n = 18), who observed a significant increase. Only a small minority (6.8%, n = 3) reported stable usage, and a negligible 2.3% (n = 1) saw a decrease.

These findings suggest a growing awareness and integration of AI/ML and automation in biopharmaceutical manufacturing. The high percentage (90.9%) reporting some level of increase signifies a clear shift towards these technologies. However, the dominance of "moderate increase" indicates that adoption may not yet be widespread. Overall, the survey suggests a positive and evolving landscape for AI, ML, and automation in biopharmaceutical manufacturing. – See Figure 27.

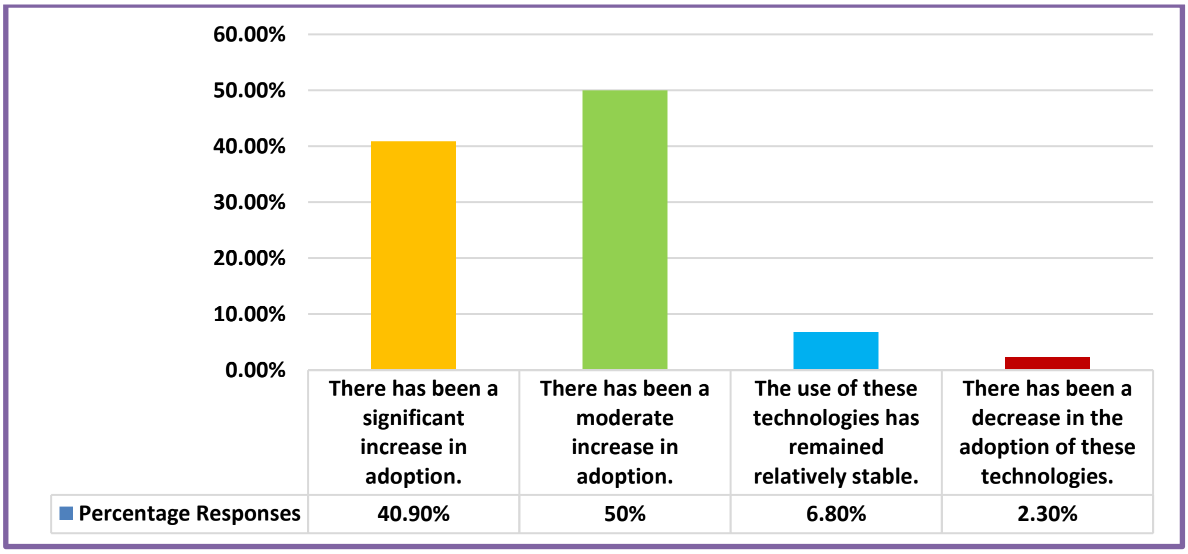

Figure 27 Q19- Evolution of AI, ML, and automation technologies in biopharmaceutical manufacturing over the past 5 years

Challenges hindering the wider adoption of AI, ML, and automation

Question 20 investigated the biggest hurdles to implementing artificial intelligence (AI), machine learning (ML), and automation in biopharmaceutical manufacturing. The results revealed several key challenges, with a significant portion of respondents (over 50%) selecting multiple options.

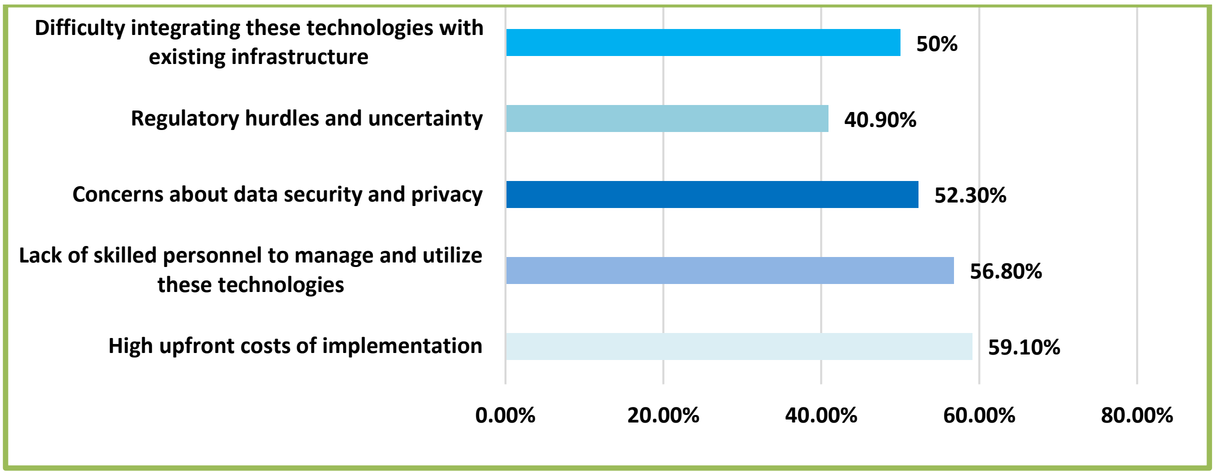

Figure 28 Q20- Challenges hindering the wider adoption of AI, ML, and automation

High upfront costs (59.1%) emerged as the most prominent concern, highlighting the financial burden associated with initial investment and infrastructure development for these advanced technologies. Lack of skilled personnel (56.8%) closely followed, indicating a critical talent gap in the industry. This suggests a need for training programs or targeted recruitment to bridge the knowledge and expertise gap required to effectively manage and utilize these new technologies. Data security and privacy (52.3%) were also major concerns, reflecting the sensitivity of biopharmaceutical data and the potential risks associated with breaches or misuse. Implementing robust security measures will be crucial for wider adoption. Integration challenges (50%) point to the difficulty of seamlessly incorporating AI/ML and automation with existing manufacturing infrastructure. Regulatory uncertainty (40.9%), though less prevalent, still poses a significant hurdle. Clear and adaptable regulations are needed to guide the development and implementation of these technologies within the biopharmaceutical industry. – See Figure 28.

The results depict these various challenges hindering the wider adoption of AI, ML, and automation in biopharmaceutical manufacturing. Addressing the high upfront costs, developing a skilled workforce, ensuring data security, facilitating integration with existing systems, and navigating regulatory hurdles will be critical for successful implementation.

Weighing the benefits and challenges of AI, ML, and automation in biopharmaceutical manufacturing

The survey question asked participants in the biopharmaceutical manufacturing industry to express their overall viewpoint on the impact of artificial intelligence (AI), machine learning (ML), and automation. Specifically, it aimed to understand if the perceived benefits of these technologies outweigh the challenges associated with their implementation. Participants were presented with four answer choices.

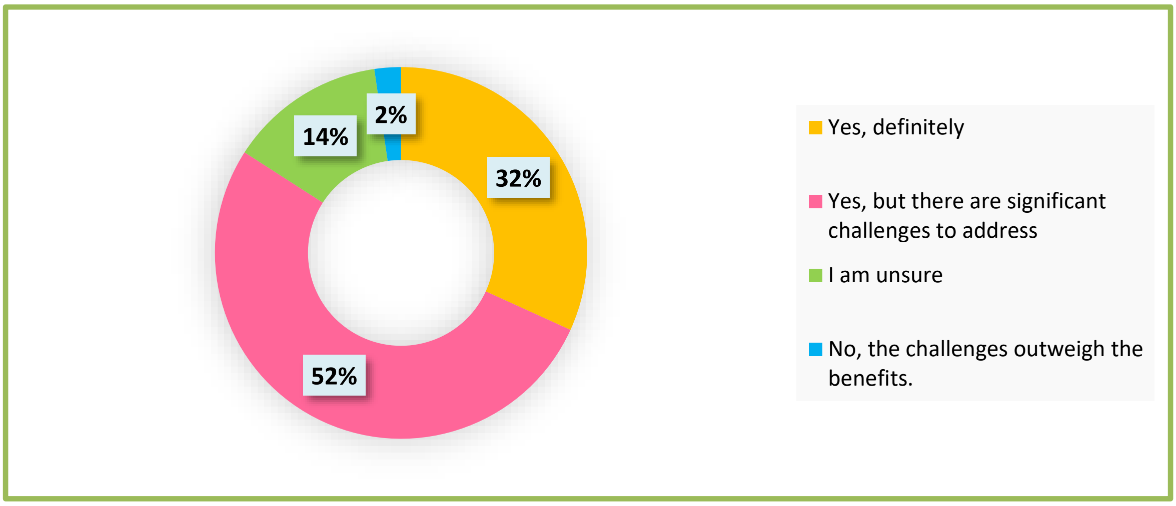

Figure 29 Q21- Benefits and challenges of AI, ML, and automation in biopharmaceutical manufacturing

- Yes, definitely. This indicates a strong belief that the advantages of AI, ML, and automation are clear and significant. (31.8%, or 14 people)
- Yes, but there are significant challenges to address: This suggests agreement on the positive impact of these technologies but acknowledges the existence of substantial hurdles that need to be overcome. (52.3%, or 23 people)
- I am unsure. This reflects indecision or a lack of clarity on the overall balance between benefits and challenges. (13.6%, or 6 people)

- No, the challenges outweigh the benefits. This signifies a firm conviction that the drawbacks of AI, ML, and automation outweigh their potential contributions. (2.3%, or 1 person)

The results indicate that a majority (84.1%, or 37 people) believe AI, ML, and automation have a positive impact, with 31.8% (14 people) fully convinced and 52.3% (23 people) acknowledging challenges. However, a noteworthy 13.6% (6 people) remain unsure, and a small minority (2.3%, or 1 person) believes the challenges outweigh the benefits. – See Figure 29.

5 CONCLUSIONS AND RECOMMENDATIONS

5.1 Overview

The chapter explores the impact of AI on biopharmaceutical manufacturing through research. It provides a summary of the important findings and explores their relevance to the research questions. The purpose of this connection is to evaluate the contribution of the survey results to the existing literature in this field. The survey results and established literature will be compared and examined. The objective of this comparison is to discover valuable insights and areas that may need more research.

Finally, considering the limitations of the study, recommendations for future research will be provided. To fully understand the impact of AI on biopharmaceutical manufacturing, suggestions will be formulated to build upon the current findings and address limitations.

5.2 Summary of the findings and its relevance to the research questions

Research Q1- *What artificial intelligence (AI) techniques are now in use in the biopharmaceutical industry, and which will be employed in the future?*

The use of artificial intelligence (AI) technology into the biopharmaceutical companies has caused widespread interest due to its transforming potential. Existing literature and survey results provide insight into the most common AI techniques in use and their implications for the future of biopharmaceutical manufacturing.

AI, particularly machine learning (ML), has emerged as an important player in the biopharmaceutical industry, revolutionizing drug discovery and manufacturing processes. Data analysis is used to identify processes, locate targets, and improve manufacturing efficiency, according to studies (Vora et al., 2023). By evaluating big datasets, ML systems improve quality control and predicted drugs interactions, resulting in more efficient production processes (Aswal et al., 2022). The widespread usage of machine learning (ML) and robotic process automation (RPA) demonstrates their ability to streamline operations and innovation in the industry (Rathore et al., 2023).

Furthermore, the literature emphasizes the relevance of AI in personalized medicine, emphasizing its capacity to modify drugs to meet particular patients' needs, hence improving safety and quality (Paul et al., 2021). AI applications go beyond drug discovery to include process optimization, dosage form design, and quality control, showing its versatility and significance in pharmaceutical manufacturing (Vora et al., 2023). The use of AI-powered robotics and automation enhances manufacturing productivity and quality control measures (Chi Cheng, 2023).

The survey findings support the literature by demonstrating the prevalence of ML and RPA in organizations, indicating their fundamental importance in AI adoption. Furthermore, participants show a cautious belief about AI's future potential in biopharmaceutical manufacturing, recognizing its innovative power while highlighting existing challenges. Thematic analysis identifies growing AI techniques, such as digital twins, process monitoring, and predictive analytics, that are essential to future industry enhancements. Particularly, the emphasis on specialized AI applications indicates a deeper approach to addressing industry-specific challenges (Dashpute et al., 2023). While some techniques, such as generative AI and AI-powered digital twins, have received significant attention for their potential impact on drug discovery and production efficiency, others, such as explainable AI (XAI), have been recognized as critical for ensuring transparency and regulatory compliance.

Overall, the analysis of existing literature and survey responses highlights AI's varied role in transforming the biopharmaceutical industry. From improving drug discovery procedures to optimizing manufacturing operations and boosting quality control measures, AI techniques show great potential for accelerating innovation and efficiency in biopharmaceutical manufacturing. However, achieving this goal requires addressing current challenges and ensuring the smooth integration of artificial intelligence technologies adapted to the industry's specific requirements.

Research Q2- *How has the adoption of AI, machine learning (ML) & RPA in biopharmaceutical industry increased in recent years?*

In recent years, the biopharmaceutical industry has seen a significant increase in the adoption of artificial intelligence (AI), machine learning (ML), and automation, transforming various aspects of research, development, and manufacturing. The findings of the survey and the latest literature shed light on this transformative trend, offering insight into its implications for the manufacturing industry.

The survey's results show a considerable surge toward AI adoption, with 77.3% of respondents claiming current use of AI in R&D or manufacturing processes. Furthermore, the duration of AI, ML, and automation implementation indicates a recent boom in adoption, with the majority of organizations using these technologies in the last 1-2 years. This shows the rapid adoption of AI-powered technology within the biopharmaceutical manufacturing sector.

Furthermore, the most common AI techniques used within industries are machine learning, followed by robotic process automation (RPA), natural language processing (NLP), and computer vision. These findings highlight the wide range of AI applications in biopharmaceutical manufacturing, including process optimization, quality control, batch monitoring, and predictive maintenance. The survey also asked about the perceived effectiveness and significance of AI investment in biopharmaceutical manufacturing, demonstrating a positive view among respondents. Nearly half of respondents viewed AI as "extremely critical" for manufacturing, highlighting its ability to significantly enhance procedures and increase competitiveness in the sector.

However, despite the positive adoption rates, challenges to widespread implementation remain. High upfront costs, a lack of skilled workers, data security issues, integration difficulties, and regulatory uncertainties emerge as important barriers. Addressing these difficulties will be essential for unlocking the full potential of AI, machine learning, and automation in biopharmaceutical manufacturing, as well as ensuring the industry's long-term expansion and continued innovation.

In conclusion, the survey results and literature highlight the increasing adoption and significant impact of AI, ML, and automation in the biopharmaceutical sector. While promising, addressing problems and ensuring responsible adoption will be essential for achieving the full potential of these technologies in enhancing efficiency, innovation, and competitiveness in the sector.

Research Q3- *How has AI changed the biopharmaceutical model, especially in manufacturing sector?*

The research question focuses into how AI has changed the biopharmaceutical model , particularly in the manufacturing sector. Both survey results and existing literature show significant advancements and efficiency brought about by AI.

AI has been proven helpful in process optimization in biopharmaceutical manufacturing. Machine learning (ML) techniques are used for evaluating large datasets, allowing for real-time monitoring, improved quality control, and supply chain optimization (Vora et al., 2023; Rathore et al., 2023). These improvements are supported in the survey, where 70.5% participants highlighted AI's involvement in process optimization and 61.4% highlighted quality control improvements. Furthermore, more than half of those surveyed mentioned AI's impact on batch monitoring (56.8%) and predictive maintenance (52.3%), highlighting the technology's crucial role in real-time process enhancements.

Predictive maintenance, driven by AI, is also emerging as an important component, allowing for quick identification of equipment issues and reducing downtime, hence increasing total productivity (Aswal et al., 2022). This approach aligns with survey findings, in which the majority (63.6%) reported significant reductions in process times and streamlined production as a result of AI. Furthermore, 47.7% of the participants reported a significant increase in productivity, which shows AI's positive influence.

Another important factor to consider is the impact of AI on cost reduction. While the survey found that 59.1% of participants believe AI will reduce costs in the long term, 34.1% have already seen these benefits. However, high initial investments remain to be a barrier, as indicated by some respondents (6.8%), who have yet to see significant savings in costs. The literature supports this, projecting AI's ability to reduce costs through optimized usage of resources and increased efficiency (Kolluri et al., 2022; Vora et al., 2023). To summarize, AI has significantly changed biopharmaceutical manufacturing by increasing efficiency, productivity, and cost-effectiveness.

Research Q4- *What specific benefits and challenges have AI-enabled technologies brought to the biopharmaceutical industry?*

AI-enabled technologies have provided considerable benefits while also posing significant hurdles to biopharmaceutical companies, as seen in the literature review and survey findings. One of the key benefits of AI in this area is its ability to streamline lab processes and automate production, resulting in increased operational efficiency and productivity. For example, AI-powered automation reduces the need for manual data analysis and management, increasing the overall efficiency of biopharmaceutical operations (Hafke, 2023). Furthermore, AI helps to analyse process data in order to detect and prevent future difficulties, resulting in increased safety and reliability in industrial processes (Stucky, 2023).

Survey results support these findings, with 81.8% of industry professionals stating higher efficiency as a key benefit of AI in biopharmaceutical manufacturing. Furthermore, 61.4% of the participants stated that AI helps speed up the time to market, while 59.1% highlighted its role in improving product quality. Another key benefit observed by 43.2% of participants is cost savings, as AI allows for the creation of more efficient processes and lowers the need for human effort.

However, the incorporation of AI technologies involves major challenges. The survey indicated that the most significant challenge, highlighted by more than 60% of respondents, is integrating AI with existing systems. This difficulty is frequently caused by old infrastructure and incompatible data formats, which prevent seamless integration. Furthermore, 50% of respondents identified a lack of internal AI expertise as a key obstacle, highlighting the need for biopharmaceutical organizations to engage in training or hire skilled staff. Data quality and availability issues were mentioned by 15.9% of participants, highlighting the importance of clean and accessible data for successful AI adoption. Furthermore, nearly 29.5% of participants reported regulatory uncertainty, highlighting the need for regulatory agencies to provide clearer standards to support AI adoption.

Despite these challenges, the biopharmaceutical industry's general outlook toward AI, machine learning, and automation is positive. A remarkable 84.1% of survey respondents believe that the benefits of these technologies outweigh the drawbacks, emphasizing their potential to transform the sector by increasing efficiency, productivity, and cost-effectiveness (Devereson et al., 2022; Kolluri et al., 2022). Addressing the identified challenges through targeted investments in infrastructure, training, and regulatory clarity will be critical to bringing out AI's full potential in biopharmaceutical manufacturing.

Table 8 Illustrating Gaps in the literature: Possible Solutions Derived from Survey Results

Gaps in Literature	Possible Solutions from the Findings
I. Need for a thorough understanding of specific regulatory challenges, guidelines, and ethical frameworks associated with AI use in biopharmaceutical manufacturing	- Develop clear guidelines and frameworks in collaboration with regulatory bodies to navigate AI implementation in compliance with ethical standards.
	- Highlight workforce development initiatives focusing on specialized AI applications and training programs.
II. More research on the specific skills and abilities needed, potential gaps in the existing workforce, and effective ways for upskilling workers in the industry	- Implement comprehensive training programs to bridge the skills gap, focusing on AI literacy and technical expertise in biopharmaceutical sector.
	- Investigate AI techniques such as digital twins, process monitoring, and predictive analytics for advanced modeling of intricate biological processes.
III. Explore advanced modeling techniques to handle the complexity and variability of biological systems in biopharmaceutical manufacturing	- Promote knowledge sharing and collaboration among researchers to accelerate the development and adoption of innovative AI applications in the industry.

5.3 Conclusion

Objective 1: Identify and characterize the current state of AI adoption in the biopharmaceutical industry, including the specific AI techniques (machine learning) and automation tools that are being used.

Machine learning (ML) and robotic process automation (RPA) are predominant AI techniques in the biopharmaceutical industry. Artificial intelligence (AI) is extensively used for drug discovery, process optimization, and quality control, showcasing its adaptability and significance. Survey results indicate the widespread adoption of ML and RPA, reflecting their fundamental importance in biopharmaceutical manufacturing.

Objective 2: Assess the trends and factors driving the increasing adoption of AI, machine learning (ML), and RPA in the biopharmaceutical industry, exploring the factors that have contributed to this growth in recent years.

According to the survey results, the biopharmaceutical industry has seen a significant rise in the usage of AI, ML, and automation technologies. The majority of organizations have implemented these technologies within the last 1-2 years, indicating rapid adoption. Positive perceptions among participants highlight AI's role in enhancing procedures and competitiveness.

Objective 3: Examine the transformative impact of AI on the biopharmaceutical model, particularly in the manufacturing sector, analysing how AI has disrupted traditional processes and introduced new methodologies.

AI has revolutionized biopharmaceutical manufacturing by optimizing processes, improving quality control, and enabling predictive maintenance. Real-time monitoring, batch monitoring, and predictive maintenance are key areas where AI-driven advancements have been significant. Despite initial challenges, AI has brought about efficiency, productivity, and cost-effectiveness enhancements.

Objective 4: Assess the specific benefits that AI-enabled technologies have brought to the biopharmaceutical industry, encompassing efficiency improvements, productivity gains, and cost reduction opportunities.

AI-enabled technologies have led to higher efficiency, accelerated time to market, improved product quality, and cost savings. Challenges include integrating AI with existing systems, a lack of internal AI expertise, data quality issues, and regulatory uncertainty. Despite challenges, the industry remains optimistic, with the majority believing that the benefits outweigh the drawbacks.

In conclusion, the biopharmaceutical industry is adopting AI at a rapid rate because of its transformative potential to improve competitiveness, efficiency, and innovation. Addressing challenges and ensuring responsible implementation are crucial for fully achieving the advantages of AI-enabled technologies in biopharmaceutical manufacturing. Various aspects of the manufacturing process will benefit from the use of AI (automation and ML) in the biopharmaceutical manufacturing industry. According to the research, using these intelligent technologies will improve quality control measures, improve operational efficiency, and reduce production costs. Furthermore, the use of artificial intelligence and ML algorithms will enable better predictive maintenance, improve equipment utilisation, and reduce downtime.

5.4 Recommendations for further research

While this study has provided valuable insights, further research is necessary to fully understand the long-term impact of AI on biopharmaceutical manufacturing. Here are some recommendations for future research:

- Long-term studies will be crucial for understanding the long-term effects of AI integration in biopharmaceutical manufacturing, particularly in relation to job opportunities arising from technological advancements.
- Comparing AI-driven techniques with traditional methods can provide valuable insights into their advantages and disadvantages.
- The study may have limited perspectives due to its reliance on LinkedIn for participants. Despite extensive efforts to reach out, the low response rate suggests that more time is required to achieve better research results. In order to ensure comprehensive findings, future research should extend study durations and increase sample sizes by conducting surveys and interviews with experts worldwide.
- Concentrating research efforts on certain areas of biopharmaceutical manufacturing, such as upstream or downstream processing, can yield specific insights, aid in making informed decisions, and guide future advancements.

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Appendix A – Survey Questionnaire

The Impact of AI (Machine Learning and Automation) on the Biopharmaceutical Manufacturing Industry

Dear Participants,

Greetings!

My name is Ruchi Sayal, and I am a student at Griffith College, Dublin, pursuing a Master of Science degree in Digital Transformation in Life Science. As part of my academic research, I am conducting a comprehensive study titled "The Impact of AI (Machine Learning and Automation) on the Biopharmaceutical Manufacturing Industry." As the biopharmaceutical sector continues to evolve, embracing cutting-edge technologies is crucial for driving innovation, enhancing efficiency, and improving patient outcomes. Artificial intelligence (AI), including machine learning (ML) and automation, has emerged as a transformative force in this regard, revolutionising various facets of biopharmaceutical manufacturing. The purpose of this survey is to gather insights from professionals like yourself who are actively involved in the biopharmaceutical industry.

Your participation will contribute to a comprehensive understanding of how AI technologies are shaping the industry landscape, driving advancements, and addressing challenges in biopharmaceutical manufacturing. Your participation in this study is voluntary, and all responses will be kept confidential and anonymized. The data collected will be used solely for academic research purposes and will not be shared with any third parties.

Thank you in advance for your participation. Your insights will be instrumental in furthering our understanding of the transformative role of AI in the biopharmaceutical manufacturing industry.

Before you begin the survey, By clicking 'Agree' below, you acknowledge that you are voluntarily participating in this survey, understand the purpose of the survey, and consent to the use of your responses for research purposes. Your responses will be anonymized, kept confidential, and used solely for research purposes. Do you agree to participate in this survey? *

- ○ Agree
- ○ Disagree

1) Does your company currently use any artificial intelligence (AI) techniques in your biopharmaceutical research and development (R&D) or manufacturing processes? *

- ○ Yes
- ○ No

2) How long has your company been using AI, ML, and automation technologies? *

- ○ Not applicable
- ○ Less than 1 year
- ○ 1-2 years
- ○ 3-5 years
- ○ More than 5 years

GRIFFITH COLLEGE

1) Does your company currently use any artificial intelligence (AI) techniques in your biopharmaceutical research and development (R&D) or manufacturing processes? *

- ◯ Yes
- ◯ No

2) How long has your company been using AI, ML, and automation technologies? *

- ◯ Not applicable
- ◯ Less than 1 year
- ◯ 1-2 years
- ◯ 3-5 years
- ◯ More than 5 years

3) Which specific AI techniques is your organization currently utilizing? *

- ☐ Machine Learning
- ☐ Natural Language Processing (NLP)
- ☐ Deep Learning
- ☐ Computer Vision
- ☐ Robotics Process Automation (RPA)
- ☐ Other:

4) What are the biggest challenges your company faces in adopting AI in biopharma? *

- [ ] Lack of internal expertise in AI
- [ ] Difficulty integrating AI with existing systems
- [ ] Data quality and availability issues
- [ ] Regulatory uncertainty around AI-derived results
- [ ] Other:

5) How important do you believe AI, ML, and automation will be to the future success of the biopharmaceutical industry? *

	1	2	3	4	5	
Not important	○	○	○	○	○	Very important

6)Which of the following areas within biopharmaceutical manufacturing have been impacted by AI technology? *

- [ ] Quality control
- [ ] Process optimization
- [ ] Predictive maintenance
- [ ] Batch monitoring and control
- [ ] Regulatory compliance
- [ ] Supply chain management
- [ ] Other:

7) In your opinion, what specific benefits has AI brought to the biopharmaceutical manufacturing sector? *

- [ ] Increased efficiency
- [ ] Improved product quality
- [ ] Cost reduction
- [ ] Faster time to market
- [ ] Enhanced safety and compliance
- [ ] Other:

8) Have you personally been involved in or witnessed the implementation of AI technologies in the biopharmaceutical manufacturing sector? *

- ◯ Yes
- ◯ No

9) If yes, how would you rate the effectiveness of AI in improving manufacturing processes within the biopharmaceutical industry? *

- ◯ Very effective
- ◯ Somewhat effective
- ◯ Not effective

10) On a scale of 1 to 5, how critical do you believe it is for biopharmaceutical companies to invest in AI technologies for manufacturing? *

	1	2	3	4	5	
Not critical at all	◯	◯	◯	◯	◯	Extremely critical

11) In your experience, how has AI impacted the efficiency of biopharmaceutical manufacturing processes? *

- ◯ AI has significantly reduced process times and streamlined production.
- ◯ AI has a minor impact on efficiency, with some minor improvements.
- ◯ AI has made biopharmaceutical manufacturing more complex and time-consuming.

12) To what extent do you believe AI has improved productivity in biopharmaceutical manufacturing? *

- ◯ AI has led to a substantial increase in output and yield of biopharmaceuticals.
- ◯ AI has shown some promise in improving productivity, but results are mixed.
- ◯ AI has not had a noticeable impact on productivity in biopharmaceutical manufacturing

13) How effective do you think AI is in reducing costs associated with biopharmaceutical manufacturing? *

- ◯ AI has significantly lowered production costs by optimizing resource usage.
- ◯ AI may lead to cost reductions in the long term, but upfront investment is high.
- ◯ AI has not shown any significant benefit in terms of cost reduction for biopharmaceuticals.

14) How optimistic are you about the future potential of AI for improving biopharmaceutical manufacturing? *

- ◯ I am very optimistic that AI will revolutionize biopharmaceutical manufacturing.
- ◯ AI has the potential for further improvements, but challenges remain.
- ◯ I am skeptical of the long-term benefits of AI in biopharmaceutical manufacturing.

15) In your experience, how prevalent is the use of Artificial Intelligence (AI) in biopharmaceutical manufacturing today? *

- ◯ Not prevalent at all
- ◯ Used in some niche applications
- ◯ Moderately used across various functions
- ◯ Widely adopted as a standard practice

16) Please share any other AI techniques you have encountered in biopharmaceutical manufacturing.

Your answer

17) Which of the following AI techniques do you believe will be most impactful in the future of biopharmaceutical manufacturing? *

- ☐ Reinforcement learning for optimizing complex manufacturing processes.
- ☐ Explainable AI (XAI) for building trust and regulatory compliance.
- ☐ AI-powered digital twins for real-time process simulation and prediction.
- ☐ Generative AI for accelerating drug discovery and design.
- ☐ All of the above

18) Please share any other emerging AI techniques you believe will be important in the future of biopharmaceutical manufacturing.

Your answer