”Integrating Artificial Intelligence into Root Cause Analysis for CAPA systems: A Survey Based Study on Perception, Readiness and Implementation Challenges in the Indian Pharmaceutical Industry”

Dissertation Research Report

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CANDIDATE DECLARATION

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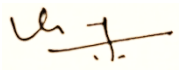
I, hereby declare that this dissertation, entitled"Integrating Artificial Intelligence into Root Cause Analysis for CAPA systems: A survey based study on perception, readiness and implementation challenges in the Indian Pharmaceutical industry", submitted in partial fulfilment of the requirements for the award of the degree MSc. Pharmaceutical Business & Technology at Griffith College, is entirely my own work and has not been submitted, in whole or in part, for any other qualification at this or any other institution. All the sources of the information, data, figures and ideas used have been duly acknowledged in accordance with academic referencing standards.

I affirm that I have conducted this research in adherence to the highest standards of academic integrity, honesty, and ethical conduct and in compliance with the ethical guidelines of Griffith College, and that all necessary ethical approvals have been obtained. I further confirm that this work complies fully with the university's policies on academic integrity.

Candidate Signature: 

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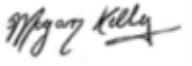
Supervisor's Signature: 

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LIST OF ABBREVIATIONS

ABBREVIATION	FULL FORM
AI	Artificial Intelligence
RCA	Root Cause Analysis
CAPA	Corrective and Preventive Action
GMP	Good Manufacturing Practice
R&D	Research and Development
IT	Information Technology
QMS	Quality Management Systems
FDA	Food and Drug Administration
ICH	International Council for Harmonization
CFR	Code of Federal Regulations
FMEA	Failure Mode and Effect Analysis
EMA	European Medicines Agency
NIPER	National Institute of Pharmaceutical Education and Research
FICCI	Federation of Indian Chambers for Commerce and Industry
NLP	Natural Language Processing
GAMP	Good Automated Manufacturing Practices
CDSCO	Central Drug Standard Control Organization
XAI	Explainable AI
SHAP	Shapely Additive Explanation
LIME	Local Interpretable Model Agnostic Explanations
LIMS	Laboratory Information Management System
ERP	Enterprise Resource Planning
eBMR	Electronic Batch Manufacturing Record
HESS	Human Error Investigation Software
RCDT	Root Cause Determination Tool
CLAT	Cognitive Load Assessment Tool
PIL	Participant Information Leaflet
DPDPA	Digital Personal Data Protection Act
GDPR	General Data Protection Regulation
QA	Quality Assurance
QC	Quality Control
RA	Regulatory Affairs
CRO	Contract Research Organization
CDMO	Contract Development/Manufacturing Organizations

ABSTRACT

This study investigated the perception, organizational readiness and implementation challenges of integrating Artificial Intelligence (AI) in to Root Cause Analysis (RCA) within Corrective and Preventive Action (CAPA) systems in the Indian pharmaceutical industry. A quantitative survey was conducted among 101 professionals working in quality assurance, quality control, manufacturing and regulatory roles. Collected Data were analyzed using descriptive statistics, frequency distributions and measures of central tendency to identify existing attitudes, readiness levels and perceived barriers. The results showed that the majority of respondents recognized AI's potential to enhance the RCA accuracy, reduce human errors and improve compliance with Good Manufacturing Practices (GMP) standards, with two-third of total sample size agreeing on its benefits for efficiency and decision making. However, readiness levels were not found to be same, with approximately 60% reported having some relevant technical infrastructure and other 40% believed their organizations had both the technology and skilled personnel required for effective implementation. Key barriers included high implementation costs, limited AI expertise, resistance to change and uncertainty about regulatory acceptance. Participants have identified a strong need for clearer regulatory guidelines, targeted training programs, pilot implementation projects and improved data quality and security to support AI adoption. The findings indicate that although optimistic belief towards AI adoption in CAPA systems is strong, there are some practical limitations which constrain the current progress. This study concludes that successful integration will require coordinated efforts between industry stakeholders and regulators, strategic investments in infrastructure and training, and structured change management initiatives. This research contributes real world data on an underexplored geographical context, giving a combined view of perceptions, readiness and challenges to help shaping the policies and organizational strategies which promote AI adoption. Recommendations includes initiatives for small scale pilot programmes, promoting industry-regulator collaborations and developing more regulatory guidelines for AI- validation. In future, more investigations has to be done in relation to changes in AI-adoption over time, assessment of cost-effectiveness and comparisons with other regulated industries.

Chapter 1

INTRODUCTION

The pharmaceutical industry plays a critical role in safeguarding the consistent production of high quality, safe and effective medicinal products. In a highly regulated environment, ensuring the product quality and compliance is considered very significant. In order to minimize the risk of product failure, regulatory issues and patient harm, organizations are required to implement most robust quality management frameworks (Klimenkova *et al.*, 2019). One of the central pillars of the quality assurance in this pharmaceutical industry is the Corrective and Preventive Action (CAPA) system. CAPA provides a structured framework for identifying, investigating and addressing non-conformances, deviations and other quality issues. Root Cause Analysis (RCA) is considered as the heart of the CAPA system, which aims to find out the underlying cause of a problem and also ensure that the corrective actions taken against them not only fix thing superficially but also it prevents the recurrence of the same problem in the future (Jain and Jain, 2018).

Apart from the critical importance of RCA in maintaining the pharmaceutical quality and regulatory compliance, traditional RCA methods are often manual, time consuming and vulnerable to subjectivity. These limitations can lead to inadequate investigations, repeated failures, delays in CAPA closures and inconsistent documentation. As the complexity of pharmaceutical operations increases with advancements in global supply chain, technologies and stricter regulatory expectations, the approach for RCA also need to be for more intelligent, efficient and data driven by its nature. In this context, Artificial Intelligence (AI) has emerged as a promising tool with the potential to enhance the effectiveness of RCA within the CAPA system significantly (Menon and Shabaraya, 2022).

Artificial Intelligence (AI) is referred as the ability of machines and software systems to simulate human intelligence by understanding the data, recognizing patterns and making decisions. AI technologies such as machine learning, natural language processing and data analytics can be effectively employed to identify trends in deviations, predict potential failures and also for assisting in root cause identification. Integration of AI technologies in this aspect could significantly reduce the burden of manual investigation and enhance the consistency and accuracy of CAPA outcomes (Lynch, 2024). AI can also play an important role in proactive quality management by helping in early detection of

device failures and risk signals from various data sources such as batch records, audit findings, complaints and manufacturing data.

In a global perspective, while pharmaceutical industry is exploring the use of AI in the areas like drug discovery, clinical trials and manufacturing, its application in quality assurance applications especially in CAPA and RCA remains limited or underexplored in the countries like India. There is a growing interest in digital transformation across Indian Pharmaceutical organizations which mainly driven by the factors such as global competitions, regulatory pressures and unavoidable need for operational excellence (Arunagiri *et al.*, 2024; Lynch, 2024). However the actual integration of AI into CAPA systems is still in its early stages. This could be due to multiple challenges including limited awareness, lack of internal capabilities, infrastructure gaps, and uncertainties about the return of investment and other regulatory issues.

With this background, it is very essential to understand more into the readiness of Indian pharmaceutical companies to adopt AI in CAPA processes, the perception of professionals working in these organizations and the practical challenges they face. Despite the vast amount of literature on AI application in pharmaceutical production and Research and Development (R&D), there is a lack of experimental research focuses specifically on quality systems and CAPA processes in the Indian context. Considering this gap, the main objective of this study is to explore how professional in quality assurance and Information Technology (IT) perceive the use of AI in RCA and CAPA systems. It also aims to assess organizational readiness and implementation challenges from technological, organizational and regulatory perspectives (Chindhalore *et al.*, 2025).

To achieve this, there are four specific objectives set for the study that includes:

- To investigate professional's perceptions of AI and its impact on RCA effectiveness;
- To assess the level of organizational readiness for adopting AI in CAPA systems and identify key influencing factors;
- To identify implementation challenges including technological, organizational and regulatory barriers
- To provide practical recommendation for overcoming these challenges and facilitating the successful implementation of AI in RCA processes.

This study focuses mainly on the Indian Pharma industries targeting professionals who are directly or indirectly involved in quality assurance, compliance, operations or digital transformation activities. The primary data for this study is mainly collected through a structured survey questionnaire distributed among professionals from various functional areas. Although pharmaceutical operations are globally operated and regulated by international regulatory bodies, this study mainly focus on the Indian market, where things are quite different in the case of digital progress, awareness about the rules, available resources and workplace culture, compared to western countries. The scope of this study is also limited to the application of AI in quality systems especially in RCA and CAPA. The significance of this study lies in its potential to generate new positive insights that can guide pharmaceutical companies in making informed decisions about digital transformation in quality systems. The finding of this study are expected to benefit multiple stakeholders including quality managers, compliance officers, operational excellence teams and digital transformation professionals. This study can serve as a reference benchmark for industrialists for evaluating their own organization's preparedness and alignment with digital strategies accordingly. The insights from this study could also help AI consultant of application providers to customize their technologies for meeting the specific industrial needs. Furthermore, academic community may use these findings as a foundation for further research.

In summary, this study will investigate on the perception of professionals working in the Indian pharmaceutical industry, regarding the integration of AI in RCA within CAPA systems and also to what extent these organizations are prepared for such a kind of digital transformation. By identifying these current perceptions, readiness levels and key implementation challenges, this research aims to generate some positive and prospective insights that can support more effective adoption of AI in quality systems. As the pharma industries always look forward for greater operational efficiency and regulatory compliance through technological innovation, this study contribute academic and practical knowledge to bridge the gap between AI's potential and its real world application in pharmaceutical quality management.

This dissertation is structured into five chapters. Chapter 1 provides the introduction. Chapter 2 presents the comprehensive literature review, summarizing previous research related to AI applications in pharmaceutical quality systems, RCA, CAPA and also will highlight the key gaps in the existing scenario. Chapter 3 will outline the methodology

used to conduct this study, including survey design, sampling strategy and data analysis. Chapter 4 will present and discuss all the findings of this study in correlation with the existing literature. Chapter 5 will collude the study with a summary of major findings, implications and recommendations for future research.

Chapter 2

LITERATURE REVIEW

2.1. The importance of CAPA and RCA in pharmaceutical quality management systems

The CAPA system is an essential component of pharmaceutical Quality Management Systems (QMS), which serves as a crucial element for maintaining product quality, regulatory compliance and continuous improvement (Figure 1). CAPA processes are mandated by all the major international regulatory bodies such as Food and Drug Administration (FDA), European Medicines Agency (EMA) and International Council for Harmonization (ICH) using their regulatory frameworks like Code of Federal Regulations (CFR) part 820, EudraLex volume 4 and ICH Q10. All these regulations emphasize the systematic identification, investigation and resolution of quality related issues to prevent their recurrence in the future (Avellanet, 2009; VanDuyse *et al.*, 2021).

CAPA systems are basically designed to address the potential non conformances in the pharmaceutical production environment by identifying the deviations, implementing corrective actions for solving the immediate issues and also for executing the preventive measures to reduce the recurrence of the risks (Arunagiri *et al.*, 2024). These systems plays a critical role in ensuring the compliance with Good Manufacturing Practices (GMP), minimizing the product recalls and improving the patient safety. As highlighted by Arunagiri et al., a robust CAPA system not only addresses compliance deficiencies but also fosters a culture of accountability and quality risk management. Many studies have already shown that an effective and well-structured CAPA system can significantly reduce the deviation recurrence rates (Jain and Jain, 2018; Lynch, 2024).

CAPA is not an independent function because it is always embedded across various other pharmaceutical operations such as deviation management, change control, compliance handling, and audit findings and out of specification kind of results (Arunagiri *et al.*, 2024). these interactions actually reinforce the CAPA as in important quality assurance function where it integrate quality data across the product life cycle and also enables a systematic and data driven approach to process improvements. Pharmaceutical companies that implemented CAPA systems aligned with Q10 principles showed better performance in regulatory inspections and faster market access timelines, clearly shows the value of

the CAPA in creating pharmaceutical competitiveness (VanDuyse *et al.*, 2021; Arunagiri *et al.*, 2024).

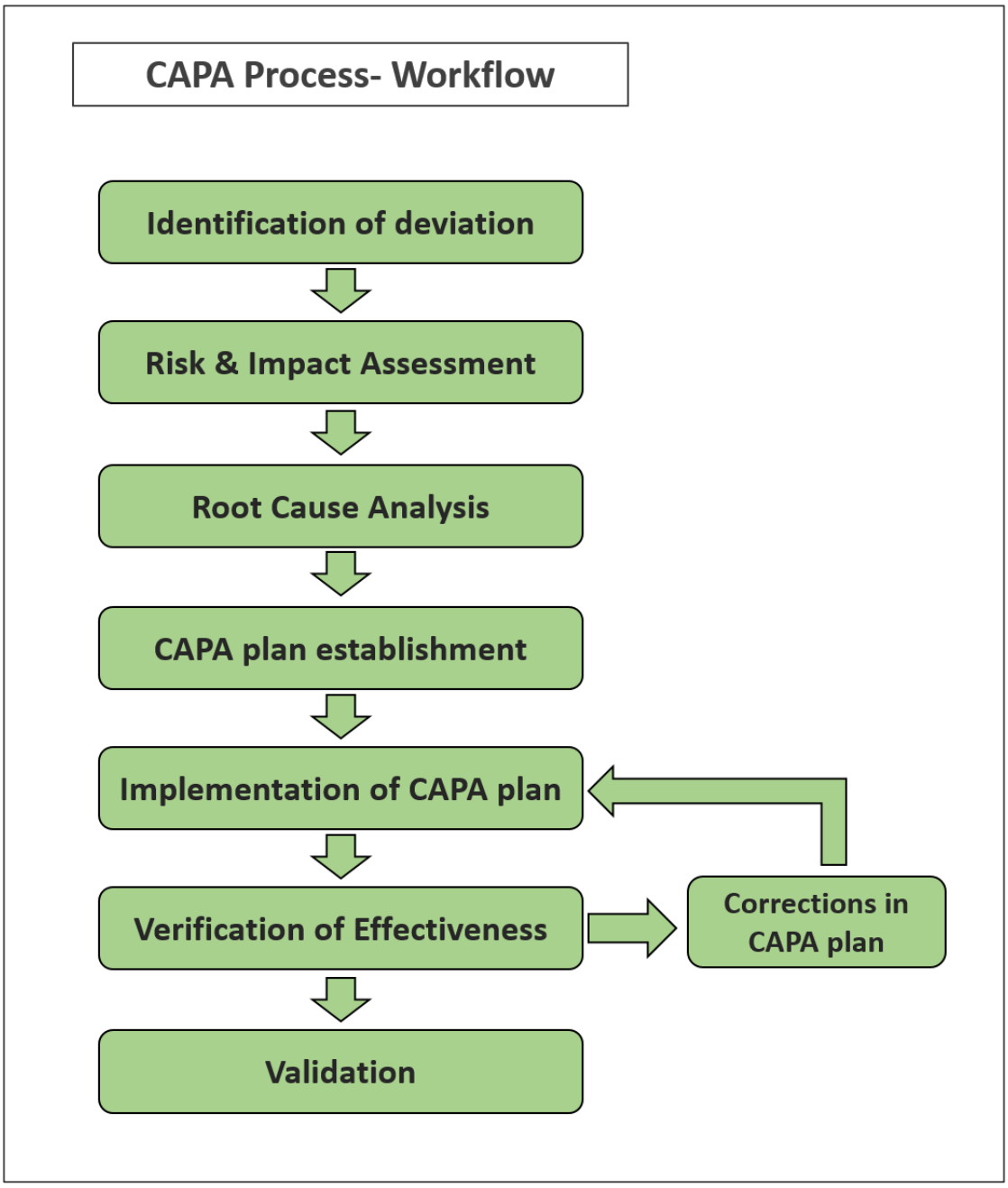

Figure 1. CAPA Process- Workflow. Diagram demonstrates the sequential steps in the process of CAPA

The effectiveness of the CAPA system mainly depends on Root Cause Analysis (RCA), a structured problem solving methodology that aims to identify the underlying reasons for a deviation or a quality failure. Rather superficial investigations, RCA enables organizations to go deeper into the issues with more clarity and address fundamental

issues that contribute to non-conformities. RCA usually performed with the help of tools such as 5 whys, Ishikawa diagrams, fault tree analysis and Failure Mode and Effects Analysis (FMEA) (Menon and Shabaraya, 2022). The efficiency of CAPA process directly linked to the success of the RCA. The companies those who have used structured RCA methodologies had shown to have higher closure effectiveness and significantly lesser repeat deviations compared to those who used context based approaches (Solé *et al.*, 2017). During the Audits or inspections regulatory bodies will be so keen to scrutinize the depth and robustness of RCA and if needed, they can issue warning letters in case the company have failed to have adequate investigations on deviations or to have scientific and logical justifications for rout causes which can be further judged as an ineffective CAPA implementation (Avellanet, 2009; VanDuyse *et al.*, 2021). As a result of this, there is growing emphasis on creating a knowledge-driven CAPA system where RCA is supported by detailed data analysis by cross-functional teams.

In essence, CAPA serves as the backbone of pharmaceutical quality assurance by providing a systematic framework for addressing and preventing quality issues. Within the CAPA system, RCA plays a crucial role in ensuring all the actions are targeted, effective and sustainable. Together, CAPA and RCA enhance regulatory compliance and also drive a culture of continuous improvement and operational excellence in pharmaceutical industry.

2.2. AI in Pharmaceutical Quality Systems

Artificial intelligence is becoming an important tool in the pharmaceutical industry. It can help in improving the efficiency, reducing the human mistakes and supporting continuous improvement in quality. One of the key areas where AI can be effectively useful is the CAPA system, which considered as the major part of the pharmaceutical quality management system. CAPA. Traditional CAPA systems aim to prevent recurring quality issues by addressing root causes, but their slow, paper based and reactive nature limits timely and effective problem resolution abilities (Bhat *et al.*, 2025; Chindhalore *et al.*, 2025).

AI can help improve CAPA systems in many ways. It can use machine learning to find patterns in past data, natural language processing to understand written reports and predictive analytics to give warnings about possible problems in the future. For example, AI can study old reports to find out what usually causes a certain kind of error and it can

suggest the best way to fix that error. This can save to a greater extend and can help quality teams to work in a faster manner (Rakočević and Markovic, 2024). In some advanced systems, AI can even help in automatic identification of a root cause and can suggest the right corrective steps as well. AI can continuously monitor the production data in real time to detect deviations from standard data and suggest preventive actions to handle those deviations. This actually makes CAPA system more proactive than being just reactive.

Although these benefits are promising, the use of AI in CAPA systems is still limited in many countries including India, which is a major player in pharmaceutical manufacturing. The major reasons for this scenario are lack of proper digital systems, shortage trained staffs, concerns about data security and regulatory uncertainties in validation of AI (Jain and Jain, 2018; Arunagiri *et al.*, 2024; Lynch, 2024). Many quality experts suggest that Ai should be used to support human decisions rather than replacing them. Even global regulators like FDA and European Medicines Agency (EMA) are very keen about giving proper guidance and assurance on AI tools that they are transparent, explainable and properly tested before being used in pharmaceutical quality processes (Avellanet, 2009).

India is still at an early stage of using AI in CAPA systems, it is very relevant to have more research on this topic. And also it is very important to study how industry professionals feel about AI, whether they are ready to use it and what are the major challenges they face(Gustafson *et al.*, 2025)This information can help companies to plan better in future and encourage safe and effective use of AI in pharmaceutical quality systems.

2.3. Perception of AI in the Pharmaceutical Industry

The perception of AI in the pharmaceutical industry plays a very important role in deciding how quickly and successfully AI is accepted and used. Perception in this context refers to how professionals understand AI that includes, whether they trust it, understand it and feel comfortable in using it. A positive perception always encourages faster adoption, and on their other side negative perception that includes doubts and fears can slow down or completely prevent the use of AI systems, even if the technology is found to be very effective and useful (Gustafson *et al.*, 2025).

Studies have shown that people working in different departments within the pharmaceutical industry have mixed opinion about AI. Professionals in roles such as IT,

data science and digital transformation are usually more open and optimistic about AI. They strongly believe AI can improve productivity, reduce human errors and do the decision making more efficient. However, people working in other departments like quality assurance, regulatory compliance and manufacturing are found to be more cautious. They are very hesitant mainly because they don't have a proper understanding about how AI systems are working and how these systems make decisions. In that context, the logic or rationale behind the AI's decision making will be unclear or difficult to explain (Rakočević and Markovic, 2024).

In a highly regulated environment like pharmaceutical industry, where every decision must be well documented and justified, this lack of transparency and lack of logical clarity can become a very serious concern. And if professionals are reaching to a situation where they find difficulty in interpreting the justification for AI's decision making, then it could serious problems during the audits and inspections. It is very hard to trust AI when users are not sure it will work reliably in real situations especially when patient safety and rules has to be followed (Chindhalore *et al.*, 2025).

Another major reason for negative perception is the fear that AI will take away jobs. Many employees worry that once AI tools are introduced, they might lose their roles or be replaced by the machines. This concern is particularly strong in departments that involve repetitive tasks like data entry, documentation and basic decision making. However, the recent studies have shown that AI is more likely to support workers rather than replace them completely. AI can become a significant help in handling the time-consuming tasks and can allow professionals to focus on more important works such as critical thinking, supervision and decision making. But, most of time, it's unfortunate that this message is not always communicated clearly and can create confusions and fear (Kimta, 2024).

From Indian pharma perspective, these issues are even more challenging. Many companies in India are still at an early stage of digital development, which means that the exposure to AI is very much limited. Generally, lack of awareness about AI and its benefits makes it harder for employees to trust or use it confidently (Chindhalore *et al.*, 2025). Cultural resistance to change is another important factor. People who have been following the traditional practices for many years may be reluctant to try new technologies, especially if they do not fully understand how they work or they have not received proper training. A recent study on digital readiness in Indian pharmaceutical

companies found that only a small fraction of employees are confident in using AI tools. More than half of the respondents said they need more training and support for using such technologies in their daily work (Adhikari, 2020). This actually highlighted the fact that the perceptions are influenced not by the attitudes but also by the knowledge and skills. So it is very important to have proper training and support for employees to improve their competencies and thereby their positive perception (Festa *et al.*, 2022; Das *et al.*, 2024; Chindhalore *et al.*, 2025).

Therefore, developing a positive perception about AI in the pharmaceutical industry is not just about introducing the technology but also involves educating the staff, building the trust and guiding them how AI can be used safe and effective manner. Increased transparency of the systems that clearly explain how decisions are made, can really help to increase the confidence among users especially in quality-related areas. So addressing the concerns around explain ability, job security and usefulness will be essential to ensure that AI becomes a helpful and accepted tool in pharmaceutical quality management systems.

2.4. Organizational and Technological Readiness

Organizational and technological readiness actually exist as the backbone for successful digital transformation mainly by the implementation of AI with in CAPA systems in pharma sector. The ability of an organization to support AI mediated changes depends not only the availability of technology but also on the management of resources, infrastructure and all other factors that facilitate such integration process. Organizational readiness means mainly the support form management with a clear strategy for using AI and also having the employees who are trained on using new technologies (Muhyi *et al.*, 2025). Many companies do have an incorrect impression that they are actually ready for AI, but later they realize that they are not especially in the case of staff skills and their ability to manage the changes. In other words, simply having the AI is not enough and peoples should also know how to use them correctly.

Some large scale Indian pharmaceutical companies like Sun Pharma and Dr. Reddy's have already made some good level of progress in using AI. These companies are mainly supported by global partnerships and investments in research and development. These companies often use advanced digital quality systems that can be connected to AI tools. For example, they uses systems like SAP, which can help to collect and analyze data in

real time. By this way, companies can use AI to find problems early, understand the trends and also they can take the actions quickly as possible (McDermott *et al.*, 2024).

However, still many small and medium scale pharma companies in India still use older systems that are not connected to AI. These legacy systems cannot easily work with AI because they don't support automation and real time data analysis. Studies have shown that, lesser than 30% of Indian pharma companies have established digital quality systems and even fewer companies have the systems which need to be established completely. Adequate and effective digital tools are very much necessary for the complete establishment of AI in quality systems. Another major issue is the deficiency of skilled human resources. AI in CAPA systems requires professionals who understand both pharmaceutical quality standards and working of AI. Unfortunately, there is a big shortage of such skilled professionals in India. There were reports showing that, pharmaceutical education in India still focuses more on basic science and very less on digital skills (Pumplun *et al.*, 2019). Because of this reason, companies struggle to find people who can manage and use AI tools effectively. Industry bodies like National Institute of Pharmaceutical Education and Research (NIPER) have started training programs to reduce this skill gaps. However, a report from (Federation of Indian Chambers of Commerce and Industry (FICCI) have clearly showed that only 12% of pharma professionals have received formal training in AI or data analysis and only a very small number of those people work in quality systems.

Company culture is the important factor that affects the readiness. In many old companies, employees are used to working in strict environment and by following set rules. This kind of environment can make it harder to try new technologies. It was shown that, the companies with rigid structures, the working professionals may be afraid of making mistakes or losing their jobs, so they don't fully support AI. This actually make the process of digital change more difficult. Another important factor is the trust in AI tools. As the CAPA systems deal with product safety and quality, companies must able to explain and give justification for every decision made by the AI systems. If the AI system suggests a root cause or any corrective action to manage the change, the staffs and regulators should have a proper understanding on how the AI came to that decision. If they are not able to understand and explain the same, the trust would be lost on AI. Therefore, companies should make sure that AI tolls are transparent and easy to audit (Pumplun *et al.*, 2019; Muhyi *et al.*, 2025).

Technological readiness is another critical factor that affects the readiness. It is all about whether the company has the right digital tools and secure systems in place to support AI. This consist of IT infrastructure, systems that follow good data management practices and platforms that work well with AI. Companies also need the ability to work with external technology providers that can help to develop and implement AI supports. These kind of collaborations can give companies access to technical expertise for better learning and faster adaptation. There are reports for companies have shown external collaborations have helped in better possibilities for digital transformation. Larger companies usually have more money to invest in digital projects. They can afford to upgrade their systems and train their staffs. But for small and medium companies, they have less budgets and often cautious about investing in AI especially whenever its benefits are not immediate. Appropriate government support initiatives in the form of grants, tax reductions or other upgrade programmes could help these companies to get started. Another important factor is Vendor support for the AI implementation in the existing systems. Many vendors in India are still improving their platforms and may not offer all the AI features yet. Even if a company wants to adopt AI they may not be able to do that because their software vendors are not upgrading their systems (Tetteh-Caesar *et al.*, 2024).

2.5. Technical and Implementation Challenges

Using AI in CAPA in pharmaceutical industry brings many technical difficulties (Figure 2). Even though AI is capable of improving the effectiveness of problem identification and prevention, putting into practice in reality is not easy especially in highly regulated environments like pharma quality systems. One of the biggest challenge is data quality. AI system generally need good, clean and organized data for its proper working. But in many pharma companies, the data is often scattered and incomplete. Sometimes the quality data like complaints, deviation reports and audit reports are handwritten, scanned or not maintained in proper manner (Lynch, 2024). This makes it hard for AI to gather, read, sort and understand the data. Natural Language Processing (NLP) tools can help turn data into useful insights. But they work only if the input data is clean and standardized. The unclear data can lead AI to produce incorrect results.

Another major technical issue is about connecting the AI tools to existing systems. Since AI models are dynamic in their leaning and updating processes, it is hard to validate them in the traditional way. And there are no specific validation rules available for AI in

pharma quality systems yet, which makes companies more cautious about using it (Avellanet, 2009). Another major concern is about the data privacy and cyber security. AI usually require large amount of data and might need to be integrated with external storage systems or cloud platforms. This actually can increase the risk of data breaches and in order to prevent this companies might need strong protection measures before using AI. Many AI tools built separately and may not work smoothly with older systems. Integration of these tools to the existing systems might take more time and extra cost, which makes AI implementation harder (Sugandha *et al.*, 2023).

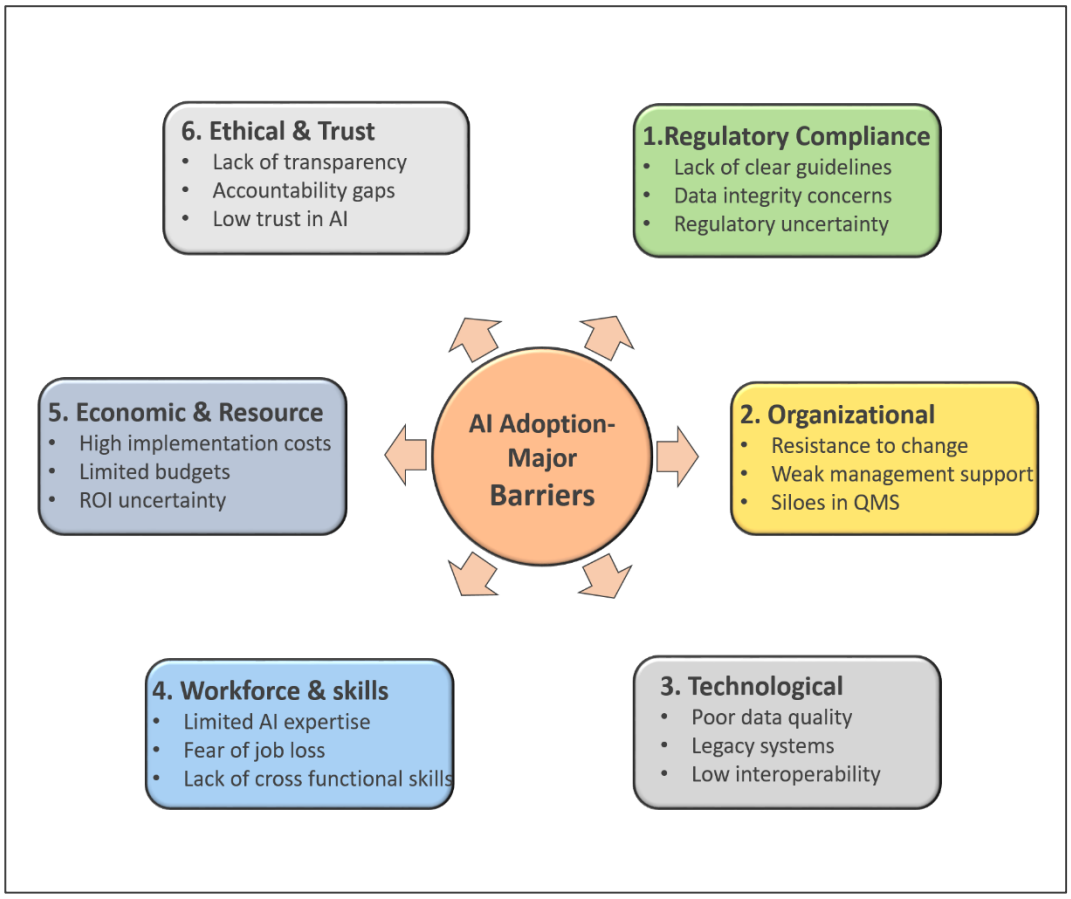

Figure 2. Major Barriers for AI adoption
(Based on existing literature).

2.6. Regulatory Landscape

The use of AI in pharma manufacturing and quality systems is increasing in interest, but the regulatory framework for guiding its use is still not fully developed. Although global regulatory bodies like FDA and EMA are exploring the role of AI in healthcare and drug development, there is a limited focus on AI applications in pharma manufacturing and

quality assurance systems (Conway, 2025). FDA has released guidance related to the use of AI or Machine Learning (ML) based software systems in clinical areas. FDA's "medical Device Action Plan" describes important topics like transparency, explainability and the need to track updates to AI models throughout their use. However, these guidelines mainly focus on clinical or diagnostic tools and not giving a proper explanation on how AI should be used in manufacturing operations and quality systems like CAPA. Because of this reason, even for the companies already using AI in these areas are running without a clarity for their validation and compliance (Gude and Gude, 2024).

In pharmaceutical manufacturing, companies must follow the regulations like 21 CFR part 11, which require accurate, secure and validated electronic records. Another widely used standard is Good Automated Manufacturing Practices version 5 (GAMP 5), which gives guidelines for validation of automated systems. Bothe these frameworks are meant for the traditional systems with fixed functionality (Avellanet, 2009). But for the AI systems, especially those have dynamic updation with respect to their data do not always behave in the same way. This makes them difficult to validate using traditional methods which further creates confusions about how to meet existing compliance standards when using AI in CAPA.

In India, the Central Drugs Standard Control Organization (CDSCO) has not yet issued specific rules for AI use in Pharmaceutical manufacturing or quality systems. Although, the application of AI in healthcare and clinical trials are being discussed, its role in GMP operations remains unclear (Das *et al.*, 2024). For Indian companies those who are following Schedule M or WHO-GMP, using AI is even harder because there are no clear national rules. They have to try new things by making sure that they don't fail to meet standards during the audits. This regulatory uncertainty is a major reason why many pharmaceutical companies are cautious about using AI in quality systems especially in CAPA. Without having the clear rules, all the companies have a big fear that inspections may not accept AI-generated decisions, especially for those which are not fully explained. These conditions lead companies to become more reluctant on investing in AI tools when the compliance risks are unknown (Conway, 2025).

The lack of global regulatory harmony is another major concern for the adoption of AI. The companies operate in different countries has to handle or face different rules and guidelines, which increase the complexity and cost of implementing the AI tools.

Harmonized international guidelines would make it easier for companies to adopt AI confidently (Tupsamudre *et al.*, 2022). Since the rules for using AI in CAPA systems are not fully developed yet, companies are facing lot of difficulty in moving forward more confidently. They are trying to rely on their own risk checks and staying alert to the changes. So, more clear and practical guidelines are needed form regulators in order to support safe use of AI in pharma quality systems.

2.7. Ethical Concerns

The use of AI in pharmaceutical quality systems, including CAPA processes introduces several important ethical and operational challenges. Although, AI has the potential to improve the pace and accuracy of investigations, its implementation must be handles carefully to ensure fairness, transparency and data privacy. One of the most significant ethical concern is data privacy. In CAPA investigations, sensitive data such as safety records, supplier performance data and confidential manufacturing informations may be analyzed. This this data is not properly protected, there is an increased risk of unauthorized access, data breaches or data misuse (Tupsamudre *et al.*, 2022). As more companies rely on AI tools that store or process data in digital platforms or cloud platforms, the risk of cyber breaches are so high. To have more protection for organizations they must ensure AI systems follow strong data protection rules, such as outlined in India's Digital Personal Data Protection Act (DPDPA), 2023. This law emphasizes the responsibility in handling the personal data that include the consent, usage and secure storage.

Another ethical challenge is the possibility for bias in AI decision making. AI systems have a dynamic updation system where they keep learning from the data they are trained on. And, if the training data contains any kind of errors, gaps or biases, the AI may repeat those mistakes, which can lead to inaccurate conclusions. In CAPA investigations and especially in RCA, the decisions must be objective, reliable and based on facts. If AI systems have any kind of unintentional bias over training data, the outcomes could affect product quality and patient safety negatively. To solve these issues, researchers came up with a new solutions and is nothing but the use of explainable AI (XAI). These explainable AI tools help the users to understand how and why AI model made a particular decision. This is very much important in regulated environments like

pharmaceutical manufacturing and quality systems, where transparency and traceability are critical (Tupsamudre *et al.*, 2022).

The methods such as SHAP (Shapely Additive Explanations) and LIME (Local Interpretable Model-Agonistic Explanations) are increasingly being explored to make AI models more interpretable. These tools give visual and numerical explanations for AI predictions which helps quality professionals to assess whether a result or output make sense or not. But the use of these explainable AI tolls in CAPA systems is still at its early stage. There is very limited research is happening on how these tools works in real world pharma settings where data is so complex, incomplete and sometimes difficult to interpret. Apart from that, lack of proper training on these explainable AI tools and other related resources also withholding their effective use. So, more studies are needed to evaluate the practical impact of explainable AI tools in improving the reliability of CAPA decisions.

2.8. Case studies on AI adoption in CAPA (Indian Pharmaceutical Industry)

Some Indian Pharmaceutical companies are adopting AI tools to improve CAP processes, particularly for Root Cause Analysis. Two notable examples are AmpleLogic and Rishabhsoft, which provide AI-driven solutions for Pharmaceutical Quality management systems. AmpleLogic offers an AI- enabled Quality Management system that help companies like Nacto Pharma and Biocon in automatic detection of deviation, initiation of CAP workflows and maintenance of regulatory compliance by integrating with existing systems like Laboratory Information Management System (LIMS), Enterprise Resource Planning (ERP) and Electronic Batch Manufacturing Record (eBMR) (AmpleLogic, 2025).This allows the companies for faster resolution of quality issues and reduces manual errors. On the other hand, Rishabhsoft has developed the Human Error Investigation Software (HESS) which uses tools like the Root Cause Determination Tool (RCDT) and Cognitive Load Assessment Tool (CLAT) to identify human related errors and improve the accuracy and efficiency of investigations (Rishabhsoft, 2022). These tools are capable of supporting the structured Root Cause Analysis and creating the audit-ready records. While both platforms enhance decision making and automation in CAPA processes, the broader adoption of these tools in the Indian pharma industry is still pending or still developing. These systems have shown a strong level of potential to

improve quality, reduce compliance risk and help companies toward more proactive problem solving.

2.9. Key Debates and Research Gaps

The literature reveals several ongoing debates around the integration of AI in CAPA systems. One major debate involves trade-off between accuracy and interpretability. While complex AI models offer higher predictive power, they often lack transparency which is considered as a non-negotiable requirement for regulated industries. Another important concern is about whether AI can be used as a decision-support tool or allowed to make autonomous decisions in quality investigations. People generally don't fully agree on the extend of control the machines should have in the sensitive areas like pharmaceutical compliance. Apart from that, most academic research and industry case studies focus mainly on AI use in drug discovery and supply chain optimization, were minimal focus is given on quality systems like CAPA. Few studies examine how organizational culture, leadership and training influence AI adoption in QMS, especially in countries like India. Additionally, region specific studies that focus on the unique economic, infrastructural and regulatory challenges are also lacking.

By considering these gaps, there is a substantial scope for further investigation. First of all, future research could develop a validated, GAMP 5 compliant framework for integrating AI into CAPA systems with proper guidelines on data governance, model validation and change management. Secondly, more studies are required to assess employee perceptions, digital skill levels and organizational culture as main predictors of AI readiness. A survey based study can help identify practical barriers and enablers specific to the Indian pharmaceutical landscape. Thirdly, pilot studies testing explainable AI models with in the CAPA workflow would contribute valuable insights into usability, compliance and acceptance. At last, a collaboration between academia, industry and regulators is essential to harmonize standards and create AI solutions that effective, auditable and compliant with global GMP expectations. These efforts will collective promote the integration of AI into pharmaceutical quality systems which can further enhance the patient safety and operational excellence.

CHAPTER 3

RESEARCH METHODOLOGY

This chapter outlines the research design and methodological approach used to find out the perceptions, readiness and implementation challenges related to the use of AI in RCA for CAPA systems in the Indian Pharmaceutical industry. It provides details of the research philosophy, approach, design, data collection methods, sampling strategy, data analysis techniques, conceptual framework and ethical considerations.

3.1. Research Philosophy

This research adopts a positivist philosophical approach, which is based on the belief that reality is objective and can be measured through observation and analysis. In positivism, knowledge is considered valid only when it is based on measurable and observable facts. This philosophy is very much suitable for studies that aim to find out the relationships between variables and produce generalizable results.

In the context of this study, this positivistic approach is appropriate because it focuses on gathering data on how professional in the Indian pharmaceutical industry perceive and respond to AI in CAPA systems. The major goal is to analyze measurable factors such as perception, organizational readiness and implementation challenges to identify patterns and relationships. Since this study relies on statistical analysis to reach conclusions, a positivistic view supports this structure and ensures an evidence based approach.

3.2. Research Approach and Design

3.2.1. Research Approach

This study follows a quantitative, deductive approach. In Deductive approach, reasoning start with general theories and moves towards testing specific hypothesis. This approach is suitable for confirming existing theories and applying them to new contexts. In this case, the study uses well established concepts from the technology adoption literature and applies them to Indian pharmaceutical industry experience with AI in CAPA systems. A quantitative approach is chosen because it allows the collection and analysis of numerical data. This type of data measures the intensity of perceptions, readiness levels and barriers, and making it possible to identify statistical correlations and trends. According to the key

principle of quantitative research, this study also aims to provide results which are objective, measurable and reproducible.

3.2.2. Research Design

This study uses a cross sectional survey design, where data is collected from participants at single point in time. This design is practically feasible for gathering data from a large group of respondents, especially when they are geographically spread out. These type of cross sectional surveys are commonly used in organizational research to capture the opinions, attitudes and behaviors. The use of this structured online survey allows for standardized data collection, which make data analysis much easier. It is also time saving, cost effective, especially in the areas where reaching participants in different regions would be difficult.

3.3. Conceptual Framework

The conceptual framework serves as the foundation for both the questionnaire design and data analysis.in this case, it connects four key constructs, which are perception of AI, organizational readiness, Implementation barriers and intensions to adopt AI in CAPA systems especially in RCA. Perception of AI includes how professionals think about the usefulness, easiness for use and the risks associated with implementing AI in CAPA processes. Organizational readiness mainly focuses on the company's preparedness or willingness to adopt AI in terms of availability of resources, leadership support, technical infrastructure and training. Implementation barriers refers to the major challenges that may prevent or delay AI adoption, such as lack of regulatory clarity, high costs, limited technical knowledge or poor data quality. Adoption intension is the possibilities or chances that the company will adopt AI in their CAPA systems within a definite period. This kind of conceptual framework assumes that positive perceptions and high organizational readiness will support the intension to adopting AI by overcoming the implementation barriers.

3.4. Quantitative Survey Questionnaire Development

A structured questionnaire was developed to collect primary data (Appendix 1). The questionnaire was prepared in English, as it is used as the professional language in most pharmaceutical organizations in India. The survey consist of several sections, where each sections corresponds to the specific research questions. The first section includes a brief

and clear explanation for important concepts such as AI, RCA and CAPA. This is to ensure that all respondents understand the context of questions. The second section collects demographic and background information such as job role, years of experience and department in which they are working. These information are useful for grouping responses and exploring patterns across different professional categories. The main section of the questionnaire consist of statement about perception, readiness, barriers and adoption intention. Participants are asked to rate their level of agreement using a five point Likert scale ranging from “strongly disagree” to “ strongly agree”. This scale allows respondents to express the intensity of strength of their opinions in a structured way. The final section provides the optional space for additional comments. The questionnaire items were developed based on the findings from the literature review to ensure its relevance and validity.

3.5. Target Population and Sampling Strategy

The target population for this study includes professionals currently working or who have worked recently, in the Indian pharmaceutical industries. More specifically, participants are selected from departments closely involved in CAPA activities such as quality assurance, manufacturing, compliance and regulatory affairs. These professionals are likely to have practical insights into AI use and digitalization in quality systems. The study uses a purposive sampling method, which means that participants are chosen based on specific characteristics relevant to the study. Inclusion criteria include direct involvement in CAPA or related quality processes, experience with AI or digital tools in their professional roles and good proficiency in English. Individuals not working in the pharmaceutical industry or not involved in quality related roles are excluded from the study.

The estimated sample size was found to be 380 participants. But considering the constraints and feasibility factors the target size was kept to be 100-150 participants. This size is considered as adequate for conducting statistical analysis including correlation and regression. Participants will be recruited through professional networking platforms such as LinkedIn, pharmaceutical associations, alumni groups and direct mails. The survey link will be shared along with an invitation message encouraging for participation. The participants will be also encouraged to share the survey with colleagues to improve the response rate.

3.6. Data Collection Procedures

The survey will be administered through Google forms. It is an easy and secure platform for digital data collection. The form will remain open for a period of four weeks to allow enough time for responses. During this time, weekly reminders will be sent through email and social medial platforms to encourage the participation. Before starting the questionnaire, each participant will be shown a Participant Information Leaflet (PIL) (Appendix 2) explaining the purpose, nature and voluntary nature of the study. At the starting of the survey questionnaire there will be a consent section where respondents must agree to participate before continuing. No personal or identifiable data will be collected. This helps protect participant's privacy and encourages honest responses. All responses will be stored securely and only accessed by researcher and the academic supervisor. The collected data will be downloaded in Microsoft Excel for cleaning, such as removing incomplete responses and also according to the inclusion exclusion criteria. After cleaning, the raw data will be transferred to statistical software for statistical analysis.

3.7. Data Analysis

The analysis will be done with the help of descriptive statistical methods, such as mean, standard deviation and frequency distributions to obtain a general overview of the participant's responses. These statistical methods will help summarizing the trends in perception, readiness and implementation barriers. Reliability testing for each section of the questionnaire will be done by using Cronbach's alpha, will help to ensure the consistency and reliability of data. A Cronbach's alpha value of above 0.70 will be considered acceptable. A correlation analysis will be used to examine the relationship between the key variables. Multiple regression analysis may also be used to analyze how a combination of factors can predict the outcome. Group difference based on the job role and years of experiences will be also tested using t-test or ANOVA, it is really needed. All results will be interpreted using a standard level of statistical significance ($p < 0.05$).

3.8. Ethical considerations

Ethical approval for the study was obtained from the ethics committee before the start of data collection (Appendix 3). Participants were informed about the nature of the research and their insights, including the right to withdraw at any stage with having any consequences. The Participant Information Leaflet (PIL) will be provided to all

participants and which will give a clear explanation on voluntary participation, purpose and confidential nature of this research. All the data will be stored on a password protected device and only used for academic purposes. The study fully complies with Indian's Digital Personal Data Protection Act (DPDPA) and European Union's General Data Protection Regulation (GDPR), ensuring that participant rights and data security are maintained throughout the research process.

CHAPTER 4

FINDINGS AND ANALYSIS

This chapter gives a comprehensive analysis of the collected data through the structured survey conducted. The chapter mainly aims to interpret and present the insights gathered form professionals across various functional roles with in the Indian pharmaceutical sector, focusing on their perception, readiness and organizational experiences with AI in the context of CAPA systems. The purpose of this chapter is to systematically analyze the responses and identify patterns, trends and significant differences across respondent groups. The major goal is to uncover the degree of awareness and approach about AI integration, the existing enablers and barriers to its adoption and the readiness of the pharmaceutical organizations. These findings are very crucial for reaching to meaningful conclusions and practical recommendations for the effective integration of AI into quality management systems especially in RCA and CAPA processes.

To address the four major objective of this study comprehensively, the data analysis have used both descriptive and inferential statistics. Descriptive statistics were used to summarize the distribution, central tendencies and variability of responses, which will provide a broad overview of existing perceptions, readiness levels and perceived challenges. Cronbach's Alpha was calculated to test the internal consistency and reliability of survey responses. To analyze the differences between the groups, chi-square tests were conducted, which will provide a comparison of responses based on variables such as job role, type of organization and years of experience. Each section of analysis corresponds directly to one of the four research objectives, which will further ensure that the results are not only data driven but also strongly aligns with the aims of the study.

4.1. Descriptive profile of respondents

A total of 107 responses were initially received, out of which 101 were found to be valid after applying inclusion exclusion criteria. These 101 responses were later analyzed for this study. The survey sample contained professionals from four key areas within the Indian pharmaceutical industry. Majority of them (88.11%) were currently working in Indian pharma industry and a small portion were working in the past (11.8%) (Figure 3). That includes, production/manufacturing, Quality Assurance (QA), Quality Control (QC), manufacturing and Regulatory Affairs (RA) (39.8, 32.03, 25.24 and 1.9 %

respectively) (Figure 4). The majority of respondents belonged to QA, QC and Production roles. This actually shows that all respondents were more likely the persons who have interactions with the quality systems especially with the RCA and CAPA processes. This actually make their responses very relevant for understanding perceptions and readiness related to AI integration in these systems.

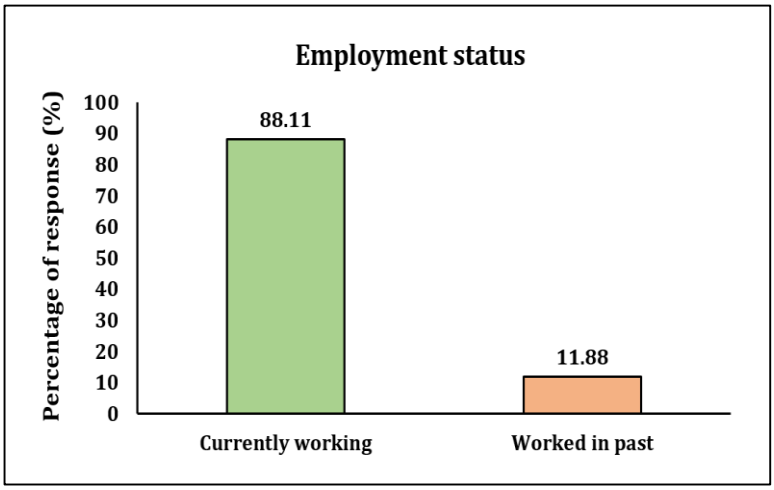

Figure 3. Employment Status of the participants. Shows the distribution of participants by current and past employment in Indian pharmaceutical industry

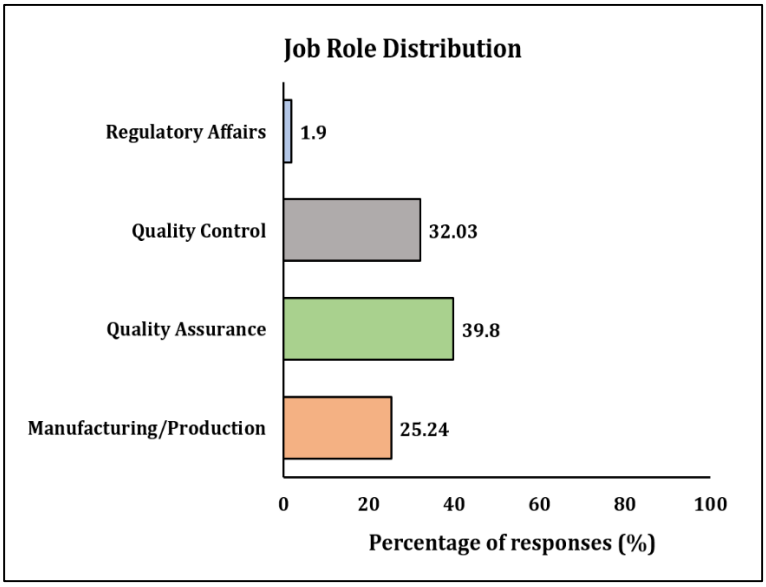

Figure 4. Job role distribution. Shows the distribution of by job role in Indian pharmaceutical industry

In terms of Industry experiences, the respondents represented a broad range of experience levels. A considerable portions had between 3 and 8 years of experience in the pharma sector. Participants included both experiences professional with over 10 years of

experience and early-career individuals with less than 3 years of experience have also offered a mix of insights to the study (Figure 5). This distribution allows for an exploration of how professional experience may influence the openness to AI adoption and perceived challenges. Regarding the type of organizations represented in the sample, participants were employed in a mix of settings including large-scale Indian pharmaceutical companies, small to medium sized companies, multinational companies and Contract Research/Development and Manufacturing Organizations (CROs/CDMOs) (Figure 6). It was observed that majority of respondents were employed across small, medium and large scale pharmaceutical companies. This organizational diversity is significant because AI adoption can vary widely depending on the company size, structure and resource availability.

Figure 5. Professional experience. Shows the distribution of respondents by years of professional experience

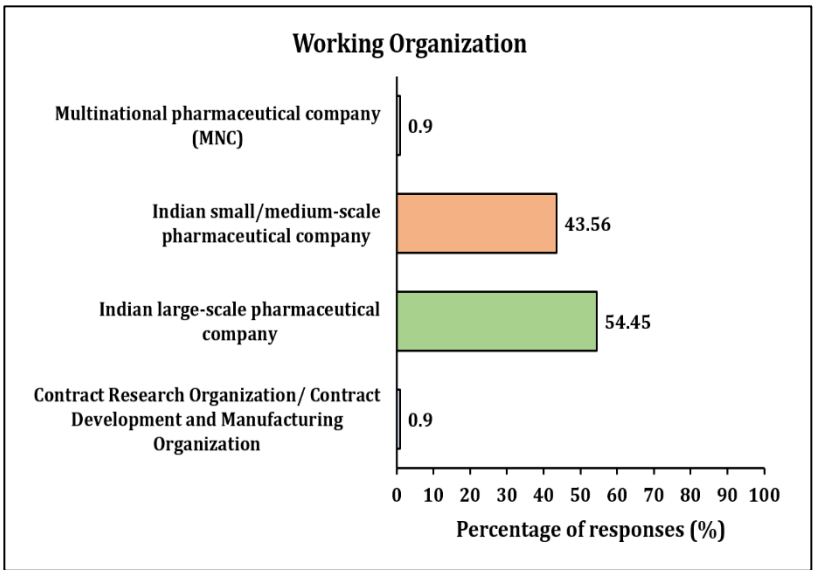

Figure 6. Working organization. Shows the distribution of respondents by type of organizations they are employed.

The analysis also looked into the current state of CAPA implementation in respondent's organizations. A substantial number or respondents have reported that they are working in organizations with fully digital (55.44%) or partially digital/manual (43.56%) CAPA systems (Figure 8). A smaller segment have shown that their organization had not yet adopted digital CAPA systems or they are unsure about the existing system. These findings clearly shows that they are on a transition to the digital quality systems from their existing scenario. Another important parameter assessed was the level of exposure to AI-based tools within quality or manufacturing functions. A large majority of respondents reported that they are aware about the AI tools, which shows the growing awareness and familiarity of respondents with emerging technologies. This scenario can be considered as an encouraging sign, because familiarity often serves as a strong precursor for the readiness. However, the extent to which organizations are prepared on a strategic implantation of AI still need to be explored more.

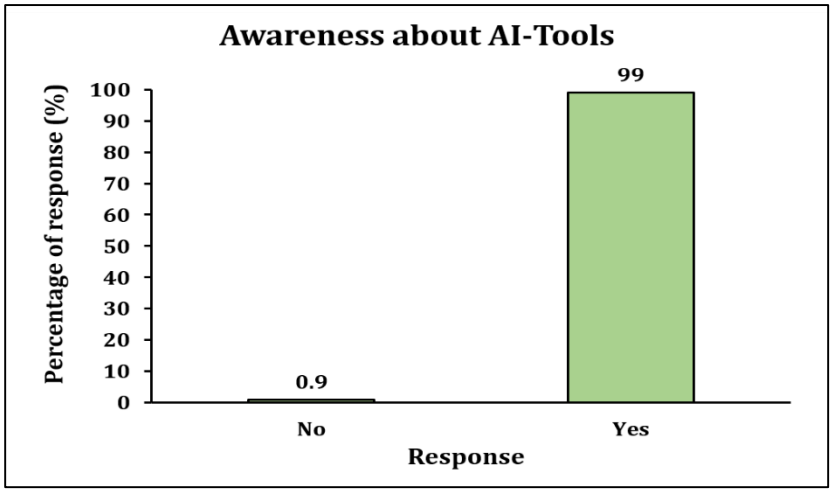

Figure 7. Awareness about AI-Tools. Shows the distribution of respondents by AI-tools awareness.

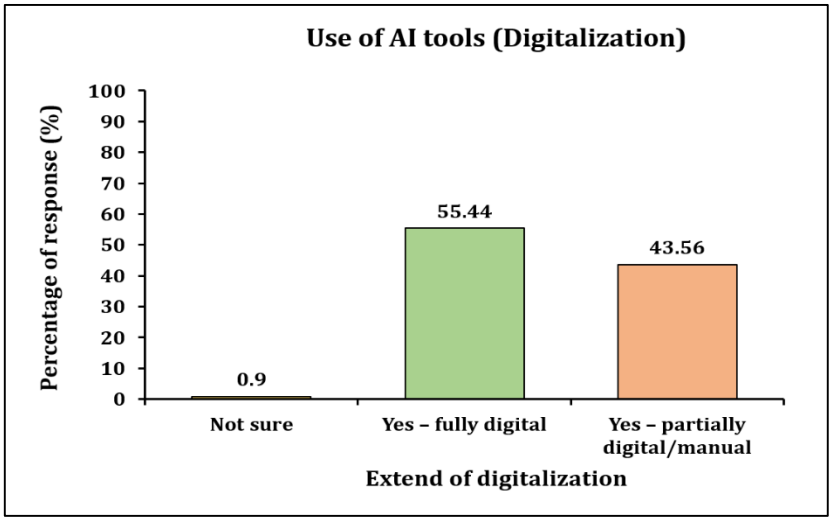

Figure 8. Extend of AI use. Shows the distribution of respondents by extent of digitalization in the industries they are employed.

4.2. Findings for objective 1: Perception of AI in RCA/CAPA

The perceptions were assessed using a set of five Likert scale statements that considering individual and organizational attitudes towards the use of AI in enhancing accuracy of RCA, decision making, prevention of recurrence, strategic values and personal support for adoption. The five Likert items assessing perception of AI in RCA/CAPA demonstrated excellent internal consistency, with a Cronbach's Alpha of 0.925, confirming that they are reliable and supporting the same underlying concept. Descriptive analysis of the responses were done and which revealed that the overall perception of AI in RCA/CAPA is positive among the participants. The average rating for the statement 1 "AI can improve the Accuracy of RCA" and "I am personally supportive of AI adoption in RCA/CAPA" were found to highest with a mean score 3.95 (on a five point scale) and 3.94 respectively (Figure 9&10). This clearly indicates a strong personal and overall willingness among professionals to support the AI-driven tools. This was followed closely with other statements such "AI can help in better decision-making during CAPA", "AI-based RCA can reduce recurring deviations" and "My organization views AI as a strategic quality enabler" with means scores 3.86, 3.81 and 3.71 respectively (Figure 10). The median and Modal score were found to be consistently 4 which showed the agreement of most participants with all the five positive statements. The variability of the response was found to be very moderate which reflect the differences in organizational context and AI exposure.

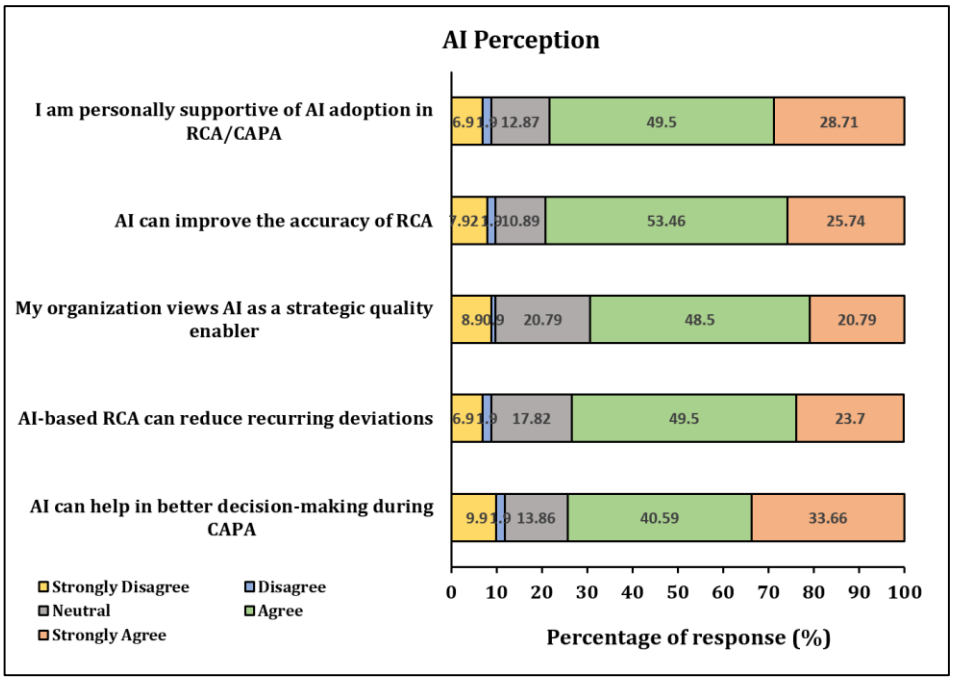

Figure 9. AI Perception. Shows the distribution of responses of respondents on AI Perception. Responses were collected by using a five point Likert scale.

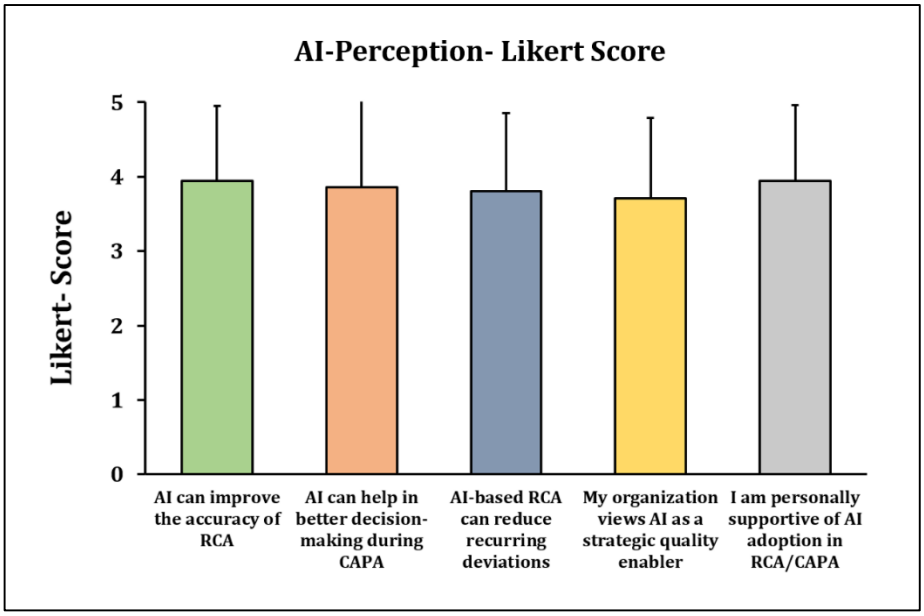

Figure 10. AI-perception-Likert score. Shows the Likert scale distribution of respondent's perceptions towards AI integration.

The result of the analysis was demonstrated with the help of a stacked bar diagram showing the percentage distribution of responses across all five perception statements. A significant proportion of participants responded "Agree" or "Strongly Agree" particularly on personal and functional benefits of AI. Notably the response distribution for organizational perception showed slightly higher number of neutral responses indicating a potential mismatch between individualistic perspective and institutional readiness. Since the Chi-square test could generate valid p-values due to small expected cell counts in certain categories, a paired t-test was conducted by pairing the statements in all possible combinations, which allowed comparison of mean differences across responses. This approach provided insights into the relative significance of individual statements, even though group-wise statistical differences could not be established. Although, a comparative review of responses provided useful insights. Professionals working in Quality Control (QC) and Quality Assurance (QA) groups have shown a stronger agreement levels with positive perception statements particularly regarding AIs ability to improve RCA accuracy and decision making (Figure 11). In contrast, respondents from production and regulatory affairs roles had a tendency to provide more neutral responses, which indicate a degree of caution or uncertainty about the benefits of AI in CAPA systems.

Similarly, professional experience appeared to play an important role in perceptions. The professionals with experience ranging from 3-8 years showed most positive perceptions, while both early career and experienced professionals were slightly more neutral in their responses (Figure 11). Variations were observed across different organization types as well. Respondents working in large scale organizations showed higher average scores, possibly giving an indication about their greater exposure to global best practices and digital transformation initiatives. In contrast, those working in small scale organizations have given more varies responses suggesting that resource availability and strategic priorities may influence organizational readiness to AI (Figure 11). Although these trends are not statistically conclusive, they provide valuable qualitative insight into how they may influence the perception of AI adoption within the industry.

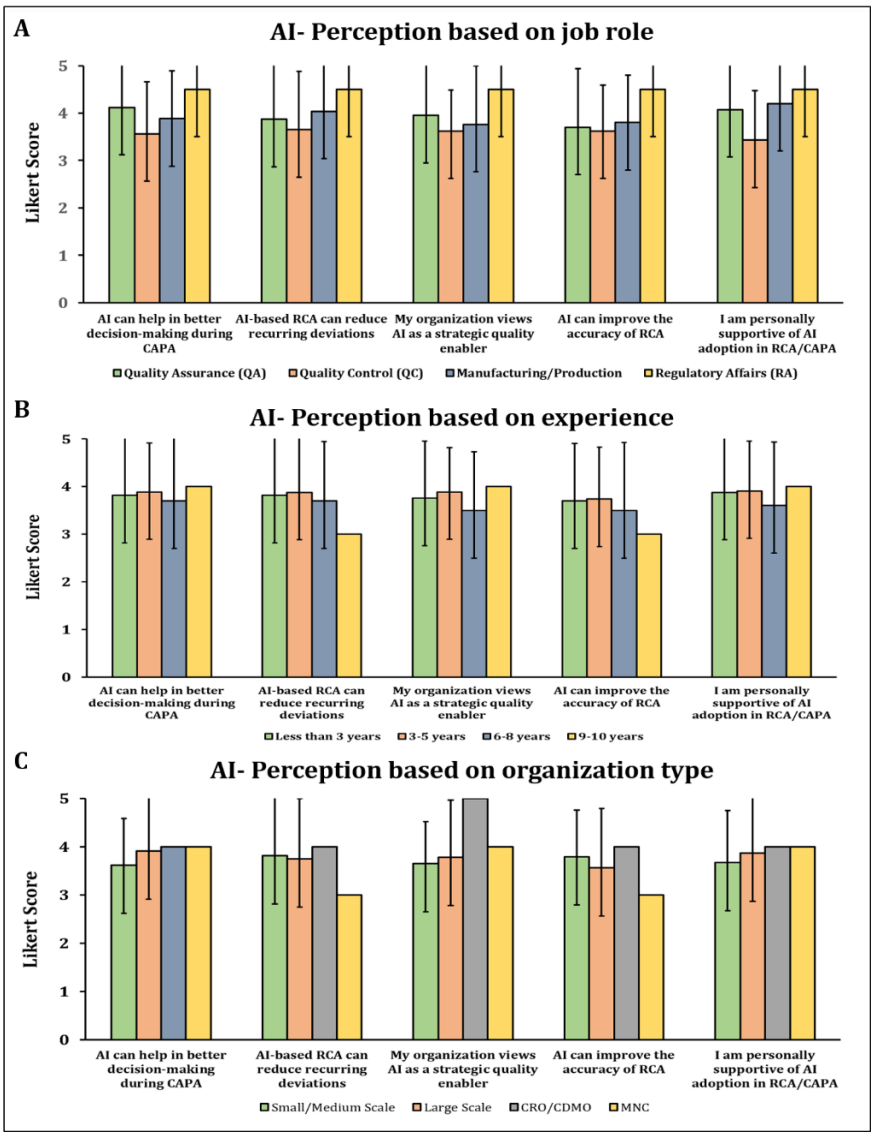

Figure 11. AI- perception- categorical comparison. Shows comparison of Likert scale scores for AI perception across respondent groups categorized by Job Role (A), Years of Professional Experience (B), and Type of Organization (C).

4.3. Findings for research objective 2: Organizational readiness

This section of findings related to the second research objective which was aiming to assess the readiness of pharmaceutical organizations in India to adopt AI based tools within RCA and CAPA processes. Organizational readiness was explored through questions related to perception regarding the preparedness, leadership support, training and awareness initiatives and the presence of required infrastructure and resources. The received responses have given a multidimensional view of the current status of digital transformation happening at quality systems across surveyed organizations.

When respondents were asked to rate their organization's overall readiness for adopting AI in RCA/CAPA systems, the majority of them responded as either "Moderately Ready" (52.47 %) or "Very Ready" (37.62%), which clearly suggests a general optimistic outlook toward AI integration (Figure 10). A smaller Proportion (6.9%) reported that their organizations are already using AI, indicating early implementation among a few digitally transformed firms. Only 3% of participants rated their organization as "Slightly Ready", while none of the respondents reported their organizations are completely unprepared, clearly indicating a basic level of awareness and openness to technological advancements in the future (Figure 12).

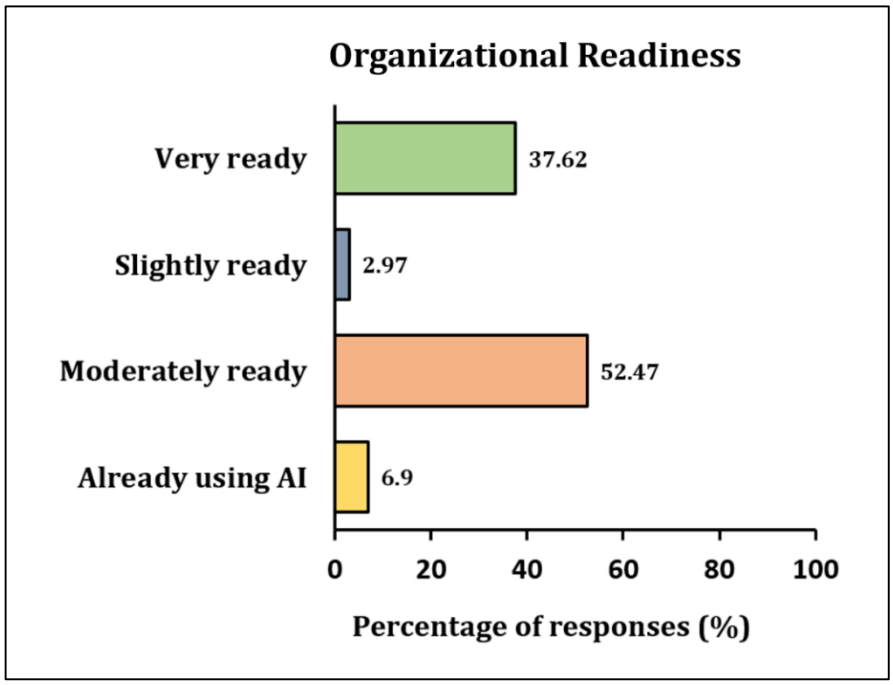

Figure 12. Organizational Readiness. Shows the distribution of respondent's ratings on perception of organizational readiness for AI adoption

When it comes to the training and awareness efforts, although organizations are appear to be making some progress, their approaches are different. Almost half of the respondents (48.5%) stated that their organizations had conducted multiple structured training programmes related to AI in quality or manufacturing (Figure 13). An additional 42.57% have reported that their organizations had offered only few informal sessions or workshops. This clearly shows that, although formal training is becoming more common, there is still a need for more organized and widespread learning (Figure 13). A smaller portion (6.93%) have reported that there are scheduled programmes for the near future and 1.9% reported the complete absence of any AI related training or awareness activities (Figure 13).

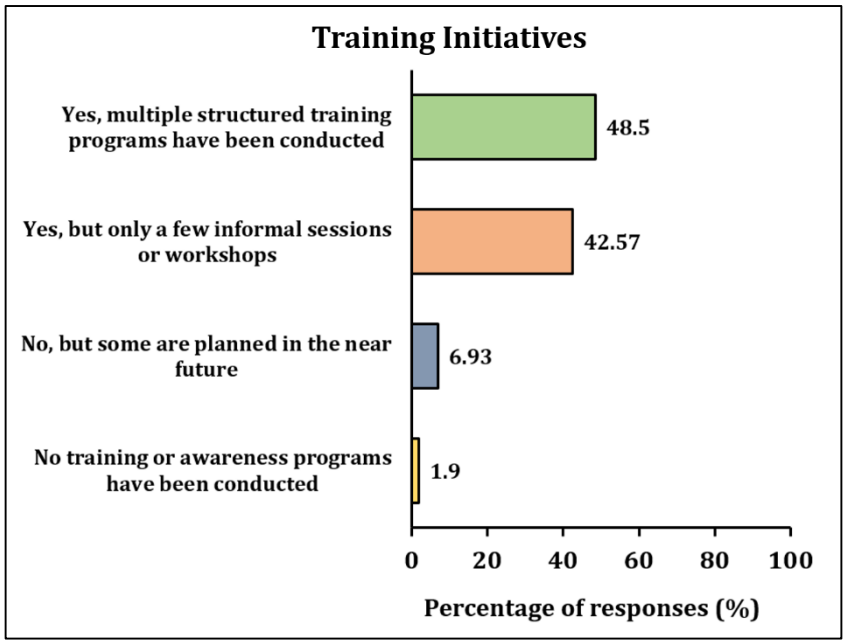

Figure 13. Training Initiatives. Shows the distribution of respondents responses on training initiatives in their organizations

Respondents were also asked to evaluate their organization's leadership attitude toward implementing AI tools. A majority (47.52%) of participants were reported their perception about their leadership as "Very supportive", with active promotion and allocation of resources towards AI initiatives (Figure 14). Another 37.62% of respondents have responded their leadership as "Supportive but cautious", which shows a positive, supportive but a careful or cautious attitude. On the other hand, 12.87% perceived their leadership as neutral and very small portion (Around 2% combined) of respondents have reported their perception about their leadership as either "Unsupportive" or "Strongly

opposed" (Figure 14). These results shows that the environment is more predominantly encouraging with varying levels of commitment and support at leadership level.

For the further evaluation of organizational readiness, participants were asked to identify the enabling factors present within their organizations. The most commonly reported enabler was "Trained Staff in AI/Data analytics" (58.41%) and which was followed closely by the enablers such as "A digital transformation or innovation team" (54.45%) and "A digital QMS or electronic CAPA system" (44.55%) (Figure 13). Other enablers included "Management support for AI" (37.62%) and "Dedicated budget for digital projects" (11.88%) (Figure 15). These findings highlight that, when some infrastructure and talented workforce are in place, there is still a lack of funding and overall planning in some other areas.

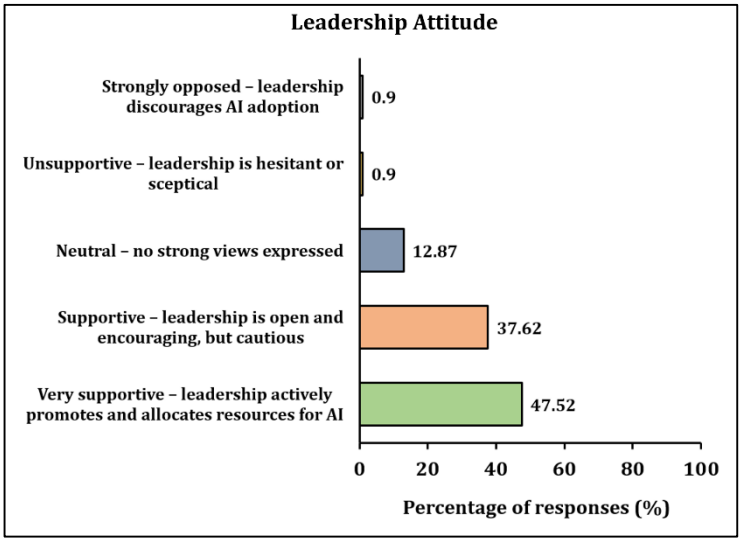

Figure 14. Leadership Attitude. Shows the distribution of respondent's responses on leadership attitude in their organization

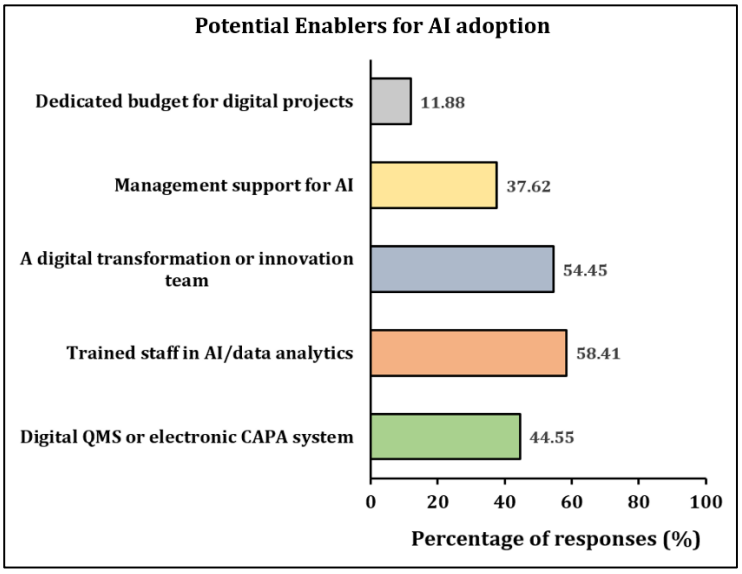

Figure 15. Potential enablers for AI adoption. Shows the distribution of respondent's responses on factors which enables the successful Ai-adoption

Although group comparisons using Chi-square tests were attempted to assess whether organizational readiness differed by type of organization, the test could not be validated due to small subgroup sizes and low expected frequencies in several categories. Therefore, no statistical significance in the differences between the groups were confirmed. However, a qualitative review of the data suggests that respondents from large scale pharma companies have reported slightly higher readiness levels and more frequent training activities compared to those from small/medium scale organizations or CROs/CDMOs. So, overall the survey results have given an indication that most pharmaceutical organizations represented in this study are at least moderately prepared for AI adoption within CAPA systems. While leadership support and training efforts and generally being positive, some of the enablers such as dedicated budgets and cross-functional coordination still appears to be limited in some organizations.

4.4. Findings for research objective 3: Implementation Challenges

This section addresses the third research objective, which is to identify and assess the major challenges faced by the Indian pharmaceutical organizations to implement AI in RCA/CAPA. So as part of this assessment, respondents were asked to rate nine potential challenges using a five-point Likert scale ranging from “Not a Challenge” to “Critical Challenge”. The responses were later analyzed for identifying the participant’s perceptions about possible and potential barriers and also for ranking them based on their severity (Figure 16).

The descriptive statistics revealed that “Lack of trained personnel” was reported as most critical challenge, with a mean score of 3.81 and a mode of 5, which actually shows that many respondents viewed this as a critical barrier for AI adoption. This was followed closely by “Lack of organizational trust” (with a mean score of 3.7) and “High cost of implementation” (with a mean score of 3.66), which were considered as major to critical issues by the majority of respondents (Figure 17). Other challenges received similar high concern ratings included “Inadequate infrastructure” (mean score 3.65), “Difficulty in GxP validation” (mean score 3.64), “Resistance to change” (mean score 3.63) and “Poor data quality” (mean score 3.63). Even “Vendor Limitations” (mean score 3.5) and “Regulatory uncertainty” (mean score 3.5) were also considered as secondary concerns in AI adoption, which is a clear indication of respondent’s recognition of these factors as moderate to major barriers (Figure 17). The Median score for each item was consistently

4 and most items has a mode of 4 or 5, which further reinforces the fact that the perceptions are the reflections of differences in company size, role specific exposure.

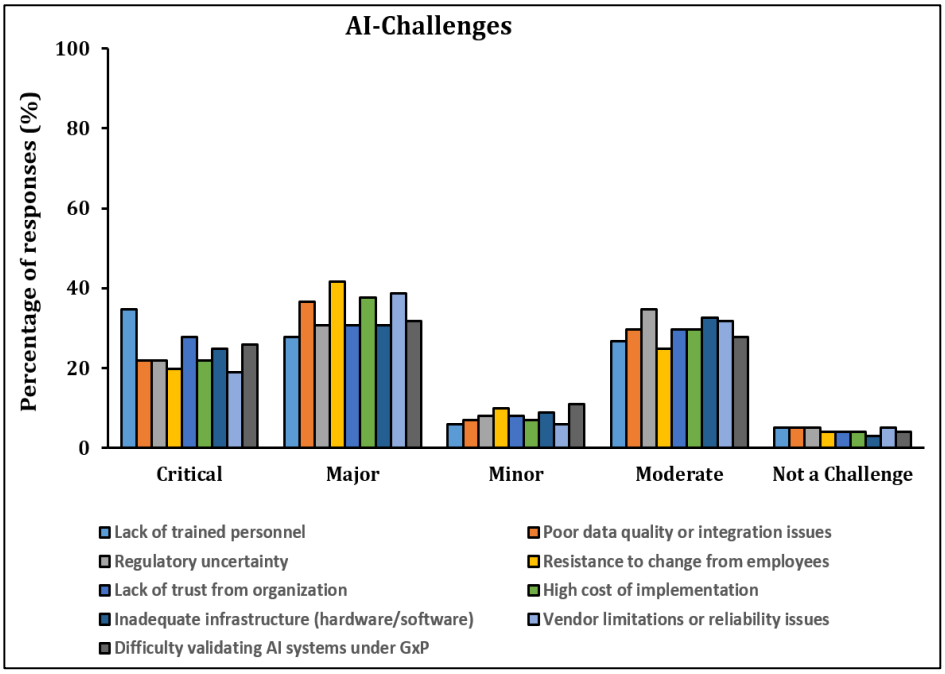

Figure 16. AI-Challenges. Shows the distribution of respondents ratings for the potential challenges or barriers for AI adoption

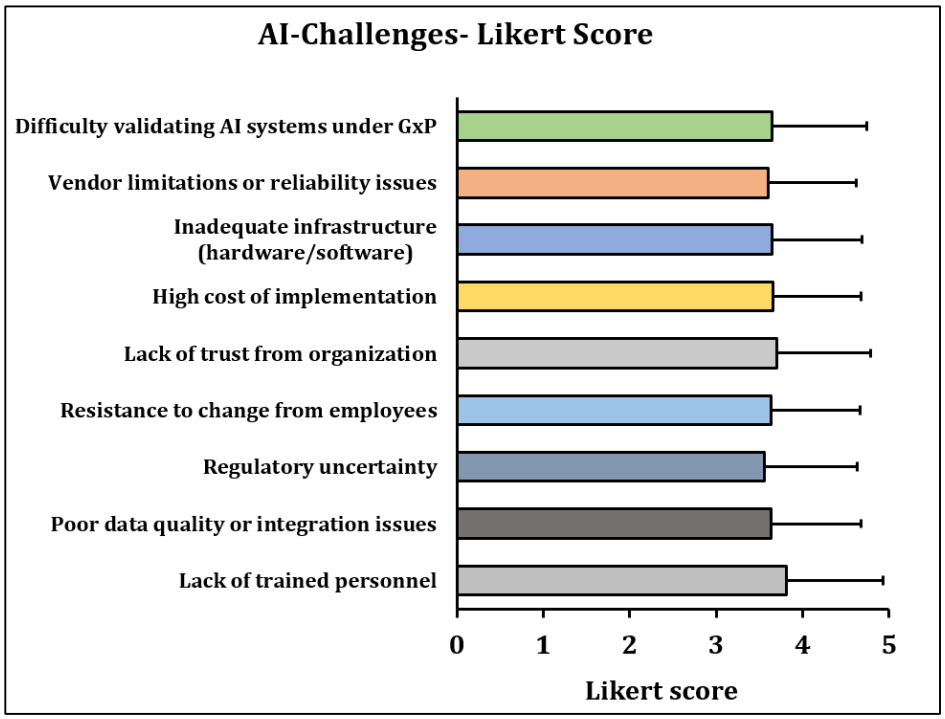

Figure 17. AI-challenges- Likert scoring. Shows the Likert score for the respondents responses for the potential challenges for AI adoption

To evaluate the reliability of challenge- related responses, Cronbach's Alpha was calculated. The value was estimated to be 0.95, indicating excellent internal consistency across the nine challenged items. A paired t-test was performed between the statements by pairing them in all possible combinations to assess the significance of difference in responses and no statistical differences were observed. A review of trends suggested that respondents from small or medium scale organizations were more likely to report higher concerns about infrastructural limitations and costs compared to large scale organizations. Similarly QA, QC professionals, who are directly engaged in CAP workflow rated the challenges such as data quality, validation difficulties and lack of AI-trained staffs as more severe, where as those work in production and regulatory affairs were responded with more neutral or moderate ratings.

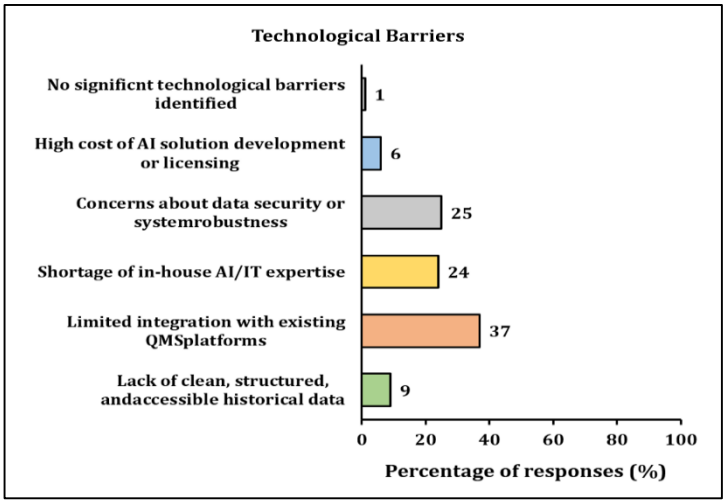

Figure 18. Technological barriers. Shows the respondents responses on the potential technological barriers for Ai adoption

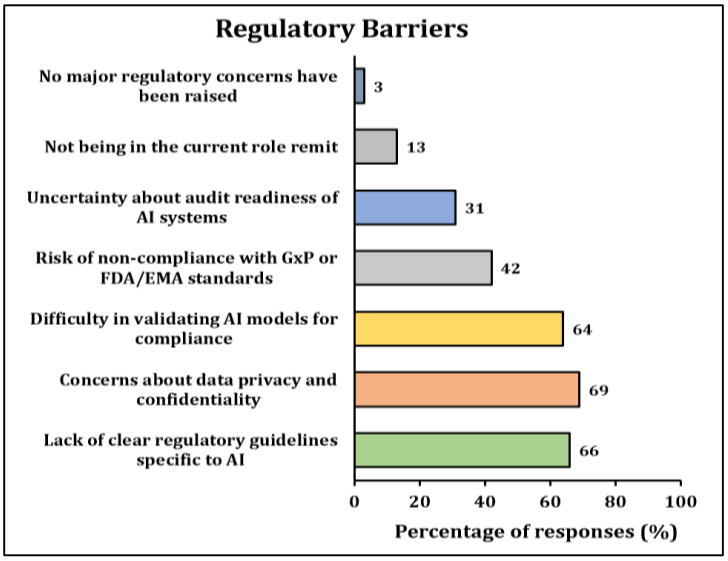

Figure 19. Regulatory barriers. Shows the respondents responses on the potential technological barriers for Ai adoption

Overall, the detailed analysis of the data have highlighted that the challenges to AI adoption in RCA and CAPA systems are not independent, rather they are part of a dependent complex mix of technical (Figure 18), regulatory (Figure 19), financial and organizational issues. More coordinated efforts are required to address these challenges which should involve leadership, IT, quality assurance, and regulatory compliance teams. The major insights from this analysis could form the basis for a better understanding about the support factors which are necessary to enable successful AI integration.

4.5. Findings for research objective 4: Recommendations and Future Outlook

This section addresses the respondent's perspectives on the necessary support mechanisms, regulatory expectations and future outlook regarding the AI adoption in CAPA systems. Participants were asked to identify the types of support they expect to become most critical for successful implementation of AI in CAPA processes. A majority of respondents have given more emphasis on the need for structured and continuous support through training and capacity building initiatives.

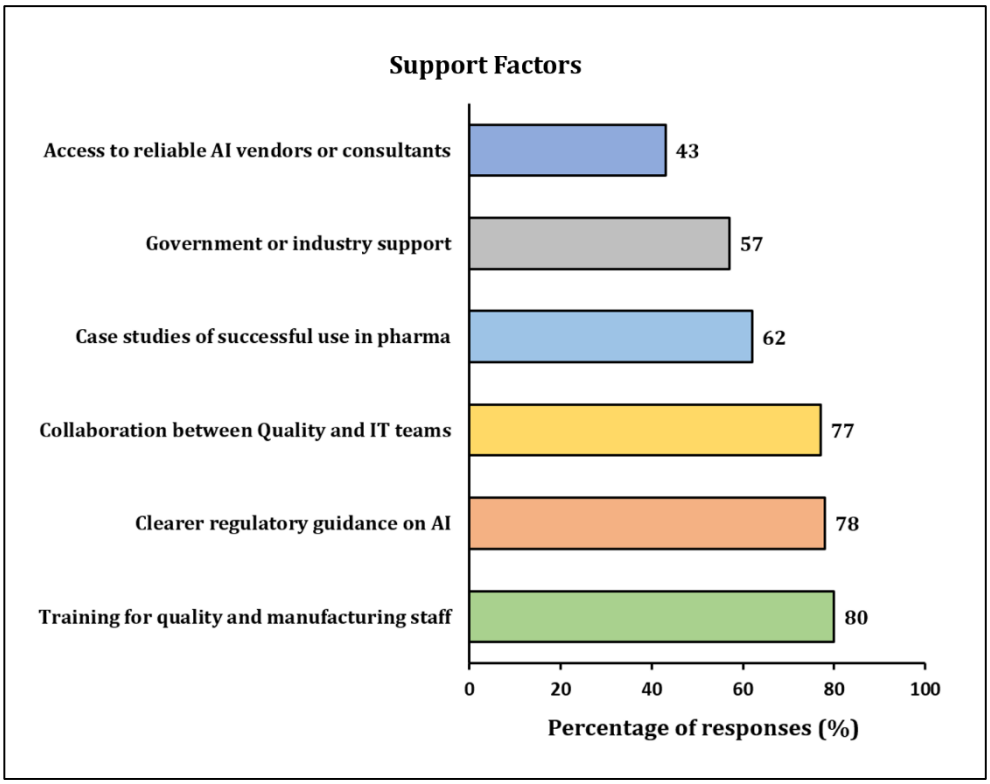

Figure 20. Support factors. Shows the distribution of participant responses towards varying potential support factors for successful implementation of AI in future

More specifically, 80% of respondents have reported that the major supportive factor for the better implementation of AI can be done mainly by providing “Better training for quality and manufacturing staff”. Not lesser, but a very close proportion of participants (78% and 77% respectively) believe that “Clear regulatory guidance on AI” and “Better collaboration between quality and IT teams” can become the contributing factors for supporting the effective and successful integration of AI for quality management systems in future. The other supportive factors include the “Case studies of successful use of AI in pharma” (62%), “Government or industry support” (57%) and “Access to reliable vendors or consultants” (43%) (Figure 20). Even though they are moderate in their percentage, these responses clearly indicates the professional’s strong belief on involvement of training, government positive interventions and reliable vendors can make a good supportive impact on the future initiatives for AI implementation in Indian pharmaceutical quality management systems.

From a regulatory perspective, a substantial majority of respondents (81%) have expressed the need for clear and dedicated regulatory guidelines on the use of AI in pharma quality systems (Figure 21). Additionally, 76% of participants have reported that providing industry level workshops and forums on AI could significantly enhance the awareness about the AI, its use and could possibly improve the chances for future adoption of AI based technologies (Figure 21). The lack of formal frameworks and validation protocols for AI-enabled decision making was considered as a critical barrier for to wider adoption. 70 % of respondents have emphasized the importance of having proper regulatory framework for validating and auditing the AI based tools and all of them should be in compliance with the standards by US FDA, EMA and CDSCO for better audit readiness and product quality. Around 20% of respondents also reported that they think, controlled environments where AI applications could be tested and validated under the observation of regulatory bodies can also have a crucial role as a supporting factor for future AI implementation (Figure 21). A major portion of respondents also believe that stronger policies can protect the very sensitive quality and manufactory data handled by AI systems and it can reduce data breaches and cyber security related issues to a greater extend. Respondents were also highlighted the need for joint forums, workshops and policy consultations to align expectations and develop governance models that reflect the operational readiness of industries.

A strong majority (99%) of respondents believed that AI will become a standard part of RCA and quality risk management practices with in next five years (Figure 22). This clearly show the strong optimism for Indian pharmaceutical professionals regarding the future possibilities for the AI implementation in quality management systems in every organizations irrespective of the type or scale of the organization. Although, respondents are also skeptical about the same by pointing to many possible challenges and barriers against that long term goal.

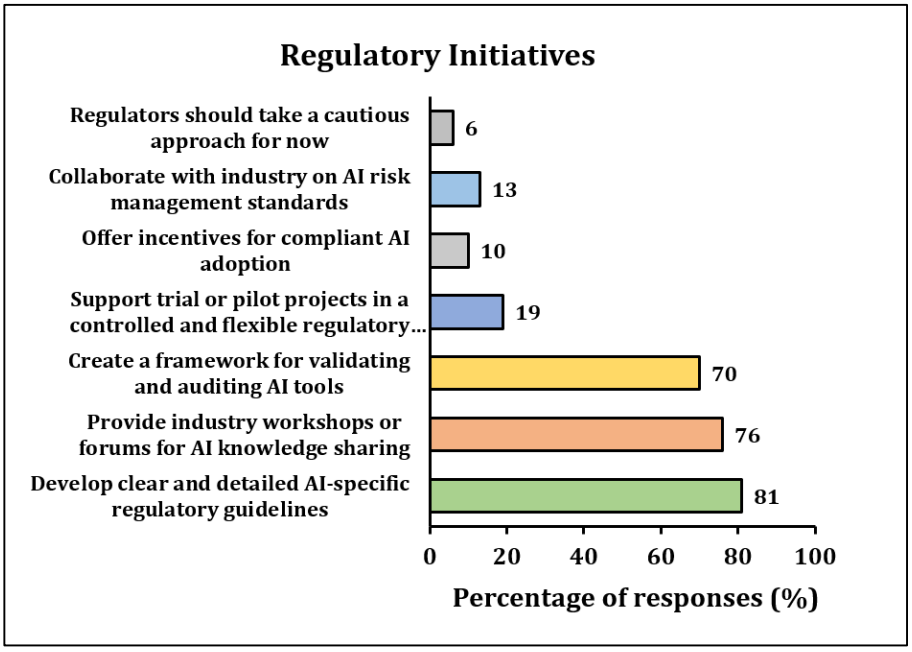

Figure 21. Regulatory Initiatives for future AI-adoption. Shows the participant's response on regulatory initiatives required for successful adoption of AI in RCA within CAPA processes

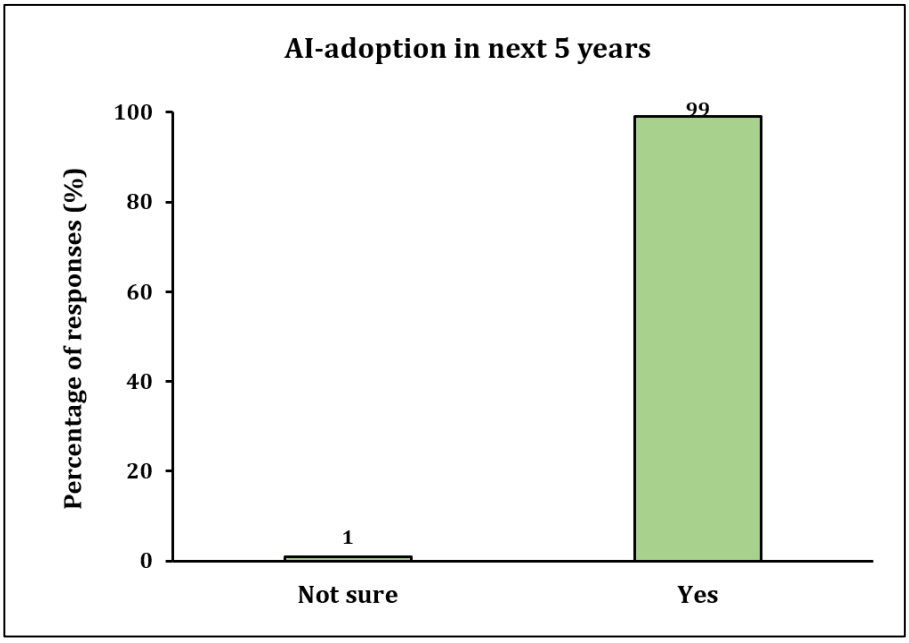

Figure 22. AI-adoption in next 5 years. Shows the distribution of participant's responses over AI-adoption possibilities in next 5 years

Despite the differences on views regarding the pace and extend of AI adoption, a common agreement was emerged that AI holds transformative potential for enhancing objectivity, speed and consistency in RCA and CAPA management. The finding s of this study suggest that with the right blend of training, technological readiness, regulatory clarity and strategic vision, AI can significantly improve the effectiveness of pharmaceutical quality systems in India.

In this study, a paired t-test was used instead of Chi-square test because the data consisted of Likert scale responses collected from same participants. The paired t-test is suitable when comparing mean differences between two related sets of continuous data. Making it appropriate for this analysis. The objective was to evaluate the changes in participant's perceptions and readiness within the same group, where the paired t-test provided a more accurate and reliable approach. Future studies should also consider increasing the sample size and refining the survey items to improve sensitivity, thereby enhancing statistical power and achieving more generalizable findings that support the study's objectives in a better way.

The overall findings from this study provide meaningful insight into the evolving process on AI adoption in RCA and CAPA systems with in the Indian pharmaceutical industry. The results reveal a high degree of personal openness to AI and an encouraging level of organizational readiness in certain contexts. But it also highlight a persistent gap between individual support and institutional commitment. This difference is consistent with previous research findings indicating that while employee enthusiasm can be a catalyst for change, the pace and scope of adoption ultimately depend on leadership vision, resource allocation and regulatory clarity (Miozza, 2024; Hassan *et al.*, 2024). The identification of core challenges such as skill shortages, infrastructure limitations, cost constraints and trust barriers reflects the obstacles reported in global pharmaceutical and life science transformation studies (Rakočević and Markovic, 2024; Khanfar *et al.*, 2025).

Importantly, the study's findings highlight the interdependence of perception, readiness and enabling conditions. Although, high awareness of AI tools and the occurrence of partially or fully digital CAPA systems provide a technical foundation for integration, identified recommendations such as targeted training, regulatory guidance and pilot projects offer more opportunities when moving forward. The outcomes suggests that the Indian pharmaceutical sector is not starting from zero, instead they are positioned in a

transitional phase where both cultural and infrastructural developments are very much needed for converting readiness into full implementation.

By connecting these findings to existing literature, it becomes clearer that the Indian pharmaceutical Industry's paths aligns with global digital transformation trends. But it does have its own uniqueness in regional dynamics characterized by resource distribution, regulatory frameworks and organizational diversity (Radhika, 2025; EY, 2025). The outcomes of this study thus have both academic and practical relevance. Academically, they extend understanding of AI adoption in a critical but underexplored context and practically, they provide industry stakeholders with a strong evidence base for designing targeted strategies for addressing both technical and humane factors in AI-enables quality management.

CHAPTER 5

CONCLUSIONS & RECOMMENDATIONS

5.1. Conclusions

The main objective of the present study was to investigate the perception, readiness and implementation challenges associated with integrating AI into RCA within CAPA systems in the Indian pharmaceutical industry. The analysis of 101 survey responses from professionals working mainly in QA, QC, manufacturing and Regulatory affairs provides an important picture of how Indian companies view AI adoption in quality systems. The finding have revealed that when there is strong level of awareness and enthusiasm among working individuals, particularly QA and QC staff who are directly engaging with CAPA workflows, organizational strategies and resources are yet to fully align with this enthusiasm. Production and regulatory professionals tended to adopt a more neutral stand, which actually shows that they are relatively far distant form CAPA workflows in terms of their professional engagement. This difference is very significant as it is explaining their attitude towards AI in quality systems are strongly influenced by the nature of professional roles. This is a point which is less visible in the existing literature on organizational perceptions (Shinners *et al.*, 2020; Kim *et al.*, 2023; Yu *et al.*, 2025).

At the organizational level, readiness was generally assess as moderate to high, with larger firms more likely to report advanced infrastructure, leadership support and structured training programmes. In contrast, smaller firms showed more limited investment and resource availability which aligns with the existing literature describing uneven readiness patterns between large and small or medium scale organizations (Ayinaddis, 2025; Zavodna, 2025). This actually gives a same reflection of studies on AI readiness in other regulated sectors such as healthcare and finance, where resource constraints and lack of proper governance hinders the adoption (Kim *et al.*, 2023; Aldemir and Uçma Uysal, 2025; Alnajjar *et al.*, 2025). The identification of enabling factors such as digital quality management system, trained personnel, and innovation teams aligns closely with international standards especially with the peoples have experiences in United states and Europe where digital infrastructure has been shown to accelerate technology adoption (Radziwill, 2018; Ibrahim, 2019; Brandenburger *et al.*, 2021). However, some of the barriers such as lack of skilled staff, lack of organizational trust, cost concerns and challenges in validating AI tools under GxP standards shows that Indian

firms face the similar hurdles as their global counterparts (Mohanty, 2024; Coyle, 2025; Chettri, 2025). Issues related to regulatory uncertainty and data quality concerns are not only unique to India, but comparable concerns have been reported in Europe also. In Europe, this was observed in surveys on the implications of the new AI act for pharmaceutical and medical device industries and in United States which was observed with the FDA's evolving AI/ML based software for medical device framework (Zhou and Gattinger, 2024; Granlund *et al.*, 2024; Sillberg *et al.*, 2025; Spagnolli *et al.*, 2025; Das *et al.*, 2025).

The comparison between primary and secondary research reveals both convergence and divergence. Similar to global studies, this research also highlight the optimism around AI adoption is negatively affected by the regulatory and infrastructural challenges. However, unlike much of the existing literature that focuses primarily on AI in drug discovery, clinical trials or Pharmacovigilance, this study is novel in focusing on RCA with in CAPA systems, which is area considered a s very critical for compliance and product quality. This research work have contributed some empirical evidence from India, to the growing but still limited literature on AI in pharmaceutical quality management. Moreover, by showing the differences between functional roles such as QA, QC and production, this study provides new insights into how attitudes and readiness vary within organizations. This role based analysis has not been widely documented in existing research and which can be effectively utilized for tailored training and change management strategies.

The result have also got some broader impact for the future direction of the pharmaceutical industry. Existing global literature suggests that AI will be strongly integrated to the pharmaceutical value chain, especially in the areas such as R&D, manufacturing and regulatory compliance (Han and Tao, 2024; Chen *et al.*, 2024). This study shows that Indian professionals are confident that AI will become a regular part of RCA and CAPA within five years, indicating that India is ready to follow the global trends. However, the progress will depend on the ability of companies and regulators to bridge the current gaps in skills, infrastructure, governance and trust. By overcoming these barriers, companies can use AI in CAPA systems to reduce the errors, improve compliance, boost efficiency and for gaining a good position in local and global markets. For regulators, these findings highlight the urgency of providing clear guidelines and validation frameworks as regulatory uncertainty remains as a major problem for AI adoption.

5.2. Recommendations

Based on the study findings and their comparison with the existing literature, several recommendations can be made for industry, regulators and researchers. For industry, companies should begin with carefully designed pilot projects that allow them to test AI tools in RCA on a limited scale before moving to broader implementation. Such pilot projects are not only going to reduce the risks, but also build organizational confidence and help to generate sufficient data to justify their investments. Training programmes should be customized to roles, with QA and QC staff receiving more advanced AI-focused training considering their direct involvement with CAPA workflows, while production and regulatory staff should be receiving proper AI awareness sessions that address the trust and resistance issues. The AI integration should also be a part of broader change management programmes that emphasize transparency, communication and staff involvement. This is supported by case studies from AstraZeneca and other multinational firms where AI governance frameworks include decentralized standards, employee education and strong alignment with organizational ethics. More importantly, companies should also invest in strengthening their infrastructure, ensuring that CAPA data are clean, accessible and suitable for AI-driven analysis. Conducting a cost-benefit analyses should help companies to secure their budgets and to demonstrate long term return on investment.

From a regulatory perspective, India can take valuable lessons from international frameworks such as the EU AI Act and the FDA's AI/ML Action Plan (Singh, 2024; EU, 2024). Both emphasize the importance of validation, transparency, continuous monitoring and the principles that can be adapted for AI applications in pharmaceutical quality systems. Indian regulators such as the CDSCO should develop specific guidance for AI use in RCA and CAPA, including requirements for model validation, data governance and audit trails. Establishing a friendly regulatory environments where companies can test AI solutions under regulatory supervision would encourage innovation while maintaining oversight, which is almost same as digital health sandboxes being checked in EU and US. Regulators should also facilitate knowledge sharing through workshops and collaborative platforms where companies can present their data for pilot projects, discuss challenges and develop best practices. By providing clarity and boosting the collaboration, regulatory bodies can reduce organizational hesitations and accelerate safe adoption.

For academic and research community, this study highlights several areas for the future exploration. Mixed method approaches that combine surveys with interviews can offer a deeper understanding of technical, cultural and governance challenges. Interviews should target specific roles and seniority levels (includes QA managers, QC supervisors, production heads, regulatory affairs heads etc.) to capture insights into decision making, leadership attitudes and workforce concerns. Longitudinal studies would allow researchers to track changes in perception and readiness over time, especially as regulatory frameworks evolve. Comparative studies between Indian firms and those in other regulated industries such as medical devices, or between India and other countries with more mature regulatory frameworks could identify unique barriers and enablers. Another important initiative could be the development of validated readiness assessment models specifically customized to AI adoption in pharmaceutical quality systems. Such models could provide practical tools for companies to assess their preparedness and prioritize interventions. Future research should also explore the long term impacts of AI adoption on quality outcomes such as reduction in deviations and recalls, improved compliance and overall patient safety profiles.

If this research study were to be repeated, several changes would be made to strengthen its design. Increasing the sample size to include a broader range of organizations, from small to large scale, would improve generalizability. By including qualitative methods such as interviews or focus groups, study could provide deeper insights into organizational culture, leadership and decision making. A longitudinal design would capture changes in readiness and adoption overtime, providing a more dynamic picture of industry progress. Further, integrating data from real world AI pilot projects would allow the assessment of performance outcomes such as reduction in repeated deviations or faster closure of CAPA investigations. These modifications would not only enhance the robustness of findings but also align the future research more closely with industry needs.

In conclusion, this study offers both theoretical and practical insights. This study adds to the limited research on AI use in pharmaceutical quality systems, especially in India, by focusing on RCA within CAPA. It shows that, while optimism and awareness are high among individuals, organizational readiness and implementations challenges are become crucial deciding factors for the AI adoption. This study provides actionable recommendations for industry, regulators and researchers supported by both primary data

and international comparisons. For industry the major recommendations include, pilot projects, role specific training, investments in infrastructure and incorporating AI to change management. For regulators, major suggestions include the development of clear guidelines and encouragement for collaborative regulatory environments for building trust and clarity. For researchers, the major challenge lies in developing robust, longitudinal and comparative study design that capture the data from complex interactions between technology, people and regulations. Ultimately, successful integration of AI in CAPA systems has the potential to transform pharmaceutical quality management, reducing the risks due to deviations, improving the efficiency of the system and strengthening patient safety. So, by addressing these major barriers identified, and implementing the recommendations suggested, Indian pharma industry can come to a forefront position in the case of AI-driven operational excellence.

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Appendix 1: Survey Questionnaire

Introduction

You are invited to participate in an academic research survey titled: **"Exploring Perception, Readiness, and Implementation Challenges of Artificial Intelligence in CAPA Systems: A Survey-Based Study in the Indian Pharmaceutical Industry."**

I am Vinod Paul, a postgraduate student pursuing an MSc in Pharmaceutical Business and Technology at Griffith College Dublin. As part of my academic dissertation, I am conducting a research study on the use of Artificial Intelligence (AI) in Root Cause Analysis (RCA) within Corrective and Preventive Action (CAPA) systems in the Indian pharmaceutical industry. The purpose is to explore professionals' perceptions, assess organizational readiness, and identify key challenges in implementing AI within Quality Management Systems (QMS). AI is increasingly being used to improve accuracy and efficiency in RCA, a critical step in CAPA processes aimed at preventing quality issues. With the industry evolving toward digital transformation, your insights will help understand the practical aspects of AI adoption.

Estimated time to complete the survey: approximately 15- 20 minutes.
Participation is voluntary, and all responses will be kept confidential and used solely for academic purposes.

If you have any questions or require clarification before or during the survey, please feel free to contact:

Researcher: Vinod Paul, vinod.paul@student.griffith.ie

Supervisor: Megan Kelly megan.kelly@grifith.ie

Section 1: Consent question

Q1. Do you voluntarily agree to participate in this academic research survey?
(Please select one)

- Yes, I agree to participate
- No, I do not agree

(*If "No," please do not proceed further. Thank you for your time.)*

Section 2: About participant and organization

Q2. Are you currently working or have you previously worked in the Indian pharmaceutical industry?
(*Please select one*)

- Yes, I am currently working in an Indian pharmaceutical company
- Yes, I have worked in an Indian pharmaceutical company in the past
- No, I have never worked in an Indian pharmaceutical company

Q3. What is your current role/function?
(Select one)

- Quality Assurance (QA)
- Quality Control (QC)
- Regulatory affairs
- Manufacturing/ Production
- Operational excellence/ Lean Six Sigma
- IT/Digital Transformation
- Validation
- Other: Please specify…...

Q4. How many years of experience do you have in the pharmaceutical industry?

(Select one)

- Less than 3 years
- 3–5 years
- 6-8 years
- 8-10 years
- More than 10 years

Q5. What type of organization do you currently work in?

(Select one)

- Indian large-scale pharmaceutical company
- Indian small/medium-scale pharmaceutical company
- Multinational pharmaceutical company (MNC)
- Contract Research Organization/ Contract Development and Manufacturing Organization
- Other: Please specify……...

Q6. Does your organization currently use a CAPA system?

(Select one)

- Yes – fully digital
- Yes – partially digital/manual
- No
- Not sure

Q7. Have you heard of or used AI-based tools in quality or manufacturing functions?

(Select one)

- Yes
- No

Section 3: Your views on use of AI in RCA/CAPA

Q8. Please indicate your level of agreement with the following statements:
(Tick one option per statement)

Statement	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
a. AI can improve the accuracy of RCA.	--	--	--	--	--
b. AI can help in better decision-making during CAPA.	--	--	--	--	--
c. AI-based RCA can reduce recurring deviations.	--	--	--	--	--
d. My organization views AI as a strategic quality enabler.	--	--	--	--	--
e. I am personally supportive of AI adoption in RCA/CAPA.	--	--	--	--	--

Section 4: Readiness of your organization

Q9. How would you rate your organization's current readiness to adopt AI in RCA/CAPA?

(Select one)

- Not ready at all
- Slightly ready
- Moderately ready
- Very ready
- Already using AI

Q10. Has your organization conducted any training or awareness programs related to AI in quality or manufacturing?

(Please select one option)

- Yes, multiple structured training programs have been conducted
- Yes, but only a few informal sessions or workshops
- No, but some are planned in the near future
- No training or awareness programs have been conducted
- I am not aware of any training initiatives

Q11. How would you describe leadership’s attitude toward implementing AI-driven solutions in your department?

(Please select one option)

- Very supportive – leadership actively promotes and allocates resources for AI
- Supportive – leadership is open and encouraging, but cautious
- Neutral – no strong views expressed

- Unsupportive – leadership is hesitant or sceptical
- Strongly opposed – leadership discourages AI adoption
- Not sure / No opinion

Q12. Which of the following enablers are present in your organization?
(*Select all that apply*)

- Digital QMS or electronic CAPA system
- Trained staff in AI/data analytics
- A digital transformation or innovation team
- Management support for AI
- Dedicated budget for digital projects
- None of the above

Q13. What are the top three factors influencing your organization's readiness for AI adoption?
(*Select up to three options*)

- Leadership and management vision
- Employee awareness and training
- Quality and availability of data
- Regulatory clarity
- Cost and ROI concerns
- Reliable vendors or AI tools
- Innovation culture
- Other (please specify): ……

Section 5: Challenges in AI implementation

Q14. Please rate the level of challenge posed by the following factors in implementing AI in RCA/CAPA systems:
(*Tick one option per statement*)

Challenge	Not a Challenge	Minor	Moderate	Major	Critical
a. Lack of trained personnel	--	--	--	--	--
b. Poor data quality or integration issues	--	--	--	--	--
c. Regulatory uncertainty	--	--	--	--	--
d. Resistance to change from employees	--	--	--	--	--
e. Lack of trust from organization	--	--	--	--	--
f. High cost of implementation	--	--	--	--	--

g. Inadequate infrastructure (hardware/software)	--	--	--	--	--
h. Vendor limitations or reliability issues	--	--	--	--	--
i. Difficulty validating AI systems under GxP	--	--	--	--	--

Q15. ***Which of the following regulatory concerns does your organization face when considering AI in quality systems?***

(Select all that applicable)

- Lack of clear regulatory guidelines specific to AI
- Concerns about data privacy and confidentiality
- Difficulty in validating AI models for compliance
- Risk of non-compliance with GxP or FDA/EMA standards
- Uncertainty about audit readiness of AI systems
- Not being in the current role remit
- No major regulatory concerns have been raised
- Not sure / Not applicable

Q16. ***What is the most significant technological barrier to implementing AI in RCA/CAPA systems in your organization?***
(Please select one)

- Lack of clean, structured, and accessible historical data
- Limited integration with existing QMS platforms
- Shortage of in-house AI/IT expertise
- Concerns about data security or system robustness
- High cost of AI solution development or licensing
- No significant technological barriers identified
- Not sure / Not applicable

Section 6: Recommendations

Q17. Which of the following would help support successful AI implementation in RCA/CAPA systems in your company?
(*Select all that apply*)

- Training for quality and manufacturing staff
- Clearer regulatory guidance on AI
- Collaboration between Quality and IT teams
- Case studies of successful use in pharma
- Government or industry support
- Access to reliable AI vendors or consultants
- Other (please specify): ……

Q18. ***What do you think regulators should do to promote responsible AI adoption in pharmaceutical quality systems?***

(Select all that apply)

- Develop clear and detailed AI-specific regulatory guidelines
- Provide industry workshops or forums for AI knowledge sharing
- Create a framework for validating and auditing AI tools
- Support trial or pilot projects in a controlled and flexible regulatory environment
- Offer incentives for compliant AI adoption
- Collaborate with industry on AI risk management standards
- Regulators should take a cautious approach for now
- No opinion / Not sure

Q19. Do you believe AI will become a common part of RCA and CAPA systems in the next five years?

- Yes
- No
- Not sure

Q20. Do you have any additional comments or suggestions on the use of AI in RCA or CAPA systems?
(*Open-ended response*)

……
……
……
……
……

Appendix 2: Participant Information Leaflet (PIL)

PARTICIPANT INFORMATION LETTER (PIL)

TITLE OF THE STUDY:

"Integrating Artificial Intelligence into Root Cause Analysis for CAPA systems: A survey based study on perception, readiness and implementation challenges in the Indian Pharmaceutical industry"

I would like to invite you to take part in this research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Ask questions if anything you read is not clear or if you would like more information. Take time to decide whether or not to take part.

WHO I AM AND WHAT THIS STUDY IS ABOUT

My name is Vinod Paul, and I am currently a postgraduate student enrolled in the MSc in Pharmaceutical Business and Technology programme at Griffith College. I am conducting this research study as part of the academic requirements for completing my dissertation. This investigation is mainly for exploring the perception, readiness and implementation challenges associated with the use of Artificial Intelligence (AI) in Corrective and Preventive Action (CAPA) systems within the Indian pharmaceutical industry. This research aims to gather positive insights from industry professionals on their experiences and views related to AI adoption in Root Cause Analysis (RCA) processes, with the goal of identifying potential barriers and opportunities for improvement. The findings will contribute to a better understanding of how digital technologies can be integrated into quality management systems. This study is being undertaken solely for academic purposes and will lead to the awarding of a Master's degree upon successful completion.

WHAT WOULD TAKING PART INVOLVE?

If you agree to take part in this study, you will be asked to complete an online survey. The survey will ask about your views, experience and readiness related to using AI in RCA process of CAPA systems within the pharmaceutical industry. Your participation is

completely voluntary and you can choose to stop at any time without giving a reason. The survey does not ask for your name or any personal information, so your responses will stay anonymous. There are no expected risks or direct benefits to you for taking part, but your input will help providing useful insights for improving quality systems in the pharmaceutical field. The study does not affect your work, personal life or relationships in any way.

WHY HAVE YOU BEEN INVITED TO TAKE PART?

You have been invited to take part in this study because you are a professional working in the pharmaceutical industry and may have experience with quality management systems, especially CAPA processes. Your knowledge and experience can help us understand how people in the industry view the use of AI in these systems. You were identified through professional networks, industry groups or referrals from other participants who felt you might have some valuable insights to share.

DO YOU HAVE TO TAKE PART?

Taking part in this study is completely voluntary. You do not have to take part if you don't want to and saying 'no' will not cause any problems or affect you any way. If you decide to take part, you can also skip any question you do not want to answer. You can change your mind and withdraw from the study at any time without giving any reason and there will be no consequences for doing so. If you wish to withdraw after taking part, please contact Vinod Paul at vinod.paul@student.griffith.ie or my thesis supervisor Megan Kelly at megan.kelly@griffith.ie.

WHAT ARE THE POSSIBLE RISKS AND BENEFITS OF TAKING PART?

Taking part in this study may not benefit you directly, but your valuable inputs could help researchers and professionals to have a better understanding about how AI can be effectively used to improve RCA process and thereby CAPA systems in the pharmaceutical industry. Your contribution may help on bringing positive changes on the management of quality issues in the future. There are no major risks expected from taking part in this study. The survey is totally anonymous and your identity will not be collected, which helps to protect your privacy. There is a small possibility that thinking about workplace practices might cause minor discomfort, but you absolutely free to skip any question you do not wish to answer. If you feel uncomfortable at any point, you can stop and withdraw from the survey at any time without any consequence.

WILL TAKING PART BE CONFIDENTIAL?

Yes, your participation will be kept confidential. The survey is anonymous and no names or identification details will be collected. Your responses will be grouped with others and not linked to you personally. No confidential company data will be used without written permission and if such data is included, authorization will be obtained in advance. All data will stored securely on a password-protected computer and uploaded to college's Moodle system as part of this thesis. Confidentiality may only broke if there is a serious risk of harm to you or someone else. If such situation arises, appropriate measures will

be taken in line with legal and ethical responsibilities. Otherwise, all information will be handled with care and also in full compliance with GDPR, DPDPA and all other national data protection laws.

HOW WILL INFORMATION YOU PROVIDE BE STORED AND PROTECTED?

All information you provide will be sorted securely on a password-protected computer. The data will be back up on an external hard drive as well. Only the researcher and academic supervisor will have access to the data. Anonymised survey responses will also be uploaded to the college's secure Moodle system as part of final submission. No personally identifiable information will be collected. In line with the college policy, all data will then retained for a minimum of two years after the study is completed and will then be securely deleted. All data handling will follow GDPR, DPDPA and all other national data protection guidelines.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

The results of this study will be used exclusively for the completion of my MSc dissertation at Griffith College. The final dissertation report will be submitted to the college and may be made accessible in the college library or through an online academic repository. There are currently no plans for publication, conference presentation, teaching use beyond this academic requirement. All findings will be presented in a way that protects participant anonymity and confidentiality.

WHO SHOULD YOU CONTACT FOR FURTHER INFORMATION?

Vinod Paul
Student ID: 3148379
MSc. Pharmaceutical Business and Technology
Griffith College, Innopharma Education
Email: vinod.paul@student.griffith.ie
Phone: +353 892453421

[THANK YOU]

Appendix 3: Ethics Application & Declaration Form

Innopharma education

GRIFFITH COLLEGE

Ethics Application & Declaration Form

DISSERTATION TITLE:
”Integrating Artificial Intelligence into Root Cause Analysis for CAPA systems: A survey based study on perception, readiness and implementation challenges in the Indian Pharmaceutical industry”

RESEARCHER’S NAME: Vinod Paul

PROGRAMME OF STUDY: MSc. Pharmaceutical Business and Technology

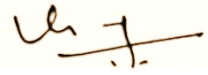
SUPERVISOR'S NAME: Megan Kelly

DECLARATION:

The information in this application form is accurate to the best of my knowledge. I undertake to abide by the principles outlined by Innopharma/Griffith College ethics policy in my research dissertation. I confirm that I have completed a full ethics assessment for my research dissertation as per the college guidelines. I will not begin my primary research until such approval from my supervisor and/or ethics Committee has been obtained.

I pledge to carry out my research according to the Innopharma/Griffith College academic integrity standards. Any results presented in my dissertation will be from my own, original research, I will reference and/or acknowledge any material or sources used in its preparation and I will not plagiarise the work of anyone else.

For Student:

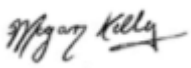
STUDENT SIGNATURE: 

DATE: 28-06-2025

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

For Supervisor:

Ethics Committee Approval Required: Yes ☐ No ☐

SUPERVISOR SIGNATURE: 

DATE: 01.07.25

For Ethics Committee (if required):
Ethics Committee Approval Given: Yes ☐ No ☐

ETHICS COMMITTEE MEMBER SIGNATURE:

DATE:

NOTE: Supervisors are responsible for ensuring their students fill in this form correctly and that all ethical areas have been considered.

SECTION 1: DESCRIPTION OF RESEARCH STUDY

1.1 Purpose and objectives of research

The pharmaceutical industry is going through a rapid change due to many technological advances, strict regulations and increasing demands for quality and patient safety. Corrective and Preventive Action (CAPA) systems are very much needed for identifying and solving quality issues, where Root Cause Analysis (RCA) playing a central role. However, traditional CAPA processes are often manual, slow and reactive in nature which further lead to repeated problems and regulatory risks. Artificial Intelligence (AI) offers a way to improve CAPA systems through data-driven RCA, real-time monitoring and predictive issue detection.

Despite its benefits, AI is not widely used in CAPA systems in the Indian pharmaceutical industry due to mixed perceptions, lack of readiness and other practical challenges. This study aims to explore the facts such as how professionals in the Indian pharma sector view AI, how ready their organizations are for adopting it and what are the major barriers exists. A Survey-based approach will help gather data on these topics and also for filling the key gaps in current research.

The study supports the learning from two course modules ('Process, Production and Pharmaceutical Quality Systems' and 'Operational Excellence') by showing how AI can improve compliance, efficiency and innovation. The goal is to provide strategies and positive insights for successful integration of AI into RCA within CAPA and thereby helping India's pharmaceutical sector to stay competitive globally.

Key objectives of this study are:

1. To investigate pharmaceutical professionals perceptions of AI and its impact on the effectiveness of RCA within CAPA systems in the Indian Pharmaceutical industry
2. To assess the level of organizational readiness for adopting AI in CAPA systems and identify the key factors influencing the stakeholder's preparedness to integrate AI in to RCA process.
3. To identify the key implementation challenges faced by the Indian pharmaceutical industry in the integration of AI into RCA for CAPA systems, including technological, regulatory and organizational barriers.
4. To provide practical recommendations for overcoming the identified challenges and facilitating the successful implementation of AI in RCA within CAPA systems, with focus on improving organizational processes and stakeholder engagement.

1.2 Research methodology:

This study adopts a positivist research philosophy to generate objective and generalizable insights through a quantitative, survey based approach. It investigates key factors that influences the integration of AI in Root Cause Analysis as part of CAPA systems in the Indian pharmaceutical sector. This approach is mainly through structured data collection and analysis to identify patterns and relationships among relevant variables. The target population consists of professionals currently or previously working in the Indian pharmaceutical industry, specifically in roles related to Quality Assurance (QA), Quality Control (QC), Regulatory Affairs, Manufacturing Operations, Compliance, Validation and IT support for Quality systems. These individuals are directly involved in CAPA processes and thus well positioned to provide meaningful input. A purposive sampling method will be used to select participants with relevant experience and English proficiency. Those not directly involved in CAPA or outside the pharma domain will be excluded. A target sample size of 380 has been calculated to ensure statistical reliability. However, due to

time constraints and geographic limitations, it may not be feasible to reach this number. A realistic response range of 100-150 participants is anticipated and this limitation will be acknowledged in the further discussions.

Data will be collected using a Google Form, distributed via email, LinkedIn and other professional networks. The questionnaire will include closed-ended questions with content informed by existing literature. To ensure clarity, brief explanations of AI, RCA and CAPA will be provided at the beginning of the survey. Prior to the participation, all respondents will receive an information sheet outlining the study's purpose, voluntary nature and the right to withdraw at any time. Informed consent will be collected at the starting of the survey questionnaire. All responses will remain anonymous and the data will be stored securely in password-protected digital storage, accessible only to the researcher and academic supervisor for the purpose of this study. Data analysis will involve descriptive statistics to summarise responses and correlation analysis to explore relationships. If needed, inferential statistical tests will be conducted to examine group level differences.

SECTION 2: POSSIBLE ETHICAL ISSUES

Answer 'yes' or 'no' to the following questions.

SUBJECT MATTER

Does the research proposal involve:

Research into specific company activities that would be deemed sensitive or confidential	No
Research into politically and/or racially/ethnically and/or commercially sensitive areas	No
Sensitive, personal, professional or corporate issues	No

RESEARCH PROCEDURES

Does the research proposal involve:

Research that might damage the reputation of companies or participants	No
Research that may negatively affect the reputation of Griffith College/Innopharma	No
Use of personal records without consent	No
Use of company data without consent	No
The offer of any inducements to participate	No
Audio or visual recording without consent	No
Using a language other than English	No

PARTICIPANTS

Does the research proposal involve:

People who are not competent and/or fluent in English	No
Does your research group include any of the following vulnerable groups	No

(Adults with psychological impairments; Adults with learning difficulties; Adults under the protection/control /influence of others (e.g. in care/prison); Relatives of ill people (e.g. parents of sick children); Hospital or GP participants recruited in a medical facility; persons under the age of 18)

<u>If you have answered NO to ALL questions, please go straight to Section 4.</u>

<u>If you have answered YES to ANY question in SECTION 2, you must fill in SECTION 3.</u>

SECTION 3: STEPS TAKEN TO AVOID ETHICAL ISSUES

[Only fill in this section if you answered YES to ANY of the questions in Section 3. For example, if you answered yes to including participants who are not fluent in English, you might put forward a plan that offers your survey in two languages to take this into account. Another example could be a study where the researcher wants to include information about the care received by children with a long-term condition but it would not be ethical to approach the children directly but it might be acceptable to instead ask parents questions about their child's care. If these plans are acceptable to your supervisor, you may not need to apply for ethical approval from the Ethics Committee].

3.1. If your ethics relates to ***Subject Matter***, outline your action plan to work around any sensitive issues.
3.2. If your ethics relates to ***Research Procedures***, outline your action plan to deal with possible ethical issues in your research procedures.
3.3. If your ethics relates to ***Participants***, outline how you will protect vulnerable persons or those that do not have English as their first language.

SECTION 4: ABOUT YOUR PARTICIPANTS

4.1. Outline your participant profile and why you have chosen them for this study
Participants for this study will be selected based on specific inclusion exclusion criteria.

The inclusion criteria are: (1) currently employed professional in the Indian pharmaceutical industry and (2) individuals with direct or indirect experience in pharmaceutical quality management systems, specifically those involved in CAPA processes and RCA. Eligible participants may include professionals working in Quality Assurance, Quality Control, Regulatory Affairs, Manufacturing Operations and Process Improvement or Digital Transformation teams. Participants will be selected across different levels of experience, including Junior, midlevel and senior roles to obtain a broad spectrum of perspectives.

The exclusion criteria are: individuals not currently employed in the pharmaceutical industry, those without any experience related to quality systems or those engaged in unrelated domains.

No business sensitive, participant related information will be required or collected as part of this research. The study will focus exclusively on professional perspectives related to AI integration in CAPA systems.

4.2 How do you plan to gain access to/contact/approach your participant(s).
To have access to all participants of this study, I will use multiple approaches to ensure effective and ethical recruitment. I will be contacting the participants mainly through my professional and academic networks, particularly via LinkedIn, by sending direct messages to individuals working in Indian pharmaceutical industry in roles related to quality assurance, regulatory affairs, manufacturing operations and process improvement. Additionally, I will distribute the survey link through email invitations to contacts currently employed in relevant sectors, along with a Participant Information Leaflet (PIL) and consent statement. I will also post the survey invitation in relevant professional forums and groups on platforms such as Whatsapp and Telegram, which are commonly used by pharma professionals for networking and knowledge sharing. In order to avoid to minimize the risk of possible bias, I will avoid targeting close colleagues, friends or family members will also request participants to share the survey with their eligible colleagues within their organizations. The questionnaire will be made and distributed through Google Forms, which allows easy access and completion. The survey link will include a brief introduction to the study, ethical considerations and informed consent section to ensure voluntary and transparent participation.

SECTION 5: INFORMATION, CONSENT AND CONFIDENTIALITY

5.1 Participant Information Letter (PIL) for participants

[You must submit an information letter for participants with this application, as part of your appendices document. For online surveys, it is sufficient to include a paragraph summarising and explaining the purpose of the research at the beginning of the survey. In all other research e.g. interviews, phonecalls, a PIL should be provided to each participant before they are asked for their consent to take part. A template PIL is available in Moodle].

Please confirm below that your information letter covers:

Description of the research topic and method	Yes
Details of what participation will involve	Yes
Rights to anonymity	Yes
Confidentiality	Yes
Rights to withdraw from the research	Yes
The contact details of the researcher and supervisor (if necessary)	Yes

5.2 Informed Consent Form (ICF) for participants

[Informed consent is required for most research. For online surveys, it is sufficient to get the participant to tick two boxes at the beginning of the survey – one to state they understand the research and one to give consent. In all other research e.g. interviews, phonecalls, a signed consent form is required. If the data is gathered online e.g. zoom, a signed consent form can be scanned and sent to the researcher. A template ICF is available in Moodle. The signed ICFs, along with the surveys, audio files or interview notes etc. must be stored in the primary data folder on moodle and can be accessed by Innopharma staff for the purposes of verifying the authenticity of the research carried out and the data collected].

Please indicate below if your research requires a signed consent form by selecting the relevant option only:

No: my research study involves an online survey only and/or does not require signed consent

SECTION 6: STORAGE OF DATA

[Please ensure that you are abiding by GDPR and the national Data protection laws https://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/).

*The student is responsible for storage of data and this will be handed over to the college in an electronic format as part of the thesis submission i.e. primary data and completed ICFs where applicable will be added to the primary data folder on moodle. The rationale is to keep data **as long as it is still useful** and there is an intention to use it further **for research** so if this is not the case then this can be stipulated here and a shorter retention period given.]*

6.1. How will you store the research data and for how long? How will you manage data protection issues?

All research data, including completed survey responses will be stored securely in electronic format on a password-protected personal computer. An extra back up will be created for all data on a external hard drive during the course of study. Upon completion of data collection and analysis, all primary data and other required documents will be uploaded to designated primary data folder on Moodle as part of the thesis submission, in line with college policy. The data will be anonymised to protect the participant confidentiality and no personally identifiable data will be collected as part of survey. In accordance with the General Data Protection Regulation (GDPR) and the Digital Personal DATA Protection Act. 2013 (DPDPA) as well as other applicable national data protection laws, access to the data will be safely limited to the student researcher and the academic

supervisor. To ensure the compliance with university policy, the data will be retained for a minimum of two years following the completion of the study and after which it will be securely deleted. All data management procedures will follow ethical guidelines and requirements to ensure responsible handling and protection of participant information.

SECTION 7: NON-DISCLOSURE AGREEMENT & STUDENT CONSENT

7.1 **Non-Disclosure Agreement (NDA)**
Will the final dissertation contain any information pertaining to any source what would warrant the use of a Non-Disclosure Agreement (NDA) e.g. industry-based research?

No

7.2 **Student consent**
If a Non-Disclosure Agreement (NDA) is not required, does the Student consent to allow their completed dissertation to be held/published by Innopharma/Griffith College?

Yes

SECTION 8: RECORDING AND RETENTION OF DISSERTATION VIVA

8.1 **Viva Recording**
The Dissertation viva will be recorded. This recording may be used to facilitate assessment by Innopharma staff, a third reader if necessary and/or if requested by the external examiner for the Programme. The recording will be held in line with current GDPR guidelines and will not be made publicly available.

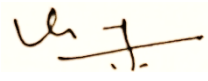
SECTION 9: DOCUMENT CHECKLIST
NOTE: Applicants must attach the following documents in electronic format to the appendix.

Which documents are added to the appendix? Please tick N/A if not applicable:

9.1 Participant Information Letter (PIL) for participant	Yes
9.2 Informed Consent Form (ICF) for participant	N/A
9.3 Questions/survey for interviewees/focus groups etc *(can be in draft form)*	Yes
9.4 Any other documents e.g. Non-Disclosure Agreement	N/A

I confirm that this application is complete and all required documents are included in the appendix.

For Student:

STUDENT SIGNATURE: 

DATE: 28-06-2025

Appendix 4: Survey Responses (Raw Data Sheets)

Does your organization currently use a CAPA s	Have you heard of or used AI-based tools in qu	Please indicate your level of agreement with the	Please indicate your level of agreement with the	Please indicate your level of agreement with the
Yes – fully digital	Yes	Neutral	Neutral	Agree
Not sure	Yes	Neutral	Neutral	Agree
Yes – partially digital/manual	Yes	Strongly Agree	Strongly Agree	Strongly Agree
Yes – partially digital/manual	Yes	Strongly Agree	Strongly Agree	Agree
Yes – partially digital/manual	Yes	Strongly Agree	Strongly Agree	Agree
Yes – fully digital	Yes	Strongly Disagree	Disagree	Neutral
Yes – fully digital	Yes	Strongly Agree	Agree	Strongly Agree
Yes – fully digital	Yes	Agree	Strongly Disagree	Agree
Yes – fully digital	Yes	Neutral	Neutral	Strongly Disagree
Yes – fully digital	Yes	Strongly Agree	Strongly Agree	Strongly Agree
Yes – fully digital	Yes	Agree	Neutral	Agree
Yes – fully digital	Yes	Agree	Neutral	Strongly Agree
Yes – fully digital	Yes	Agree	Agree	Agree
Yes – fully digital	Yes	Strongly Agree	Strongly Agree	Strongly Agree
Yes – fully digital	Yes	Strongly Disagree	Strongly Disagree	Strongly Disagree
Yes – partially digital/manual	Yes	Agree	Agree	Strongly Agree
Yes – fully digital	Yes	Strongly Agree	Agree	Strongly Agree
Yes – fully digital	Yes	Agree	Agree	Agree
Yes – fully digital	Yes	Agree	Strongly Agree	Agree
Yes – partially digital/manual	Yes	Agree	Agree	Agree
Yes – partially digital/manual	Yes	Agree	Strongly Agree	Agree
Yes – partially digital/manual	Yes	Agree	Strongly Agree	Neutral
Yes – fully digital	Yes	Agree	Agree	Strongly Agree
Yes – partially digital/manual	Yes	Strongly Agree	Agree	Neutral
Yes – fully digital	Yes	Agree	Neutral	Strongly Agree
Yes – partially digital/manual	Yes	Agree	Strongly Agree	Agree
Yes – fully digital	Yes	Agree	Agree	Agree
Yes – partially digital/manual	Yes	Agree	Strongly Agree	Agree
Yes – partially digital/manual	Yes	Neutral	Agree	Neutral
Yes – fully digital	Yes	Agree	Strongly Agree	Neutral
Yes – fully digital	Yes	Strongly Agree	Agree	Strongly Agree
Yes – partially digital/manual	Yes	Agree	Agree	Neutral
Yes – fully digital	Yes	Strongly Agree	Strongly Agree	Strongly Agree
Yes – fully digital	Yes	Agree	Strongly Disagree	Neutral
Yes – fully digital	Yes	Agree	Strongly Agree	Agree
Yes – fully digital	Yes	Strongly Agree	Strongly Agree	Strongly Agree
Yes – fully digital	Yes	Strongly Agree	Agree	Strongly Agree
Yes – partially digital/manual	Yes	Neutral	Agree	Neutral
Yes – fully digital	Yes	Strongly Agree	Neutral	Disagree
Yes – fully digital	Yes	Strongly Agree	Strongly Agree	Strongly Agree
Yes – partially digital/manual	Yes	Strongly Disagree	Strongly Disagree	Agree
Yes – fully digital	Yes	Agree	Agree	Agree
Yes – fully digital	Yes	Agree	Agree	Agree
Yes – fully digital	Yes	Strongly Agree	Strongly Agree	Strongly Agree
Yes – partially digital/manual	Yes	Agree	Agree	Agree
Yes – fully digital	Yes	Agree	Strongly Agree	Agree
Yes – fully digital	Yes	Agree	Agree	Agree
Yes – fully digital	Yes	Strongly Agree	Strongly Agree	Agree
Yes – partially digital/manual	Yes	Strongly Agree	Strongly Agree	Strongly Agree
Yes – partially digital/manual	Yes	Agree	Strongly Agree	Strongly Agree
Yes – fully digital	Yes	Strongly Agree	Strongly Agree	Strongly Agree
Yes – fully digital	Yes	Agree	Agree	Neutral
Yes – partially digital/manual	Yes	Agree	Strongly Agree	Agree
Yes – fully digital	Yes	Neutral	Neutral	Neutral
Yes – partially digital/manual	Yes	Agree	Strongly Agree	Strongly Agree
Yes – fully digital	Yes	Agree	Agree	Agree
Yes – partially digital/manual	Yes	Strongly Disagree	Strongly Disagree	Strongly Disagree
Yes – fully digital	Yes	Agree	Agree	Agree
Yes – partially digital/manual	Yes	Strongly Disagree	Strongly Disagree	Strongly Disagree
Yes – partially digital/manual	Yes	Agree	Agree	Strongly Agree
Yes – partially digital/manual	Yes	Agree	Agree	Agree
Not sure	Yes	Agree	Agree	Strongly Agree
Yes – partially digital/manual	Yes	Strongly Agree	Agree	Agree
Yes – fully digital	Yes	Strongly Agree	Strongly Agree	Agree
Yes – partially digital/manual	Yes	Neutral	Agree	Neutral
Yes – partially digital/manual	Yes	Agree	Strongly Agree	Agree
Yes – fully digital	Yes	Disagree	Neutral	Neutral
Yes – partially digital/manual	Yes	Agree	Agree	Agree
Yes – partially digital/manual	Yes	Neutral	Neutral	Neutral
Yes – partially digital/manual	Yes	Agree	Strongly Agree	Agree
Yes – fully digital	Yes	Agree	Strongly Agree	Agree
Yes – partially digital/manual	Yes	Agree	Strongly Agree	Agree
Yes – fully digital	Yes	Strongly Agree	Agree	Agree
Yes – fully digital	Yes	Agree	Agree	Neutral
Yes – partially digital/manual	Yes	Agree	Strongly Agree	Agree
Yes – partially digital/manual	Yes	Strongly Agree	Agree	Agree
Yes – fully digital	Yes	Strongly Agree	Strongly Agree	Strongly Agree
Yes – fully digital	Yes	Strongly Agree	Agree	Neutral
Yes – partially digital/manual	Yes	Agree	Agree	Strongly Agree
Yes – fully digital	Yes	Agree	Agree	Agree
Yes – partially digital/manual	Yes	Neutral	Agree	Neutral
Yes – partially digital/manual	Yes	Neutral	Neutral	Agree
Yes – fully digital	Yes	Agree	Agree	Agree
Yes – fully digital	Yes	Agree	Agree	Agree
Yes – partially digital/manual	Yes	Agree	Agree	Agree
Yes – partially digital/manual	Yes	Agree	Neutral	Agree
Yes – partially digital/manual	Yes	Agree	Neutral	Neutral
Yes – fully digital	Yes	Neutral	Agree	Agree
Yes – fully digital	Yes	Agree	Agree	Agree
Yes – fully digital	Yes	Agree	Strongly Agree	Agree
Yes – partially digital/manual	Yes	Agree	Neutral	Agree
Yes – fully digital	Yes	Strongly Disagree	Strongly Disagree	Strongly Disagree
Yes – fully digital	Yes	Agree	Agree	Agree
Yes – partially digital/manual	Yes	Agree	Agree	Agree
Yes – fully digital	Yes	Agree	Strongly Agree	Agree
Yes – fully digital	Yes	Agree	Strongly Agree	Agree
Yes – partially digital/manual	Yes	Agree	Agree	Agree
Yes – partially digital/manual	Yes	Strongly Agree	Strongly Agree	Agree
Yes – fully digital	Yes	Strongly Disagree	Strongly Disagree	Strongly Disagree
Yes – partially digital/manual	Yes	Agree	Neutral	Agree
Yes – partially digital/manual	Yes	Strongly Agree	Agree	Strongly Agree
Yes – fully digital	Yes	Agree	Strongly Agree	Neutral
Yes – fully digital	No	Disagree	Disagree	Disagree
Yes – partially digital/manual	Yes	Neutral	Strongly Disagree	Neutral
Yes – fully digital	Yes	Strongly Disagree	Strongly Disagree	Strongly Disagree
Yes – partially digital/manual	Yes	Agree	Agree	Agree
Yes – fully digital	Yes	Strongly Disagree	Strongly Disagree	Strongly Disagree

Please indicate your level of agreement with the	Please indicate your level of agreement with the	How would you rate your organization's current	Has your organization conducted any training o	How would you describe leadership's attitude to
Neutral	Agree	Very ready	No, but some are planned in the near future	Supportive – leadership is open and encouragin
Neutral	Neutral	Slightly ready	Yes, but only a few informal sessions or works	Supportive – leadership is open and encouragin
Agree	Strongly Agree	Very ready	Yes, multiple structured training programs have	Supportive – leadership is open and encouragin
Strongly Agree	Agree	Very ready	Yes, multiple structured training programs have	Supportive – leadership is open and encouragin
Agree	Strongly Agree	Moderately ready	Yes, but only a few informal sessions or works	Very supportive – leadership actively promotes
Strongly Disagree	Disagree	Very ready	Yes, multiple structured training programs have	Very supportive – leadership actively promotes
Strongly Agree	Strongly Agree	Very ready	Yes, multiple structured training programs have	Supportive – leadership is open and encouragin
Strongly Disagree	Agree	Very ready	Yes, but only a few informal sessions or works	Very supportive – leadership actively promotes
Neutral	Strongly Agree	Moderately ready	No, but some are planned in the near future	Neutral – no strong views expressed
Strongly Agree	Strongly Agree	Very ready	Yes, multiple structured training programs have	Very supportive – leadership actively promotes
Neutral	Agree	Very ready	Yes, multiple structured training programs have	Very supportive – leadership actively promotes
Agree	Agree	Moderately ready	Yes, multiple structured training programs have	Very supportive – leadership actively promotes
Agree	Agree	Very ready	Yes, multiple structured training programs have	Supportive – leadership is open and encouragin
Strongly Agree	Strongly Agree	Moderately ready	Yes, but only a few informal sessions or works	Very supportive – leadership actively promotes
Strongly Disagree	Strongly Disagree	Very ready	Yes, multiple structured training programs have	Very supportive – leadership actively promotes
Agree	Strongly Agree	Moderately ready	Yes, multiple structured training programs have	Supportive – leadership is open and encouragin
Agree	Agree	Moderately ready	Yes, multiple structured training programs have	Neutral – no strong views expressed
Neutral	Agree	Slightly ready	Yes, multiple structured training programs have	Very supportive – leadership actively promotes
Neutral	Neutral	Moderately ready	Yes, multiple structured training programs have	Supportive – leadership is open and encouragin
Agree	Agree	Moderately ready	Yes, but only a few informal sessions or works	Very supportive – leadership actively promotes
Strongly Agree	Strongly Agree	Very ready	Yes, but only a few informal sessions or works	Supportive – leadership is open and encouragin
Agree	Agree	Very ready	Yes, multiple structured training programs have	Supportive – leadership is open and encouragin
Agree	Agree	Already using AI	Yes, multiple structured training programs have	Supportive – leadership is open and encouragin
Strongly Agree	Agree	Moderately ready	Yes, multiple structured training programs have	Neutral – no strong views expressed
Agree	Strongly Agree	Moderately ready	Yes, multiple structured training programs have	Very supportive – leadership actively promotes
Neutral	Agree	Moderately ready	Yes, but only a few informal sessions or works	Very supportive – leadership actively promotes
Agree	Agree	Already using AI	Yes, multiple structured training programs have	Very supportive – leadership actively promotes
Agree	Agree	Moderately ready	Yes, multiple structured training programs have	Very supportive – leadership actively promotes
Neutral	Agree	Moderately ready	Yes, multiple structured training programs have	Supportive – leadership is open and encouragin
Agree	Agree	Very ready	Yes, but only a few informal sessions or works	Supportive – leadership is open and encouragin
Agree	Strongly Agree	Moderately ready	No, but some are planned in the near future	Very supportive – leadership actively promotes
Agree	Neutral	Moderately ready	Yes, but only a few informal sessions or works	Very supportive – leadership actively promotes
Strongly Agree	Strongly Agree	Moderately ready	Yes, but only a few informal sessions or works	Very supportive – leadership actively promotes
Strongly Disagree	Agree	Moderately ready	No training or awareness programs have been	Neutral – no strong views expressed
Agree	Agree	Moderately ready	Yes, multiple structured training programs have	Very supportive – leadership actively promotes
Strongly Agree	Strongly Agree	Moderately ready	No, but some are planned in the near future	Neutral – no strong views expressed
Agree	Agree	Moderately ready	Yes, multiple structured training programs have	Very supportive – leadership actively promotes
Agree	Agree	Very ready	Yes, multiple structured training programs have	Very supportive – leadership actively promotes
Neutral	Strongly Disagree	Very ready	Yes, multiple structured training programs have	Very supportive – leadership actively promotes
Strongly Agree	Strongly Agree	Very ready	Yes, multiple structured training programs have	Very supportive – leadership actively promotes
Agree	Neutral	Very ready	Yes, multiple structured training programs have	Supportive – leadership is open and encouragin
Agree	Agree	Moderately ready	Yes, multiple structured training programs have	Very supportive – leadership actively promotes
Agree	Agree	Very ready	Yes, multiple structured training programs have	Supportive – leadership is open and encouragin
Strongly Agree	Strongly Agree	Moderately ready	Yes, multiple structured training programs have	Very supportive – leadership actively promotes
Strongly Agree	Agree	Moderately ready	Yes, but only a few informal sessions or works	Supportive – leadership is open and encouragin
Strongly Agree	Agree	Moderately ready	Yes, but only a few informal sessions or works	Very supportive – leadership actively promotes
Agree	Agree	Moderately ready	Yes, multiple structured training programs have	Supportive – leadership is open and encouragin
Strongly Agree	Strongly Agree	Very ready	Yes, multiple structured training programs have	Supportive – leadership is open and encouragin
Strongly Agree	Strongly Agree	Very ready	Yes, multiple structured training programs have	Very supportive – leadership actively promotes
Agree	Strongly Agree	Moderately ready	No, but some are planned in the near future	Supportive – leadership is open and encouragin
Strongly Agree	Strongly Agree	Very ready	Yes, but only a few informal sessions or works	Very supportive – leadership actively promotes
Agree	Agree	Already using AI	Yes, but only a few informal sessions or works	Very supportive – leadership actively promotes
Strongly Agree	Strongly Agree	Very ready	Yes, but only a few informal sessions or works	Very supportive – leadership actively promotes
Neutral	Neutral	Moderately ready	Yes, multiple structured training programs have	Very supportive – leadership actively promotes
Agree	Agree	Moderately ready	Yes, but only a few informal sessions or works	Very supportive – leadership actively promotes
Agree	Agree	Very ready	Yes, but only a few informal sessions or works	Supportive – leadership is open and encouragin
Strongly Disagree	Strongly Disagree	Already using AI	Yes, multiple structured training programs have	Very supportive – leadership actively promotes
Agree	Agree	Very ready	Yes, multiple structured training programs have	Very supportive – leadership actively promotes
Strongly Disagree	Strongly Disagree	Very ready	Yes, but only a few informal sessions or works	Supportive – leadership is open and encouragin
Strongly Agree	Strongly Agree	Moderately ready	Yes, but only a few informal sessions or works	Supportive – leadership is open and encouragin
Agree	Agree	Very ready	Yes, but only a few informal sessions or works	Very supportive – leadership actively promotes
Agree	Agree	Moderately ready	Yes, but only a few informal sessions or works	Supportive – leadership is open and encouragin
Agree	Agree	Very ready	Yes, but only a few informal sessions or works	Neutral – no strong views expressed
Neutral	Strongly Agree	Moderately ready	Yes, but only a few informal sessions or works	Neutral – no strong views expressed
Agree	Neutral	Very ready	Yes, but only a few informal sessions or works	Neutral – no strong views expressed
Strongly Agree	Strongly Agree	Moderately ready	Yes, but only a few informal sessions or works	Very supportive – leadership actively promotes
Neutral	Neutral	Moderately ready	Yes, multiple structured training programs have	Very supportive – leadership actively promotes
Agree	Agree	Moderately ready	Yes, multiple structured training programs have	Supportive – leadership is open and encouragin
Neutral	Neutral	Moderately ready	No, but some are planned in the near future	Neutral – no strong views expressed
Agree	Strongly Agree	Very ready	Yes, but only a few informal sessions or works	Supportive – leadership is open and encouragin
Agree	Strongly Agree	Slightly ready	Yes, multiple structured training programs have	Very supportive – leadership actively promotes
Strongly Agree	Agree	Moderately ready	Yes, but only a few informal sessions or works	Very supportive – leadership actively promotes
Neutral	Agree	Already using AI	Yes, but only a few informal sessions or works	Supportive – leadership is open and encouragin
Agree	Agree	Very ready	Yes, but only a few informal sessions or works	Very supportive – leadership actively promotes
Agree	Agree	Very ready	Yes, but only a few informal sessions or works	Very supportive – leadership actively promotes
Strongly Agree	Agree	Very ready	Yes, but only a few informal sessions or works	Very supportive – leadership actively promotes
Agree	Strongly Agree	Already using AI	Yes, multiple structured training programs have	Supportive – leadership is open and encouragin
Strongly Agree	Agree	Moderately ready	Yes, multiple structured training programs have	Very supportive – leadership actively promotes
Agree	Agree	Already using AI	Yes, multiple structured training programs have	Supportive – leadership is open and encouragin
Neutral	Agree	Moderately ready	Yes, multiple structured training programs have	Very supportive – leadership actively promotes
Agree	Neutral	Moderately ready	Yes, but only a few informal sessions or works	Supportive – leadership is open and encouragin
Agree	Neutral	Moderately ready	Yes, but only a few informal sessions or works	Supportive – leadership is open and encouragin
Agree	Agree	Moderately ready	Yes, but only a few informal sessions or works	Supportive – leadership is open and encouragin
Agree	Neutral	Moderately ready	Yes, but only a few informal sessions or works	Very supportive – leadership actively promotes
Neutral	Neutral	Very ready	Yes, but only a few informal sessions or works	Very supportive – leadership actively promotes
Neutral	Agree	Moderately ready	Yes, but only a few informal sessions or works	Unsupportive – leadership is hesitant or sceptic
Agree	Neutral	Moderately ready	Yes, but only a few informal sessions or works	Neutral – no strong views expressed
Neutral	Agree	Moderately ready	Yes, multiple structured training programs have	Very supportive – leadership actively promotes
Agree	Agree	Moderately ready	Yes, but only a few informal sessions or works	Supportive – leadership is open and encouragin
Neutral	Agree	Very ready	Yes, but only a few informal sessions or works	Neutral – no strong views expressed
Neutral	Agree	Moderately ready	No, but some are planned in the near future	Neutral – no strong views expressed
Strongly Disagree	Strongly Disagree	Very ready	Yes, multiple structured training programs have	Very supportive – leadership actively promotes
Agree	Agree	Moderately ready	Yes, multiple structured training programs have	Very supportive – leadership actively promotes
Agree	Agree	Moderately ready	Yes, but only a few informal sessions or works	Supportive – leadership is open and encouragin
Agree	Agree	Moderately ready	Yes, multiple structured training programs have	Very supportive – leadership actively promotes
Neutral	Strongly Agree	Very ready	Yes, multiple structured training programs have	Supportive – leadership is open and encouragin
Agree	Agree	Very ready	Yes, but only a few informal sessions or works	Supportive – leadership is open and encouragin
Strongly Agree	Strongly Agree	Very ready	Yes, but only a few informal sessions or works	Very supportive – leadership actively promotes
Strongly Disagree	Strongly Disagree	Already using AI	Yes, but only a few informal sessions or works	Very supportive – leadership actively promotes
Agree	Agree	Moderately ready	Yes, but only a few informal sessions or works	Neutral – no strong views expressed
Agree	Strongly Agree	Very ready	Yes, multiple structured training programs have	Supportive – leadership is open and encouragin
Agree	Strongly Agree	Moderately ready	Yes, but only a few informal sessions or works	Supportive – leadership is open and encouragin
Disagree	Disagree	Slightly ready	Yes, multiple structured training programs have	Supportive – leadership is open and encouragin
Neutral	Strongly Disagree	Moderately ready	Yes, but only a few informal sessions or works	Supportive – leadership is open and encouragin
Strongly Disagree	Neutral	Moderately ready	Yes, multiple structured training programs have	Supportive – leadership is open and encouragin
Neutral	Agree	Moderately ready	No training or awareness programs have been	Supportive – leadership is open and encouragin
Strongly Disagree	Strongly Disagree	Moderately ready	No training or awareness programs have been	Strongly opposed – leadership discourages AI a

Which of the following enablers are present in y	What are the top three factors influencing your	Please rate the level of challenge posed by the	Please rate the level of challenge posed by the	Please rate the level of challenge posed by the
Digital QMS or electronic CAPA system, Traine	Leadership and management vision, Employee	Moderate	Moderate	Minor
Management support for AI	Reliable vendors or AI tools, Innovation culture	Major	Major	Major
Digital QMS or electronic CAPA system, A digit	Leadership and management vision, Employee	Critical	Major	Critical
Digital QMS or electronic CAPA system, Traine	Leadership and management vision, Employee	Critical	Critical	Critical
Digital QMS or electronic CAPA system, Traine	Leadership and management vision, Employee	Critical	Major	Critical
Trained staff in AI/data analytics, A digital trans	Leadership and management vision, Employee	Critical	Critical	Critical
Digital QMS or electronic CAPA system, Mana	Leadership and management vision, Employee	Critical	Major	Major
Digital QMS or electronic CAPA system, Traine	Leadership and management vision, Employee	Critical	Major	Critical
Trained staff in AI/data analytics	Leadership and management vision, Employee	Moderate	Minor	Minor
A digital transformation or innovation team, Mar	Leadership and management vision, Employee	Critical	Critical	Critical
Management support for AI	Employee awareness and training, Quality and	Major	Critical	Critical
Trained staff in AI/data analytics	Leadership and management vision, Quality an	Major	Major	Critical
Digital QMS or electronic CAPA system	Leadership and management vision, Employee	Major	Major	Critical
Digital QMS or electronic CAPA system, Traine	Leadership and management vision, Reliable ve	Moderate	Moderate	Moderate
Digital QMS or electronic CAPA system, Traine	Leadership and management vision, Quality an	Not a Challenge	Not a Challenge	Not a Challenge
Trained staff in AI/data analytics	Employee awareness and training, Quality and	Major	Moderate	Major
Digital QMS or electronic CAPA system	Employee awareness and training, Quality and	Minor	Moderate	Moderate
Digital QMS or electronic CAPA system, Traine	Leadership and management vision, Employee	Minor	Minor	Minor
Digital QMS or electronic CAPA system, Traine	Employee awareness and training, Quality and	Moderate	Moderate	Moderate
A digital transformation or innovation team	Leadership and management vision	Not a Challenge	Not a Challenge	Not a Challenge
Trained staff in AI/data analytics	Leadership and management vision, Employee	Critical	Major	Major
Trained staff in AI/data analytics, A digital trans	Employee awareness and training, Quality and	Critical	Major	Moderate
Digital QMS or electronic CAPA system, Traine	Leadership and management vision, Employee	Major	Critical	Major
A digital transformation or innovation team	Leadership and management vision, Employee	Critical	Major	Moderate
Digital QMS or electronic CAPA system	Leadership and management vision, Employee	Critical	Major	Moderate
Trained staff in AI/data analytics	Leadership and management vision, Employee	Moderate	Moderate	Moderate
Digital QMS or electronic CAPA system	Regulatory clarity	Moderate	Moderate	Moderate
Digital QMS or electronic CAPA system, Traine	Leadership and management vision, Quality an	Major	Minor	Major
Digital QMS or electronic CAPA system	Leadership and management vision, Employee	Moderate	Moderate	Major
Management support for AI	Employee awareness and training	Moderate	Major	Major
Digital QMS or electronic CAPA system, Traine	Leadership and management vision, Employee	Moderate	Moderate	Moderate
Digital QMS or electronic CAPA system, A digit	Leadership and management vision, Employee	Major	Critical	Major
Management support for AI	Leadership and management vision, Employee	Major	Major	Major
A digital transformation or innovation team	Quality and availability of data	Critical	Critical	Critical
Digital QMS or electronic CAPA system	Leadership and management vision	Major	Major	Major
Digital QMS or electronic CAPA system, Traine	Leadership and management vision, Employee	Critical	Critical	Critical
Digital QMS or electronic CAPA system	Leadership and management vision, Employee	Major	Critical	Major
Trained staff in AI/data analytics	Leadership and management vision, Employee	Moderate	Major	Moderate
Digital QMS or electronic CAPA system, Traine	Leadership and management vision, Employee	Moderate	Major	Moderate
Digital QMS or electronic CAPA system	Quality and availability of data	Moderate	Moderate	Moderate
A digital transformation or innovation team	Leadership and management vision, Employee	Moderate	Moderate	Moderate
Dedicated budget for digital projects	Leadership and management vision, Employee	Major	Major	Major
Digital QMS or electronic CAPA system	Employee awareness and training	Major	Major	Major
Trained staff in AI/data analytics	Leadership and management vision	Critical	Major	Critical
A digital transformation or innovation team	Leadership and management vision, Employee	Moderate	Major	Major
Trained staff in AI/data analytics	Leadership and management vision	Major	Critical	Major
Trained staff in AI/data analytics	Leadership and management vision, Employee	Minor	Moderate	Minor
A digital transformation or innovation team, Mar	Leadership and management vision, Employee	Critical	Critical	Moderate
Digital QMS or electronic CAPA system, Traine	Leadership and management vision, Employee	Critical	Critical	Critical
A digital transformation or innovation team, Mar	Leadership and management vision, Employee	Major	Moderate	Moderate
Digital QMS or electronic CAPA system	Leadership and management vision	Critical	Critical	Critical
Digital QMS or electronic CAPA system, Traine	Leadership and management vision, Quality an	Moderate	Minor	Minor
Trained staff in AI/data analytics	Leadership and management vision, Employee	Moderate	Minor	Minor
Dedicated budget for digital projects	Leadership and management vision, Employee	Moderate	Moderate	Moderate
A digital transformation or innovation team	Leadership and management vision, Employee	Major	Major	Critical
Trained staff in AI/data analytics, Management	Leadership and management vision, Employee	Critical	Critical	Critical
Management support for AI	Leadership and management vision, Employee	Moderate	Moderate	Moderate
Digital QMS or electronic CAPA system, Traine	Leadership and management vision, Employee	Critical	Critical	Critical
Trained staff in AI/data analytics	Leadership and management vision, Employee	Major	Critical	Major
Trained staff in AI/data analytics	Leadership and management vision, Employee	Critical	Major	Moderate
Digital QMS or electronic CAPA system, Traine	Leadership and management vision, Employee	Moderate	Moderate	Major
Trained staff in AI/data analytics, A digital trans	Quality and availability of data, Regulatory clarit	Major	Critical	Moderate
A digital transformation or innovation team	Quality and availability of data	Moderate	Moderate	Moderate
Trained staff in AI/data analytics, A digital trans	Employee awareness and training, Quality and	Minor	Major	Major
A digital transformation or innovation team	Leadership and management vision, Employee	Major	Moderate	Major
Digital QMS or electronic CAPA system, Traine	Leadership and management vision, Employee	Major	Critical	Major
Management support for AI	Leadership and management vision, Employee	Moderate	Moderate	Moderate
Trained staff in AI/data analytics	Quality and availability of data	Critical	Major	Moderate
Trained staff in AI/data analytics	Quality and availability of data	Major	Major	Major
Digital QMS or electronic CAPA system, Traine	Leadership and management vision, Employee	Minor	Minor	Moderate
Digital QMS or electronic CAPA system	Leadership and management vision, Employee	Critical	Major	Major
Digital QMS or electronic CAPA system, Traine	Leadership and management vision, Employee	Major	Critical	Major
A digital transformation or innovation team	Employee awareness and training, Quality and	Critical	Major	Major
Trained staff in AI/data analytics	Employee awareness and training, Quality and	Major	Major	Major
A digital transformation or innovation team, Mar	Leadership and management vision, Employee	Critical	Critical	Major
Trained staff in AI/data analytics, A digital trans	Leadership and management vision, Employee	Critical	Critical	Major
Trained staff in AI/data analytics, A digital trans	Employee awareness and training, Quality and	Critical	Moderate	Moderate
None of the above	Leadership and management vision, Employee	Critical	Major	Moderate
Trained staff in AI/data analytics, A digital trans	Leadership and management vision, Employee	Critical	Major	Major
Digital QMS or electronic CAPA system, Traine	Leadership and management vision, Employee	Critical	Major	Moderate
Trained staff in AI/data analytics	Leadership and management vision, Employee	Major	Moderate	Critical
Trained staff in AI/data analytics, A digital trans	Leadership and management vision, Employee	Major	Major	Critical
Digital QMS or electronic CAPA system, Traine	Leadership and management vision, Employee	Major	Major	Critical
Digital QMS or electronic CAPA system, Traine	Leadership and management vision, Quality an	Major	Major	Major
Digital QMS or electronic CAPA system, Traine	Leadership and management vision, Employee	Major	Moderate	Major
A digital transformation or innovation team	Leadership and management vision, Quality an	Major	Moderate	Moderate
Digital QMS or electronic CAPA system, Traine	Employee awareness and training, Quality and	Moderate	Moderate	Moderate
Trained staff in AI/data analytics, Management	Employee awareness and training, Regulatory c	Critical	Major	Moderate
Digital QMS or electronic CAPA system, Traine	Leadership and management vision, Employee	Critical	Critical	Critical
Trained staff in AI/data analytics, Management	Employee awareness and training, Quality and	Critical	Major	Moderate
Dedicated budget for digital projects	Employee awareness and training	Moderate	Moderate	Moderate
Digital QMS or electronic CAPA system, Traine	Leadership and management vision, Employee	Not a Challenge	Not a Challenge	Not a Challenge
Digital QMS or electronic CAPA system	Leadership and management vision, Employee	Moderate	Moderate	Moderate
Trained staff in AI/data analytics, A digital trans	Leadership and management vision, Employee	Major	Major	Major
Digital QMS or electronic CAPA system, Traine	Leadership and management vision, Employee	Critical	Major	Moderate
Management support for AI	Leadership and management vision, Employee	Minor	Moderate	Minor
A digital transformation or innovation team	Employee awareness and training	Moderate	Moderate	Moderate
Digital QMS or electronic CAPA system, Traine	Leadership and management vision, Employee	Major	Moderate	Major
A digital transformation or innovation team, Ded	Leadership and management vision, Employee	Moderate	Moderate	Moderate
A digital transformation or innovation team	Employee awareness and training, Quality and	Moderate	Major	Moderate
A digital transformation or innovation team	Regulatory clarity	Critical	Moderate	Major
A digital transformation or innovation team	Leadership and management vision, Employee	Critical	Major	Moderate
A digital transformation or innovation team	Leadership and management vision	Not a Challenge	Not a Challenge	Not a Challenge
Management support for AI	Employee awareness and training	Moderate	Critical	Critical
Trained staff in AI/data analytics	Leadership and management vision, Employee	Not a Challenge	Not a Challenge	Not a Challenge
Digital QMS or electronic CAPA system, A digit	Leadership and management vision, Quality an	Moderate	Minor	Moderate
Trained staff in AI/data analytics	Quality and availability of data	Critical	Minor	Minor

Please rate the level of challenge posed by the	Please rate the level of challenge posed by the	Please rate the level of challenge posed by the	Please rate the level of challenge posed by the	Please rate the level of challenge posed by the
Minor	Major	Major	Minor	Moderate
Major	Major	Critical	Critical	Major
Major	Major	Critical	Major	Major
Critical	Critical	Critical	Critical	Critical
Critical	Major	Moderate	Major	Moderate
Major	Major	Major	Critical	Critical
Major	Major	Critical	Critical	Moderate
Major	Critical	Major	Major	Major
Minor	Moderate	Moderate	Minor	Moderate
Critical	Critical	Critical	Critical	Critical
Major	Major	Major	Critical	Major
Major	Moderate	Critical	Major	Critical
Major	Major	Major	Critical	Major
Moderate	Moderate	Moderate	Moderate	Moderate
Not a Challenge	Critical	Not a Challenge	Not a Challenge	Not a Challenge
Moderate	Moderate	Major	Moderate	Major
Minor	Moderate	Minor	Moderate	Minor
Minor	Minor	Minor	Minor	Minor
Major	Moderate	Moderate	Moderate	Moderate
Major	Major	Major	Major	Major
Major	Critical	Critical	Major	Major
Minor	Moderate	Critical	Minor	Moderate
Major	Major	Critical	Critical	Major
Major	Critical	Major	Moderate	Major
Major	Critical	Major	Moderate	Critical
Critical	Major	Major	Moderate	Critical
Moderate	Moderate	Moderate	Moderate	Moderate
Major	Critical	Major	Major	Major
Major	Major	Moderate	Moderate	Major
Critical	Critical	Major	Major	Major
Major	Major	Major	Moderate	Moderate
Major	Moderate	Major	Major	Moderate
Major	Major	Major	Major	Major
Critical	Critical	Critical	Critical	Critical
Major	Major	Major	Major	Major
Critical	Critical	Critical	Critical	Critical
Major	Major	Critical	Critical	Major
Major	Critical	Moderate	Major	Major
Major	Moderate	Major	Moderate	Major
Moderate	Moderate	Moderate	Moderate	Moderate
Moderate	Moderate	Moderate	Moderate	Moderate
Major	Major	Major	Major	Major
Major	Major	Major	Major	Major
Major	Critical	Major	Critical	Major
Moderate	Major	Major	Moderate	Major
Major	Major	Critical	Major	Major
Moderate	Minor	Moderate	Minor	Moderate
Major	Critical	Critical	Critical	Critical
Critical	Critical	Critical	Critical	Critical
Moderate	Major	Moderate	Moderate	Moderate
Critical	Critical	Critical	Critical	Critical
Moderate	Minor	Minor	Moderate	Minor
Moderate	Minor	Moderate	Minor	Minor
Moderate	Moderate	Moderate	Moderate	Moderate
Major	Major	Critical	Major	Major
Critical	Critical	Critical	Critical	Critical
Moderate	Moderate	Moderate	Moderate	Moderate
Critical	Critical	Critical	Critical	Critical
Critical	Moderate	Major	Major	Critical
Critical	Moderate	Major	Critical	Moderate
Major	Moderate	Major	Moderate	Major
Minor	Minor	Moderate	Critical	Moderate
Moderate	Moderate	Moderate	Moderate	Moderate
Minor	Moderate	Moderate	Moderate	Moderate
Moderate	Major	Moderate	Major	Moderate
Major	Major	Critical	Major	Major
Moderate	Moderate	Moderate	Moderate	Moderate
Minor	Critical	Critical	Minor	Critical
Major	Major	Major	Major	Major
Minor	Not a Challenge	Minor	Moderate	Minor
Moderate	Major	Moderate	Moderate	Major
Critical	Critical	Major	Major	Critical
Major	Moderate	Major	Critical	Major
Moderate	Moderate	Major	Major	Moderate
Critical	Critical	Critical	Major	Major
Critical	Critical	Critical	Major	Major
Major	Major	Moderate	Critical	Critical
Major	Critical	Major	Moderate	Major
Critical	Moderate	Major	Major	Major
Major	Major	Major	Major	Major
Critical	Moderate	Major	Major	Moderate
Critical	Moderate	Major	Major	Major
Major	Critical	Major	Critical	Major
Major	Major	Critical	Major	Major
Moderate	Major	Moderate	Major	Moderate
Major	Minor	Not a Challenge	Major	Major
Moderate	Moderate	Moderate	Moderate	Moderate
Major	Major	Moderate	Critical	Major
Critical	Critical	Critical	Critical	Critical
Major	Moderate	Major	Critical	Moderate
Moderate	Moderate	Moderate	Moderate	Moderate
Not a Challenge	Not a Challenge	Not a Challenge	Not a Challenge	Not a Challenge
Moderate	Moderate	Moderate	Moderate	Moderate
Major	Major	Major	Major	Major
Major	Critical	Major	Moderate	Major
Minor	Moderate	Minor	Minor	Minor
Moderate	Moderate	Moderate	Moderate	Moderate
Moderate	Major	Major	Moderate	Moderate
Moderate	Moderate	Moderate	Moderate	Moderate
Moderate	Minor	Major	Moderate	Moderate
Moderate	Critical	Moderate	Major	Critical
Major	Critical	Moderate	Major	Critical
Not a Challenge	Not a Challenge	Not a Challenge	Not a Challenge	Not a Challenge
Moderate	Critical	Moderate	Moderate	Moderate
Minor	Minor	Minor	Minor	Not a Challenge
Major	Minor	Major	Major	Major
Not a Challenge	Not a Challenge	Minor	Minor	Not a Challenge

Please rate the level of challenge posed by the l	Which of the following regulatory concerns doe	What is the most significant technological barri	Which of the following would help support succ	What do you think regulators should do to prom
Minor	Concerns about data privacy and confidentiality	Concerns about data security or system robusti	Collaboration between Quality and IT teams	Provide industry workshops or forums for AI kn
Major	Lack of clear regulatory guidelines specific to A	Limited integration with existing QMS platforms	Training for quality and manufacturing staff, Cle	Develop clear and detailed AI-specific regulator
Critical	Lack of clear regulatory guidelines specific to A	Limited integration with existing QMS platforms	Training for quality and manufacturing staff, Cle	Develop clear and detailed AI-specific regulator
Major	Lack of clear regulatory guidelines specific to A	No significant technological barriers identified	Training for quality and manufacturing staff, Cle	Develop clear and detailed AI-specific regulator
Critical	Lack of clear regulatory guidelines specific to A	Concerns about data security or system robusti	Training for quality and manufacturing staff, Cle	Develop clear and detailed AI-specific regulator
Major	Lack of clear regulatory guidelines specific to A	Limited integration with existing QMS platforms	Training for quality and manufacturing staff, Cle	Develop clear and detailed AI-specific regulator
Moderate	Lack of clear regulatory guidelines specific to A	Concerns about data security or system robusti	Training for quality and manufacturing staff, Cle	Develop clear and detailed AI-specific regulator
Major	Lack of clear regulatory guidelines specific to A	High cost of AI solution development or licensin	Clearer regulatory guidance on AI, Collaboratior	Provide industry workshops or forums for AI kn
Minor	Concerns about data privacy and confidentiality	Shortage of in-house AI/IT expertise	Collaboration between Quality and IT teams	Create a framework for validating and auditing A
Critical	Lack of clear regulatory guidelines specific to A	Shortage of in-house AI/IT expertise	Training for quality and manufacturing staff, Cle	Develop clear and detailed AI-specific regulator
Critical	Lack of clear regulatory guidelines specific to A	Lack of clean, structured, and accessible histor	Training for quality and manufacturing staff, Cle	Develop clear and detailed AI-specific regulator
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Major	Concerns about data privacy and confidentiality	Concerns about data security or system robusti	Training for quality and manufacturing staff, Cle	Develop clear and detailed AI-specific regulator
Moderate	Difficulty in validating AI models for compliance,	Limited integration with existing QMS platforms	Training for quality and manufacturing staff, Cle	Develop clear and detailed AI-specific regulator
Not a Challenge	Lack of clear regulatory guidelines specific to A	Lack of clean, structured, and accessible histor	Training for quality and manufacturing staff, Col	Develop clear and detailed AI-specific regulator
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Major	Lack of clear regulatory guidelines specific to A	Shortage of in-house AI/IT expertise	Government or industry support	Develop clear and detailed AI-specific regulator
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Moderate	Lack of clear regulatory guidelines specific to A	Shortage of in-house AI/IT expertise	Case studies of successful use in pharma	Develop clear and detailed AI-specific regulator
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Not a Challenge	Lack of clear regulatory guidelines specific to A	Concerns about data security or system robusti	Training for quality and manufacturing staff, Cle	Develop clear and detailed AI-specific regulator
Minor	Not sure / Not applicable	Shortage of in-house AI/IT expertise	Training for quality and manufacturing staff	Regulators should take a cautious approach for

Do you believe AI will become a common part o	Do you have any additional comments or suggestions on the use of AI in RCA or CAPA systems?
Not sure	
Yes	
Yes	
Yes	
Yes	
Yes	No
Yes	Its always good to use technology in every field to ease our work.
Yes	Natural language processing (NLP) models can read deviation forms and suggest potential root causes based on past similar cases or linked compliance data. This doesn't replace the investigation but makes it sharper and fas
Yes	No
Yes	
Yes	
Yes	
Yes	Nil
Yes	
Yes	
Yes	
Yes	
Yes	NA
Yes	AI can enhance RCA and CAPA systems in pharma by accelerating deviation analysis, improving compliance, and preventing recurrence through data-driven insights
Yes	
Yes	
Yes	
Yes	
Yes	
Yes	
Yes	No
Yes	Yes
Yes	NA
Yes	No
Yes	
Yes	
Yes	
Yes	Nothing
Yes	
Yes	
Yes	
Yes	No
Yes	
Yes	
Yes	
Yes	
Yes	
Yes	
Yes	No
Yes	
Yes	
Yes	
Yes	
Yes	
Yes	
Yes	
Yes	AI system use in RCA or CAPA filed
Yes	AI in best in CAPA
Yes	
Yes	
Yes	
Yes	
Yes	
Yes	
Yes	
Yes	
Yes	
Yes	No
Yes	
Yes	
Yes	
Yes	No
Yes	
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Yes	No
Yes	
Yes	
Yes	
Yes	
Yes	
Yes	
Yes	
Yes	
Yes	
Yes	No
Yes	
Yes	
Yes	
Yes	
Yes	No
Yes	
Yes	No
Yes	No
Yes	
Yes	
Yes	No
Yes	No
Yes	
Yes	
Yes	Nil
Yes	
Yes	
Yes	