



Assignment Cover Sheet

Learner name(s): **Nikhila Mangalappilly Ramakrishnan**

Learner number(s): **[REDACTED]**

Assignment Type: **Individual** Year: **2025**

Course: **MSc Digital Transformation**

Module: **Dissertation**

Study Mode: **Full time**

Supervisor Name: **Eucharla Eamuaide**

Assignment Title: **AI-Enabled System Integration in Pharmaceutical Quality Control**

No. of pages: **97**

Uploaded to Moodle: **Yes**

Additional Info: **nil**

Date due: **24/08/2025**

Date submitted: **24/08/2025**

Plagiarism disclaimer:

I understand that plagiarism is a serious offence and have read and understood the college policy on plagiarism. I also understand that I may receive a mark of zero if I have not identified and properly attributed sources which have been used, referred to, or have in any way influenced the preparation of this assignment, or if I have knowingly plagiarised my work or allowed others to plagiarise my work.

I hereby certify that this assignment is my own original work, based on my personal study and/or research, it is all written in my own words and I have acknowledged all references and sources used in its preparation. I also certify that the assignment has not previously been submitted for assessment and that I have not copied in part or whole or otherwise plagiarised the work of anyone else, including other students.

I have also not used any third parties, AI tools or websites to generate any parts of my assignment.

Signed & dated: nikhila& 24/08/2025

Please note: Students MUST retain a hard / soft copy of ALL assignments as well as a receipt (issued as proof of submission).

AI-ENABLED SYSTEM INTEGRATION IN PHARMACEUTICAL QUALITY CONTROL

A thesis submitted in partial fulfilment of the requirements for MSc in Digital Transformation Life Science (QQI 9) Innopharma Faculty of Pharmaceutical Sciences Griffith College Dublin

Submitted By **Nikhila Mangalapilly Ramakrishnan**

Dissertation Supervisor: **Eucharía Esemuede**

September 2025

DECLARATION

I, Nikhila Mangalapilly Ramakrishnan, hereby affirm that the dissertation entitled “AI-Enabled System Integration in Pharmaceutical Quality Control,” submitted in partial fulfillment of the requirements for the MSc degree in Digital Transformation Life Science, is the product of my independent research.

I assert that this dissertation represents my original research, analysis, and conclusions, obtained through my own scholarly endeavor. All external sources of information, data, or ideas have been duly acknowledged through proper citation and referencing, in compliance with academic integrity standards.

I affirm that this dissertation has not been submitted, in whole or in part, for any other academic degree or professional certification. I hereby affirm that I have adhered to the ethical guidelines and regulations of my institution during the entirety of this research.

Signed: Nikhila Mangalapilly Ramakrishnan



Date: 23/08/2025

Supervisor Signature: Eucharia Esemuede



Date: 23/08/2025

ACKNOWLEDGEMENTS

I wish to convey my profound appreciation to my supervisor, Eucharia Esemuede, whose indispensable guidance and constant assistance were important during the development of this dissertation.

I wish to express my heartfelt gratitude to the professionals who generously imparted their expertise and offered crucial insights and data. Their collaboration was essential in guaranteeing the thoroughness of this study.

I express my gratitude to Innopharma Education and the faculty of Griffith College for their dedication to academic excellence and for fostering an enriching learning environment that has significantly contributed to my academic development.

I am deeply appreciative of my family and friends for their support and understanding during this academic endeavor. Their unwavering support has catalyzed motivation and inspiration, propelling me to strive for excellence in all my pursuits.

TABLE OF CONTENTS

DECLARATION.....	iii
ACKNOWLEDGEMENT.....	iv
List of Figures.....	viii
List of Tables.....	ix
List of Abbreviations.....	x
1. INTRODUCTION	1
1.1) Background and context	1
1.2) Problem statement.....	2
1.3) Research gap	2
1.4) Aim and rationale of the study.....	3
1.5) Aim and objectives	4
1.6) Structure of dissertation	5
2. LITERATURE REVIEW	6
2.1) An overview of conventional QC techniques	6
2.2) Problems with manual data entry and documentation	6
2.3) Fragmented systems and lack of interoperability	6
2.4) Regulatory and compliance burdens	7
2.5) Errors and deviations by humans	7
2.6) Restricted ability to monitor in real time	7
2.7) Challenges with data integrity and regulatory compliance.....	7
2.8) Limitations of traditional QC and the requirement for science-based methods	8
2.9) Real-time pharmaceutical quality control monitoring	8
2.10) AI-powered automated data validation.....	9
2.11) Analytical prediction in quality assurance.....	9
2.12) Combined effect on the efficiency of QC.....	9
2.13) AI tools in pharmaceutical quality control	10
2.14) Pharmaceutical quality control real-time monitoring.....	10
2.15) AI's contribution to reducing system fragmentation.....	11

2.16)	AI-powered integration of ERP, MES, and LIMS	11
2.17)	AI-powered interoperability and compliance	12
2.18)	AI and real-time data pipelines for connectivity in QC systems	13
2.19)	AI-powered process integration in the production of pharmaceuticals	14
2.20)	A case study of system integration.....	14
2.21)	Industry evidences	16
2.22)	Synthesis of reviewed literature.....	22
3.	RESEARCH METHODOLOGY.....	22
3.1)	The design of the methodology.....	23
3.2)	Testing of the design	24
3.3)	Application of the final methodological design.....	25
3.4)	Justification for the approach.....	26
3.5)	Compliance with the conceptual model.....	27
3.6)	Use of materials and chronological methods	28
3.7)	Ethical consideration.....	30
3.8)	Appendices and supplemental materials.....	30
4.	DATA ANALYSIS	31
4.1)	Introduction.....	31
4.2)	Quantitative (descriptive) analysis.....	31
4.3)	Qualitative (thematic) analysis	52
4.4)	Statistical analysis.....	62
5.	CONCLUSION AND RECOMMENDATION	65
5.1)	Summary of principal discoveries and consequences.....	65
5.2)	Comparisons between results and literature	67
5.3)	Academic and practical suggestions	68
5.4)	Constraints and contributions of the study.....	69
5.5)	Recommendations for additional research.....	70
5.6)	Conclusive reflection	70
6.	REFERENCE.....	71
	APPENDICES.....	75

LIST OF FIGURES

Figure 1: AI-Enabled Process Integration in Pharmaceutical Quality Control.....	1
Figure 2: Conceptual Integration of MES and ERP Systems.....	12
Figure 3: Four Types of Strategic Integration.....	19
Figure 4: Conceptual Framework.....	22
Figure 5: Role Confirmation.....	31
Figure 6: Manual Entry / Spreadsheet System.....	32
Figure 7: System Fragmentation / NO Automotion.....	33
Figure 8: Difficulty Accessing Real-Time QC Info from Equipment / System.....	33
Figure 9: Human Error in QC Causing Deviations/ Rework.....	34
Figure 10: AI Use in QC Processes.....	34
Figure 11: Real-Time Monitoring Availability.....	35
Figure 12: AI Data Checks & Anomaly Detection.....	36
Figure 13: Belief In Predictive Analytics.....	36
Figure 14: QC System Integration.....	37
Figure 15: AI-Driven System Communication.....	38
Figure 16: Automatic Test Result Transfer.....	38
Figure 17: QC Turnaround/ Accuracy Improvement.....	39
Figure 18: Reduction In Deviations/OOS Events.....	39
Figure 19: Formal AI Training for QC Staff.....	40
Figure 20: Established AI SOPs.....	41
Figure 21: Readiness To Expand AI in QC.....	41

Figure 22: Role Confirmation (QA)	42
Figure 23: Delays in Batch Record Approvals.....	43
Figure 24: Paper-Based or Manual QA Processes.....	43
Figure 25: Traceability or Audit Trail Problems.....	44
Figure 26: Use of AI in QA Work Flows.....	45
Figure 27: AI for Document Review or Deviation Management.....	45
Figure 28: Use of Real-Time Monitoring Tools.....	46
Figure 29: QA Systems Integrated with QC Data Sources.....	47
Figure 30: Access to Predictive Analytics.....	47
Figure 31: Improvements in QA Operations with AI.....	48
Figure 32: Improved Audit or Compliance Preparedness.....	49
Figure 33: Digital Transformation Plan with AI.....	49
Figure 34: SOPs or Guidelines for AI Use in QA.....	50
Figure 35: Need for AI Training or Skill Development.....	51

LIST OF TABLES

Table 1: Detailed Observations of Changes in QC Activities.....	52
Table 2: Benefits and Limitations of AI in QC.....	54
Table 3: QA Improvements.....	56
Table 4: QA Audit Improvements.....	58
Table 5: Benefits and Limitations of AI in QA.....	60

LIST OF ABBREVIATIONS

AI – Artificial Intelligence

CAPA – Corrective and Preventive Action

EMA – European Medicines Agency

ERP – Enterprise Resource Planning

FDA – Food and Drug Administration

GDP – Good Documentation Practice

GMP – Good Manufacturing Practice

IoT – Internet of Things

LIMS – Laboratory Information Management System

MES – Manufacturing Execution System

ML – Machine Learning

NLP – Natural Language Processing

OOS – Out-of-Specification

QA – Quality Assurance

QC – Quality Control

SOP – Standard Operating Procedure

AI-ENABLED SYSTEM INTEGRATION IN PHARMACEUTICAL QUALITY CONTROL

Nikhila Mangalapilly Ramakrishnan

ABSTRACT

This study examined the potential of artificial intelligence (AI) for enhancing system integration in pharmaceutical Quality Control (QC) operations, aiming to enhance efficiency, accuracy, and regulatory compliance. A mixed-methods approach was utilized, integrating quantitative survey analysis of QC and QA professionals with qualitative thematic coding of open-ended responses. Data from 84 industry participants were analyzed using descriptive statistics, binary coding, and frequency distribution via SPSS, facilitating the clear identification of AI adoption trends, operational advantages, and current obstacles. The results demonstrated substantial evidence of AI's impact on operational performance: 75% of participants indicated a decrease in deviations and errors, 66% noted enhancements in turnaround times, and over 60% recognized improvements in system integration and predictive analytics. Thematic insights emphasized significant enhancements, including expedited defect detection, automation of documentation, and enhanced audit preparation; however, obstacles such as elevated implementation costs, data quality requirements, and integration difficulties with legacy systems were identified. The results validate the hypothesis that AI-enabled systems markedly enhance quality control processes by reducing manual workloads, improving real-time monitoring, and strengthening compliance frameworks. The study concludes that although the integration of AI in pharmaceutical quality functions is progressing, success depends on overcoming infrastructural, training, and regulatory obstacles. Practical recommendations encompass the formulation of specific AI-specific Standard Operating Procedures, allocation of resources for workforce training, and implementation of incremental digital transformation strategies. This study provides empirical evidence regarding AI integration in pharmaceutical quality systems, establishing a basis for future research on expanding AI adoption in highly regulated industries.

Keywords: *Artificial Intelligence, Pharmaceutical Quality Control, System Integration, Digital Transformation, Regulatory Compliance, Predictive Analytics*

1. INTRODUCTION

1.1) BACKGROUND AND CONTEXT

The pharmaceutical products directly impact patient health and regulatory compliance; the industry is constantly under pressure to maintain the highest standards of product quality, safety, and efficacy. Because of their heavy reliance on manual inspections and batch-wise testing, traditional quality control (QC) systems are inadequate to handle the complexity of contemporary pharmaceutical manufacturing. These drawbacks include sluggish reaction times, human error vulnerability, and challenges in handling massive amounts of diverse data produced throughout the manufacturing process. These issues can be resolved with the help of AI technologies, especially machine learning and deep learning, which provide automated, precise, and quick quality evaluations that improve operational effectiveness and decision-making. (Rajesh and Elumalai, 2025). Traditional pharmaceutical quality control systems have several significant problems. Manual testing and inspection processes waste a lot of time and materials, which slows down production cycles and raises operating costs. Furthermore, more advanced monitoring and control systems are required due to the increasing complexity of drug formulations and manufacturing settings that cannot be supplied by conventional QC. The fragmented nature of data across different QC systems makes quality assurance even more difficult by hindering thorough analysis and seamless data transfer. (Mareana, 2024)

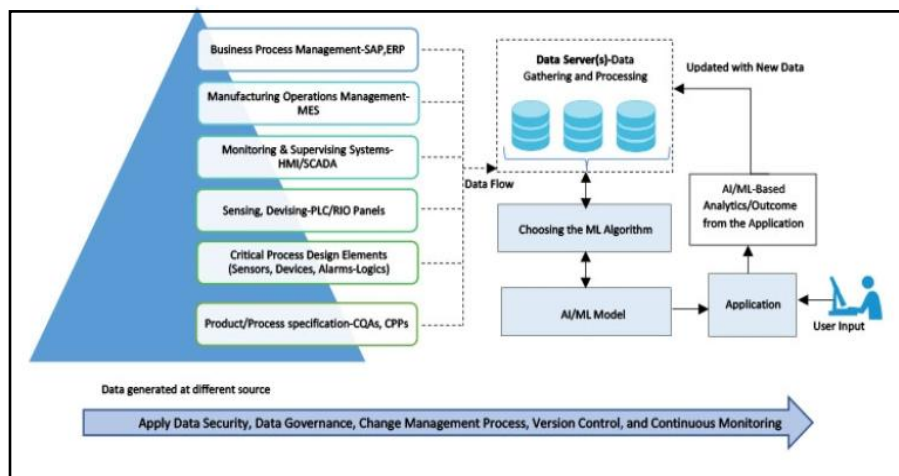


Figure 1: AI-Enabled Process Integration in Pharmaceutical Quality Control

Source: (Mussati *et al.*, 2025)

1.2)PROBLEM STATEMENT

The pharmaceutical industry continues to encounter significant obstacles to the widespread adoption of AI-enabled quality systems, despite the increase in research interest and new tools. These consist of a lack of clarity in governance structures, dependence on legacy technologies, fragmented QC and QA systems, and uncertainty regarding regulatory compliance. Predictive analytics, real-time monitoring, and automated data validation are several examples of isolated AI applications that have shown potential, but few businesses have been able to combine these technologies in a comprehensive way.

Furthermore, current case studies fail to provide strategic or scalable structures, instead concentrating more on technical demonstrations. Organizations aiming to meet strict GMP requirements while integrating AI throughout the entire QC process have limited options for guidance. Therefore, to enable the full-scale integration of AI tools in pharmaceutical QC and QA, a pragmatic, regulatory-aligned strategic framework is essential.

1.3)RESEARCH GAP

Conventional pharmaceutical quality control (QC) systems tend to have problems with fragmented data environments, manual processes, and limited real-time responsiveness. These challenges lower operational efficiency and raise the possibility of regulatory noncompliance. Although the literature recognizes these issues, it provides advice on how intelligent technologies, such as artificial intelligence (AI), can effectively and efficiently solve them on a large scale. In particular, there is an absence of thorough research on the practical ways in which AI-driven technologies like predictive analytics, automated data validation, and real-time monitoring can improve QC performance and data integrity. Additionally, even though AI can streamline data transfer and integrate disparate QC systems, current research frequently views system integration as a technical add-on rather than a strategic shift.

Even though a few case studies show quantifiable improvements in quality outcomes from the use of AI, they are dispersed and lack generalizable frameworks that might promote greater industry adoption. Furthermore, it is rare to find a single strategy designed specifically for the adoption of pharmaceutical AI that incorporates all of the current regulatory and strategic models, including QbD, PAT, and digital maturity frameworks. In order to fill these gaps, this study examines the

potential and difficulties of AI in QC and attempts to create a framework for integrated, AI-enabled pharmaceutical quality systems that is both strategic and compliant with regulations.

1.4) AIM AND RATIONALE OF THE STUDY

By facilitating real-time monitoring, automated data validation, predictive analytics, and system integration, artificial intelligence (AI) technologies offer solutions to these challenges. Critical quality parameters, including temperature, humidity, pressure, and pH, are continuously tracked by AI-powered real-time monitoring, which makes sure they stay within acceptable ranges and promptly notifies when deviations occur. This proactive approach allows effective corrective actions to address quality problems before they get worse (Birse, 2024a). By using AI's capacity to evaluate enormous datasets from various manufacturing stages, such as environmental monitoring and batch records, automated data validation can swiftly spot patterns and anomalies that might be missed by human review. This improves data integrity and compliance while also speeding up quality evaluations. (Klyushnichenko, 2025a)

AI's incorporation into pharmaceutical quality control also fits with the industry's larger move toward continuous process verification frameworks and Quality by Design (QbD). By evaluating data streams from various sources, such as sensors and laboratory information management systems (LIMS), artificial intelligence (AI) enables real-time process monitoring and control. This allows for the proactive detection of deviations and the prediction of possible quality risks before they materialize. By lowering batch failures and guaranteeing constant product quality, this capability facilitates the shift from reactive to more predictive and preventive quality control (Birse, 2024b). Pharmaceutical companies are encouraged to implement AI-driven quality systems within validated frameworks that satisfy strict regulatory requirements, as regulatory bodies like the FDA and EMA increasingly recognize the value of these systems (Niazi, 2025a). A fundamental AI capability is predictive analytics, which utilizes both historical and current data to anticipate possible quality risks and deviations in advance. Pharmaceutical companies can reduce batch failures, minimize recalls, and shorten time-to-market by implementing preventive measures in advance of issues like microbial contamination or equipment failures (Reddy, 2025). A significant development in the production of pharmaceuticals is the transition from reactive to predictive quality control.

Operational efficiency is further increased by using AI to integrate different QC systems. AI-enabled platforms can integrate various data sources, such as quality management systems (QMS) and process control systems, enabling smooth data transfer and comprehensive quality control. This integration enhances traceability, consistency, and regulatory readiness by supporting automated risk assessments, deviation management, and corrective and preventive actions (CAPA). Artificial intelligence (AI)-driven QMS tools use machine learning and natural language processing (NLP) to evaluate deviations, suggest remedial measures, and track resolution progress, speeding up investigations and lowering human error (Klyushnichenko, 2025b).

The enormous volume of data produced during the production of pharmaceuticals offers a unique opportunity to use AI to improve quality control. Automated defect detection, root cause analysis, and simplified compliance documentation are made possible by advanced AI algorithms, such as convolutional neural networks (CNNs) for image analysis and natural language processing (NLP) for documentation review. These features enhance traceability and audit readiness, which are crucial for regulatory inspections and product release decisions, in addition to lowering human workload and error rates (Birse, 2024c).

The application of AI in pharmaceutical quality control necessitates careful consideration of data quality, system validation, and regulatory compliance, despite these encouraging developments. Resolving issues like data silos, incompatibility with legacy systems, and algorithm transparency concerns requires strong governance frameworks and cross-functional cooperation. Therefore, to ensure sustainable adoption and ongoing improvement, a strategic framework for AI-enabled QC integration should include workforce training, data infrastructure improvement, technology selection, and regulatory alignment. (Niazi, 2025b)

1.5) AIM AND OBJECTIVES

AI-enabled system integration in pharmaceutical quality control represents a critical advancement for ensuring drug safety, efficacy, and regulatory compliance in an increasingly complex manufacturing environment. Artificial intelligence (AI) enables pharmaceutical companies to attain greater quality standards, operational efficiency, and agility by mitigating the drawbacks of conventional QC techniques through real-time monitoring, predictive analytics, automated data validation, and integrated quality management. The future of pharmaceutical quality control will

be greatly influenced by the strategic application of AI technologies, which will be backed by strong frameworks and industry cooperation.

The purpose of this research endeavor is to create a strategic framework for incorporating AI-enabled systems into environments related to pharmaceutical quality control (QC). The framework uses AI capabilities like predictive analytics, automated data validation, and system integration to increase operational efficiency, improve compliance, and reduce human error.

The specific objectives of the study are:

- To examine the problems that traditional pharmaceutical QC systems are currently facing.
- To evaluate the methods in which real-time monitoring, automated data validation, and predictive analytics can improve QC using AI technologies.
- To investigate how AI can be used to integrate various QC systems for smooth data transfer.
- To assess case studies from the industry that show measurable gains in quality control brought about by the use of AI.
- To provide a strategic framework for integrating AI-enabled QC systems in pharmaceutical environments.

1.6)STRUCTURE OF DISSERTATION

There are six major chapters in this dissertation:

- Chapter 1: Introduction: Provides background information on pharmaceutical quality control, the role of artificial intelligence (AI) technologies, the research gap, the study's goals and objectives, and the justification for it.
- Chapter 2: Literature Review: Examines previous research on traditional quality control issues, AI tools for data validation and real-time monitoring, system integration models, industry case studies, and strategic frameworks for implementing AI in regulated settings.
- Chapter 3: Research Methodology: Describes the research design, methodology, sampling strategy, data collection tools (such as surveys), and ethical considerations. It also covers how the methodology fits in with the goals of the study.

- Chapter 4: Chapter 4: Analysis of Data and Results – This chapter presents the survey findings via Quantitative (descriptive), Qualitative (thematic), and Statistical analyses, offering a thorough assessment of responses from QA and QC professionals.
- Chapter 5: Conclusion and Recommendations: Provides a summary of the study's findings, identifies its shortcomings, and makes suggestions for further study and real-world application of AI in pharmaceutical quality control systems.

2. LITERATURE REVIEW

2.1)AN OVERVIEW OF CONVENTIONAL QC TECHNIQUES

Manual procedures, paper-based records, and compartmentalized data systems are major components of traditional pharmaceutical quality control. Many pharmaceutical companies still use outdated legacy systems that are incompatible and rely on manual data entry, which greatly raises the possibility of human error. In a Good Manufacturing Practice (GMP) setting, these inefficiencies lead to decreased data integrity, increased deviation rates, and slower batch release times.(Yousfi, 2020)

2.2)PROBLEMS WITH MANUAL DATA ENTRY AND DOCUMENTATION

In QC labs, manual data entry results in inconsistent data capture, transcription errors, and challenging review procedures. These challenges are most significant in places where rigorous documentation and traceability are required for regulatory compliance. Batch release and regulatory submissions are frequently delayed when documentation is handled manually because batch record review becomes a bottleneck. Activities like unrecorded modifications, insufficient audit trails, and absent review signatures frequently compromise data integrity(Keezhadath and Amarapalli, 2025). These studies show that manual documentation is a bottleneck because of poor traceability and human error, both of which AI tools can effectively address.

While Yousfi (2020) focuses on legacy system inefficiencies, Keezhadath and Amarapalli (2025) emphasize documentation errors as central to delays. Together, these issues suggest systemic limitations in data integrity that AI may help resolve.

2.3)FRAGMENTED SYSTEMS AND LACK OF INTEROPERABILITY

The literature frequently addresses the fragmented nature of pharmaceutical data systems. QC tools, LIMS, MES, and ERP platforms frequently operate in silos, which results in redundant data

entry, poor data visibility, and inconsistent version control, according to (O'Connor *et al.*, 2025) Furthermore, (Rao, 2025) notes that this fragmentation greatly impairs traceability and real-time decision-making, especially in global manufacturing setups. Effective communication between systems makes it challenging to create end-to-end visibility from testing of raw materials to product release.

While interoperability is a key concern for both authors, Rao (2025) emphasizes the complexity of global manufacturing, an area where integrating AI could have the greatest benefits.

2.4) REGULATORY AND COMPLIANCE BURDENS

Regulatory speaking, conventional QC systems find it difficult to satisfy the changing requirements for data integrity set by organizations such as the FDA and EMA. According to (Sachdeva, 2024), ALCOA+ principles (Attributable, Legible, Contemporaneous, Original, and Accurate) are crucial for regulatory compliance, but legacy systems lack these features. It is more difficult to maintain version control, secure audit trails, or validate data workflows when paper-based or partially digital systems are used, which exposes businesses to compliance risks.

2.5) ERRORS AND DEVIATIONS BY HUMANS

Human error's effects on quality operations are also extensively studied. According to (Franchetti, 2024) Human error, such as inaccurate calculations, transcription errors, or missing documentation, is responsible for over 60% of deviations in QC procedures. The operational burden is increased by these errors, which also lead to more corrective and preventive actions (CAPAs) and a higher number of deviations and OOS (Out-of-Specification) results.

2.6) RESTRICTED ABILITY TO MONITOR IN REAL TIME

Real-time monitoring and alerts are not intended for traditional QC setups. This restriction slows down root cause analysis and decreases responsiveness to deviations. The (Cowman, 2018) claims that QC professionals rely on retrospective analysis when real-time insights are unavailable, which causes delays in interventions and frequently results in recurring problems. In addition to affecting quality, this responsiveness lag also affects production schedules and overall productivity.

2.7) CHALLENGES WITH DATA INTEGRITY AND REGULATORY COMPLIANCE

According to a recent review, one of the biggest challenges facing pharmaceutical quality control is ensuring compliance with continuously changing regulatory requirements. Businesses must

ensure compliance with Good Manufacturing Practices (GMP) and adapt to frequent changes in guidelines, thereby requiring constant investment in resources and training. A greater dependence on digital systems has also made data integrity crucial, increasing the possibility of data manipulation and breaches. To reduce these risks, strong data management systems and employee training are crucial because a lack of these measures could result in penalties from the government and jeopardize the safety of the product. Compliance for multinational corporations is made more difficult by differences in global regulations. (Santosh, 2025)

2.8) LIMITATIONS OF TRADITIONAL QC AND THE REQUIREMENT FOR SCIENCE-BASED METHODS

A review of the literature on pharmaceutical quality systems addresses conventional QC issues like relying excessively on end-product testing, which might not ensure consistent batch quality. Inconsistencies in sampling could result in batch rejection or undetected quality problems. The review highlights that one of the main causes of ongoing drug shortages is the pharmaceutical industry's sluggish rate of innovation and continuous improvement. To ensure quality and patient safety, it is suggested that establishing efficient pharmaceutical quality systems (PQS) that incorporate risk- and science-based approaches (such as ICH Q9, Q10, and Q12 guidelines) can allow for more flexible and timely management of product changes. (Ramnarine, 2021)

2.9) REAL-TIME PHARMACEUTICAL QUALITY CONTROL MONITORING

Pharmaceutical quality control has become a growing emphasis on real-time monitoring because it detects deviations, contamination, or anomalies during production immediately. (Utkarsha A. Wadighare and Swati P. Deshmukh, 2024) claim that machine learning algorithms can continuously analyze production data and identify shifts that are typically omitted during routine manual checks. This ongoing insight improves decision-making speed while lowering waste and product recalls. Furthermore, more effective control of Critical Quality Attributes (CQAs) can be achieved by integrating Process Analytical Technology (PAT) tools with real-time monitoring systems.

According to the European Pharmaceutical Review (Insights and Gadsby, 2023) Companies that implement real-time quality monitoring systems report more rapid investigation cycles and increased responsiveness. However, organizations are frequently unable to fully benefit from such monitoring systems due to interoperability limitations and inadequate system integration.

2.10)AI-POWERED AUTOMATED DATA VALIDATION

In QC procedures, manually validating data requires a lot of time and is prone to mistakes. An automated substitute that can identify transcription errors, flag outliers, and cross-check datasets is provided by AI-based validation systems. According to (Alizadehsani *et al.*, 2023) unstructured data, such as lab notes and batch records, can be interpreted by natural language processing (NLP) algorithms to validate entries instantly. This greatly reduces the batch release timeline and lessens the need for manual reviews. Additionally, (Simpson and Qasim, 2025a) highlight how AI can automate data review and documentation, lowering human labor costs and improving adherence to ALCOA+ guidelines. These systems enhance accountability and traceability by producing audit-ready logs in addition to validating data.

All of these results point to natural language processing (NLP) as a key technology for automating high-quality documentation. Simpson and Qasim demonstrate both operational and compliance value by concentrating on regulatory alignment, whereas Alizadehsani et al. prioritize unstructured data processing.

2.11)ANALYTICAL PREDICTION IN QUALITY ASSURANCE

Using both real-time and historical data, predictive analytics forecasts possible quality problems before they arise. The ability of this AI application to predict deviations, equipment failure, or batch inconsistency has made it prevalent in pharmaceutical quality control. Proactive interventions have been made possible by the successful prediction of sterility test failures by machine learning models trained on historical production and quality data (Andrianandrianina Johanesa *et al.*, 2024).

Similar success is reported by (Han and Tao, 2024a)with predictive models for estimating equipment degradation, which enables maintenance teams to address problems before they affect the quality of the final product. By improving risk-based decision-making, these analytics tools help strengthen Corrective and Preventive Action (CAPA) systems.

2.12)COMBINED EFFECT ON THE EFFICIENCY OF QC

Pharmaceutical QC operations can be modified by the combined use of automated validation, predictive analytics, and real-time monitoring. According to (Franchetti, 2024)Businesses that have implemented these AI tools have experienced significant enhancements in data integrity and

a 40% reduction in product release time. Real-time batch release, a crucial element of continuous manufacturing models, is also supported by these efficiencies.

However, research also identifies obstacles like resistance to change, low digital infrastructure, and high implementation costs. According to (Utkarsha A. Wadighare and Swati P. Deshmukh, 2024) a clear plan for system validation and workforce training is equally important for successful integration with advanced tools.

2.13)AI TOOLS IN PHARMACEUTICAL QUALITY CONTROL

Through automating complicated inspection procedures and analyzing enormous datasets from manufacturing processes, artificial intelligence (AI) has revolutionized pharmaceutical quality control (QC). Computer vision and machine learning algorithms, among other AI-powered systems, can currently:

- Automating data analysis allows for the early detection of quality problems by quickly spotting trends or abnormalities in batch records, environmental monitoring, and QC test results.
- Image and pattern recognition: Making sure visual quality standards are continuously fulfilled by using AI-driven computer vision to check product appearance, labels, and packaging for flaws.
- Root cause analysis: Using AI to examine intricate datasets and find structural causes of quality deviations so that remedial measures can be taken.
- Regulatory compliance includes minimizing human error, automating documentation and compliance checks, and making sure that changing regulations are followed.(Birse, 2024)

2.14)PHARMACEUTICAL QUALITY CONTROL REAL-TIME MONITORING

Consistent product quality and a rapid response to deviations during pharmaceutical manufacturing depend on real-time monitoring. Significant developments include:

- Use of sophisticated sensors and Process Analytical Technology (PAT): utilizing spectroscopic or chromatographic instruments to acquire critical quality attributes (CQAs) and process parameters (such as temperature, pH, and pressure) in real-time.

- Combining data management, visualization, and advanced analytics for ongoing process control is known as integration with cyber-physical systems.
- Application of deep learning and machine learning: Facilitating pattern recognition, feedback/feedforward process modifications, and multivariate analysis.
- Enabling Release Testing in Real Time (RTRT): Supporting Industry 4.0 initiatives for smarter manufacturing by enabling products to be released based on real-time data instead of conventional end-product testing(Wasalathanthria, *et al.*, 2020)

2.15)AI'S CONTRIBUTION TO REDUCING SYSTEM FRAGMENTATION

The fragmentation of digital systems is one of the most frequently raised obstacles to effective quality control. QC tools, data repositories, and execution systems often operate in silos, necessitating redundant manual data entry and reconciliation, as emphasized by(Han and Tao, 2024b). By facilitating automated data mapping and intelligent communication between disparate systems, artificial intelligence (AI) plays a crucial role in breaking down these silos. According to their research, AI-powered middleware and connectors can standardize and translate data formats between platforms, enhancing traceability and facilitating real-time data exchange.

2.16)AI-POWERED INTEGRATION OF ERP, MES, AND LIMS

Pharmaceutical companies using AI-integrated platforms have reported improved connectivity between their ERP, MES, and LIMS systems, according to the (Eckford, 2025) European Pharmaceutical Review. In addition to facilitating smooth data exchange, AI technologies allow intelligent automation across workflows. For example, when abnormal data is detected by LIMS, MES can initiate a deviation investigation. Data silos are removed by this interconnection, developing an ecosystem that is prepared for audits. Additionally, AI enables predictive data routing, in which machine learning algorithms identify the most effective information flow path based on past bottlenecks and production context. This is particularly crucial in adaptive manufacturing settings where dynamic quality control adjustments are required, dependent upon in-process controls.

The data silos previously mentioned by O'Connor et al. (2025) are addressed by these integration enhancements, indicating that AI not only makes connectivity easier but also makes a proactive quality culture possible.

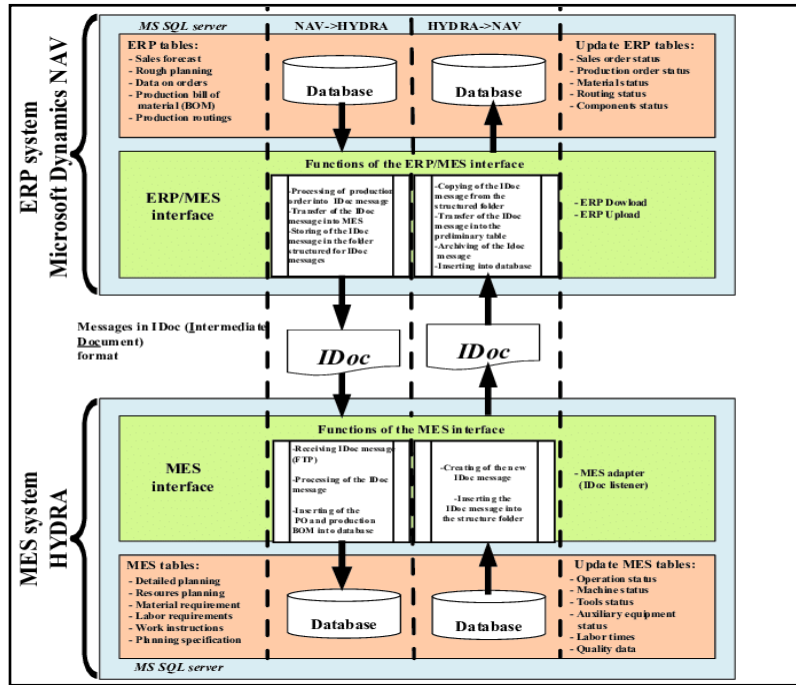


Figure 2: Conceptual Integration of MES and ERP Systems

Source : (Oman *et al.*, 2017)

2.17) AI-POWERED INTEROPERABILITY AND COMPLIANCE

Artificial intelligence (AI) integration into regulated industries like healthcare and pharmaceuticals necessitates not only technological advancement but also interoperability and regulatory compliance-supporting systems. A recent study by (Palaniappan *et al.*, 2024) examines the use of AI in a digital learning health system, highlighting its function in attaining compliance readiness and smooth data integration. The study focuses on healthcare informatics, but its conclusions are very applicable to pharmaceutical quality control (QC), where artificial intelligence (AI) must function across disparate systems while adhering to strict regulatory requirements.

The study describes how AI-enabled infrastructure can act as a data unifier, connecting data from various sources, including real-time monitoring systems, laboratory data, and electronic health records (EHRs). More accurate decision-making, longitudinal data tracking, and fully auditable automated processes are all made possible by this type of AI-driven interoperability, which is

essential for pharmaceutical quality control in accordance with Good Manufacturing Practice (GMP). Additionally, the authors stress the significance of creating AI systems that are transparent and clear, particularly when used in regulated environments.

The paper's focus on the governance and validation processes integrated into the AI lifecycle is one of its primary contributions. These include model performance monitoring, bias detection, and embedded auditing, all of which are essential for preserving regulatory compliance. This implies that AI systems for QC in the pharmaceutical industry should have integrated tools to support data integrity and audit-readiness in addition to being compatible with LIMS, MES, and ERP systems.

2.18) AI AND REAL-TIME DATA PIPELINES FOR CONNECTIVITY IN QC SYSTEMS

For integrating AI across QC systems, recent research highlights the significance of strong data pipelines:

- Real-time QC data ingestion, transformation, and storage from multiple sources are made possible by flexible data architectures.
- By processing and validating data at the point of origin, AI algorithms can ensure that only high-quality data is transmitted between systems.
- New QC tools can be easily scaled and integrated with modular pipeline design, supporting future upgrades without interfering with current workflows.
- To safeguard data during transmission and guarantee adherence to legal requirements, security protocols (like encryption and access control) are incorporated.

These methods make sure that information from analytical tools, batch records, and environmental monitoring is effectively combined and made accessible for AI-driven analysis, facilitating quicker decision-making and ongoing quality improvement.(Stout, 2025). These AI pipelines are made for modular scalability and data quality at source, addressing the underlying causes of batch variability in contrast to the conventional fragmented systems that were previously addressed.

2.19)AI-POWERED PROCESS INTEGRATION IN THE PRODUCTION OF PHARMACEUTICALS

A comprehensive examination demonstrates how AI is being used to improve data flow in pharmaceutical manufacturing and quality control:

- The extraction and harmonization of data from various QC systems, such as electronic batch records, manufacturing execution systems, and laboratory information management systems (LIMS), is rendered by machine learning and natural language processing.
- Predictive analytics and real-time monitoring facilitate the high-quality data to be transferred quickly between platforms, enabling dynamic process control and quick deviation handling.
- Industry-academia collaboration frameworks are encouraging the creation of AI tools that are compatible with legacy QC systems and modern digital platforms.
- AI-powered continuous improvement models assure that data integration procedures adapt to new technological advancements and legal requirements.

This integration improves transparency and traceability across the pharmaceutical value chain in addition to accelerating product release.(Mayuri.R.Mandlik *et al.*, 2025)

2.20)A CASE STUDY OF SYSTEM INTEGRATION

According to (Simpson and Qasim, 2025b)Pharmaceutical companies are using AI-powered platforms to automate the entire data lifecycle in quality control. According to their research, AI-supported system integration can reduce the workload associated with manual data reconciliation by up to 70%, which can result in a significant reduction in labor expenses and error rates. Additionally, NLP-based tools can automatically fill in appropriate fields in integrated databases and extract structured data from unstructured lab reports, improving the speed and accuracy of documentation. Building on this, Alizadehsani et al. (2023) explain that AI-enabled platforms can also pre-validate data before integrating it, ensuring compliance before it enters vital systems. Throughout the QC process, this is especially useful for maintaining the ALCOA+ principles (Attributable, Legible, Contemporaneous, Original, Accurate, plus Complete, Consistent,

Enduring, and Available). Only Alizadehsani et al. specifically connect integration to regulatory frameworks, despite the fact that both sources recognize efficiency gains. This suggests a possible difference in the way system performance enhancements are evaluated in the context of compliance.

The paper by Birse (2024) thoroughly examines how AI technologies can improve pharmaceutical operational procedures and quality assurance. It offers numerous real-world case studies that demonstrate how artificial intelligence (AI) is used throughout the pharmaceutical manufacturing lifecycle to enhance productivity, product quality, compliance, and predictive abilities.

The following are important AI use cases in pharmaceutical quality management:

- **Automated Data Analysis:** Compared to manual methods, AI algorithms can detect anomalies and quality deviations much more quickly by analyzing large datasets from manufacturing stages, including environmental monitoring, batch records, and quality control tests.
- **Real-Time Monitoring and Alerts:** Continuous AI-driven monitoring of vital parameters (such as temperature, humidity, and pressure) allows for real-time deviation detection and alerts, which in turn prompt corrective action to preserve product integrity.
- **Image and Pattern Recognition:** To ensure consistent visual quality, AI-powered computer vision examines product surfaces, packaging, and labeling to find flaws or nonconformities.
- **Predictive analytics and risk assessment:** AI models predict possible risks and deviations early in the process using historical manufacturing and quality data, enabling proactive interventions to avoid quality problems.

- **Root Cause Analysis:** AI analyzes intricate data from multiple sources to identify the underlying causes of quality issues, allowing for focused preventative and remedial measures.
- **Automation of Quality Documentation and Compliance:** AI facilitates the timely and accurate completion of quality records (batch documentation, deviations, and CAPA) and automates regulatory standard compliance checks.

2.21)INDUSTRY EVIDENCES

- **Pfizer: AI-Powered Batch Release and Data Review**

Pfizer has led the way in the pharmaceutical industry's digital transformation by utilizing AI to expedite QC data review procedures. (Anson *et al.*, 2023)state that Pfizer automated deviation detection and batch release documentation by integrating a machine learning model into its Manufacturing Execution System (MES). Real-time test results were continuously tracked by the AI tool, which compared them to verified specifications. Consequently, Pfizer reported a 30% decrease in human data-entry errors and a 40% reduction in the time required to review batch records.

The implementation enhanced audit readiness by logging all deviations in a time-stamped, searchable database, which facilitated quicker responses to regulatory inquiries. Additionally, the integration served as an AI-powered improvement to the current MES and LIMS infrastructures rather than necessitating a complete system replacement.

- **Novartis: Equipment Maintenance Using Predictive Analytics**

Predictive analytics has been employed by Novartis to improve the QC equipment. Using historical calibration and usage data,(Vora *et al.*, 2023) describe a pilot project that employed AI to predict probable instrument failures. With over 85% accuracy, the AI model was able to forecast maintenance requirements after being trained on years' worth of equipment performance logs.

By scheduling timely servicing, Novartis was able to minimize downtime during QC testing and prevent delays in product release due to this predictive maintenance model. A quantifiable decrease in OOS (Out-of-Specification) results resulting from instrument error and a 25% increase in laboratory uptime were both facilitated by the implementation.

- **Roche: Visual Inspection through Image Recognition**

The FDA's recent approval of Roche's digital pathology solution represents a major breakthrough in the application of artificial intelligence (AI) to visual inspection and image-based diagnostics. The solution helps pathologists more precisely and effectively detect and interpret tissue abnormalities by fusing AI-powered software with Roche's high-resolution imaging technology. This innovation is clearly applicable to pharmaceutical quality control (QC), even though it was initially created for clinical diagnostics. This is especially true in fields like particle detection, container integrity, and sterile product packaging that demand high-throughput, accurate visual inspection.

The digital pathology solution identifies healthy and abnormal tissue structures by using AI algorithms that have been trained on large histopathological datasets to identify intricate patterns. This deep learning-driven image recognition model can be applied directly to QC settings where automated systems need to identify small visual flaws on vials, ampoules, and syringes, like cracks, misalignments, or particulate matter. The case for comparable AI-based solutions in pharmaceutical manufacturing is further strengthened by the system's success in clinical validation and its capacity to satisfy strict regulatory requirements like FDA clearance.

Consistency is a major advantage of Roche's strategy. Despite their training and expertise, human visual inspectors are subject to subjectivity, fatigue, and variability. Image recognition software driven by AI offers reliable, repeatable inspection capabilities that significantly reduce false positives and missed detections. Additionally, these systems enable continuous, high-throughput inspection at a scale that is not possible with just human labor. Roche's solution, which combines hardware and software, also enables complete traceability and audit readiness, which are essential for pharmaceutical manufacturing and diagnostics. This FDA-approved innovation demonstrates the operational and regulatory viability of AI-driven image analysis in addition to being a technological accomplishment. It establishes a standard for the use of verified, highly accurate image recognition technologies in pharmaceutical quality control, which can either replace or supplement manual inspection procedures. Roche's success shows how AI can be incorporated into the larger quality ecosystem in a way that supports real-time release plans and data integrity standards (Roche, 2024)

- **GSK: Using Natural Language Processing to Document Compliance**

The use of Natural Language Processing (NLP) to expedite high-quality documentation has been studied by GlaxoSmithKline (GSK). (tn_admin, 2025)states that the NLP system was used to examine change control records and free-text deviations. The AI system used their QMS platform to classify documents, identify compliance risks, and extract important metadata into structured fields.

In addition to this automation, QA staff were able to review documentation more quickly and close CAPAs (Corrective and Preventive Actions) faster. In order to enable more focused preventive measures, GSK reported a 35% decrease in the amount of time spent handling documentation and enhanced visibility into recurring quality issues.

- **AI-Powered Cross-System Integration at AstraZeneca**

AstraZeneca enhanced interoperability between its ERP, MES, and LIMS platforms by implementing an AI-based middleware solution. How the AI platform mapped data relationships across systems and instantly detected inconsistencies is described by (Zaytsev, 2024). This made data transfer easier and ensured data consistency and accuracy across testing reports, inventory logs, and batch records.

AstraZeneca was able to reach real-time traceability from raw material testing to product release due to this system integration. The business reported a 20% overall decrease in product release schedules and a 45% improvement in the availability of QC data.

- **Strategic Integration Models and Digital Maturity**

According to (Salviotti *et al.*, 2019), achieving digital maturity in an organization includes strategic alignment across leadership, communication, workforce capabilities, and business model evolution. The process is not just about implementing technological advances. According to their extensive survey of 153 businesses, key enablers of digital maturity include top management's shared digital vision, efficient internal communication tactics, and investments in hiring or educating staff members with digital competencies. There is a strong correlation between these strategic factors and the successful implementation of digital transformation initiatives throughout the value chain. To evaluate maturity, the researchers use a value chain framework, showing that digital capabilities need to support and extend the core business functions of operations, procurement, IT infrastructure, and sales. In regulated environments such as pharmaceutical quality control (QC), these

insights provide useful information. To ensure operational efficiency and compliance, a seasoned digital organization is better equipped to strategically integrate AI systems. The study emphasizes the significance of organization-wide engagement and leadership-driven digital vision in moving from dispersed digitization initiatives to integrated, value-generating digital ecosystems.

The focus on leadership and cross-functional alignment is particularly pertinent for pharmaceutical QC, where regulatory barriers make unified strategies even more crucial, even though this study concentrated on general digital maturity. This strategic maturity offers a roadmap for the scalable adoption of AI in contrast to the fragmented systems previously discussed.



Figure 3: Four Types of Strategic Integration

Source : (Jeong *et al.*, 2014)

- **Validation and Compliance: AI in GMP Environments**

The use of artificial intelligence (AI) in pharmaceutical manufacturing presents new difficulties for the conventional validation frameworks mandated by Good Manufacturing Practice (GMP) laws. Predictability, reproducibility, and auditability are major concerns raised by the probabilistic and adaptive nature of AI models, especially those based on machine learning, as reported by (Niazi, 2025). Conventional validation models, like the V-model for static software systems, are frequently insufficient for AI systems that change

over time. The authors suggest hybrid validation techniques, which are supported by thorough lifecycle documentation and ongoing performance monitoring, and comprise both AI components and fixed, rule-based controls. Authors add that risk-based validation techniques, strong data governance, and transparent algorithm development are necessary for incorporating AI into GMP environments. They stress that AI tools must be validated using acceptance criteria that are predetermined and in line with regulatory expectations, as well as meet data integrity standards like ALCOA+. According to both studies, cross-functional cooperation and early regulator engagement are essential for the effective implementation of AI in pharmaceutical quality systems. The complex nature of implementing AI in GMP settings is reflected in this multi-layered validation approach. However, smaller businesses with a less advanced digital infrastructure might find it difficult to implement in practice.

The earlier concerns expressed by Sachdeva (2024) regarding the insufficiency of legacy validation systems for contemporary compliance are directly addressed by this hybrid validation approach.

- **QbD, or quality by design, and PAT, or process analytical technology**

Process Analytical Technology (PAT) and Quality by Design (QbD) are fundamental methods utilized in modern pharmaceutical manufacturing that are intended to improve process comprehension and product quality. According to (Kim *et al.*, 2021), QbD allows manufacturers to incorporate quality into products rather than depending only on end-product testing by incorporating risk management and statistical control into the initial stages of drug development. The authors clarify that PAT tools, which enable real-time monitoring and control during manufacturing, can be used to efficiently manage critical quality attributes (CQAs) and process parameters.

According to the paper, PAT employs technologies such as automation, chemometrics, and spectroscopy to record process variability and ensure constant product quality. In conjunction with QbD, it lowers the possibility of batch failures and enables continuous manufacturing. To improve predictive control and decision-making, the authors support integrating AI and data analytics into the QbD-PAT framework. This paper emphasizes the practical viability and regulatory alignment of integrating AI into current QbD and PAT

infrastructures for improved compliance and quality outcomes in the context of AI-enabled quality systems.

This highlights the importance of AI-enabled frameworks that encourage continuous process monitoring and support the broader move toward preventive quality strategies that Niazi (2025a) previously highlighted.

- **The Function of Cross-Functional Teams and Governance**

Multidisciplinary supervision and organized governance are essential as artificial intelligence (AI) becomes more and more integrated into pharmaceutical operations. According to the International Society for Pharmaceutical Engineering (Altrabsheh *et al.*, 2022), AI governance frameworks need to be specifically designed to function within the controlled parameters of Good Manufacturing Practice (GMP). The article highlights the lifecycle management of AI systems, from model development and validation to deployment, monitoring, and continuous improvement, by establishing a governance model that is centered on Quality Assurance (QA). A key takeaway is the necessity of cross-functional teams that include quality assurance, regulatory affairs, data scientists, IT, and operational leads. These teams ensure that AI initiatives are both scientifically robust and compliant with regulatory expectations. The article outlines how such teams collaboratively define acceptable use cases, establish data integrity standards, and build audit-ready documentation. Notably, governance is portrayed not as a barrier to innovation but as a structured enabler that bridges technical capabilities with pharmaceutical compliance standards.

Cross-functional teams comprising operational leads, data scientists, IT, regulatory affairs, and quality assurance are essential. These organizations ensure that AI projects meet regulatory requirements and have a solid scientific foundation. The article describes how such teams work together to create documentation that is audit-ready, define acceptable use cases, and set data integrity standards. Additionally, governance is presented as an organized facilitator that connects technical capabilities with pharmaceutical compliance standards rather than as an obstacle to innovation. Cross-functional governance frameworks reduce risks and encourage responsible AI adoption by encouraging shared accountability and open decision-making. This article emphasizes how important

governance and cross-functional cooperation are for pharmaceutical companies seeking to scale AI across the quality system.

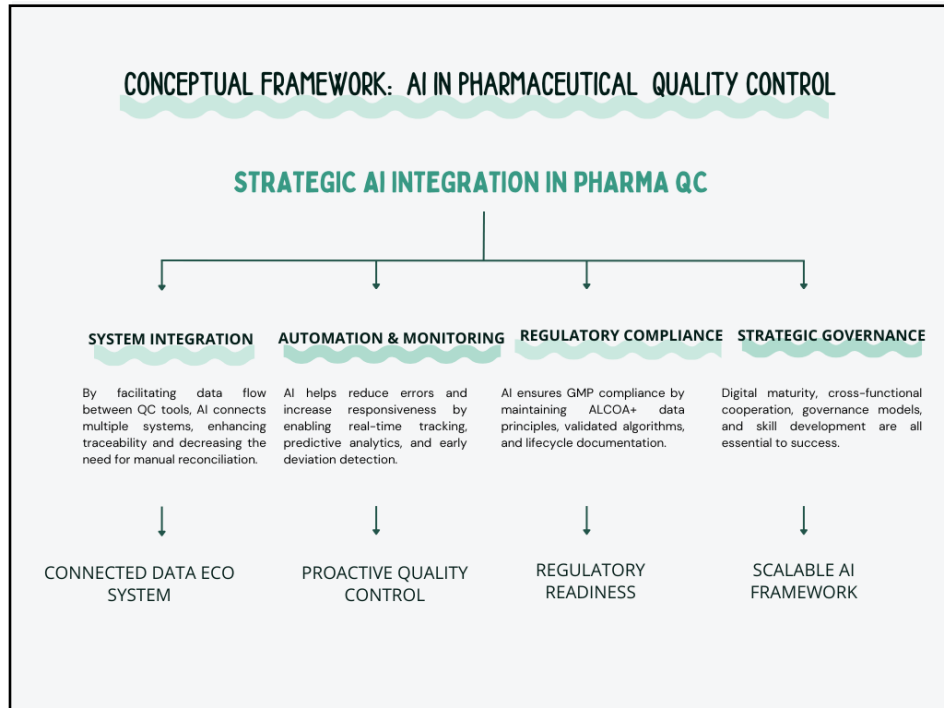


Figure 4: Conceptual Framework

2.22)SYNTHESIS OF REVIEWED LITERATURE

All of the literature agrees that traditional QC systems are inefficient and emphasizes how AI can assist in overcoming these issues. But the majority of research stays compartmentalized, either presenting case studies without providing broadly applicable strategic models or concentrating only on particular technologies, such as predictive analytics. There are also contradictions: some writers portray AI as a developed solution that is prepared for integration, while others suggest the challenges presented by legacy systems and regulations. A clear deficiency is the absence of all-encompassing frameworks that incorporate AI into data management, validation, and real-time quality control by GMP. This study proposes a comprehensive, regulatory-aligned AI integration framework for pharmaceutical quality control to close this gap.

3. RESEARCH METHODOLOGY

This study examines the strategic integration of AI-enabled systems in pharmaceutical Quality Control (QC) and Quality Assurance (QA) using a qualitative mixed-methods approach. This

approach was selected in order to record quantifiable trends as well as a deeper understanding of how experts respond to the possibilities and challenges offered by AI in regulated environments.

Due to the exploratory nature of the study, the main method of gathering data was online surveys. Both open-ended follow-up questions and closed-ended yes/no questions were included in these surveys in order to obtain comprehensive qualitative insights and spot trends. To reflect their different roles within pharmaceutical quality systems, two sets of surveys were created: one for QA professionals and one for QC professionals. The survey questions were formulated in accordance with the conceptual framework and research objectives. Predictive analytics, system integration readiness, current AI technology use, traditional QC challenges, and compliance experiences were among the main topics covered. The research supervisor was consulted during the review and refinement of the survey to guarantee its logical flow, clarity, and relevance.

Purposive sampling was used to choose participants, who included data reviewers, validation specialists, QC analysts, and QA officers with at least a year of pharmaceutical industry experience. Cochran's formula was used to determine the sample size, which resulted in a target of 126 participants to guarantee statistical validity at a 95% confidence level and a 5% margin of error. Online distribution of the survey was done through academic networks and professional sites like LinkedIn.

3.1)THE DESIGN OF THE METHODOLOGY

This study's methodological design was based on a cross-sectional survey strategy that was modified for a qualitative mixed-methods approach. The main objective was to assess how well AI-enabled systems were integrated into pharmaceutical Quality Control (QC) and Quality Assurance (QA) settings. The study used two different but parallel surveys to ensure the accuracy and relevance of responses because it recognized the different operational roles, data responsibilities, and decision-making structures in QA and QC.

The five main research objectives were directly reflected in the thematic sections of the surveys. These sections contained the following:

- The difficulties with conventional QC/QA systems
- AI application in high-quality workflows

- Integration of systems and data flow
- Evidence of quantifiable influence
- Preparedness for the strategic adoption of AI

A role-confirmation question was asked at the start of each survey to ensure that the respondent was in the appropriate professional group (either QC or QA). This was necessary to guarantee that the information gathered was relevant and accurate in its context. In order to capture complex experiences and perceptions, each section then included both closed-ended questions (yes/no, multiple choice) and open-ended follow-up prompts. While the open-ended questions gave respondents the opportunity to go into further detail about particular difficulties, advantages, and organizational procedures related to AI adoption, the closed-ended items were intended to spot patterns and trends throughout the participant pool. The survey tool was created with Google Forms, a popular and easy-to-use platform that supported desktop and mobile devices. Additionally, Google Forms allowed for automated response gathering and export into analysis programs (such as Google Sheets and Excel), preserving data accuracy and efficiency.

3.2) TESTING OF THE DESIGN

In cooperation with the research supervisor, the survey instrument underwent a systematic internal review process, even though a full-scale pilot survey with industry professionals was not practical due to time constraints and participant availability. The design needed to be comprehensible and practical for working professionals in a regulated industry, while also meeting academic standards.

Key areas that were the focus of the review process were:

- Language clarity and accessibility: A few of the first questions contained technical terms that might have been interpreted incorrectly. In order to make these more role-appropriate and neutral, they were revised. For example, the phrase "cross-platform AI integration" was changed to "AI use between systems like ERP, MES, and LIMS."
- Flow and length: According to preliminary feedback, the quantity of questions may discourage people from completion. As a result, some unnecessary or redundant items were eliminated or streamlined. In order to encourage more detailed responses without making the fatigue worse, follow-up questions were made optional.

- Logical sequencing: The questions were rearranged to make sense and move from identifying current problems to examining future preparedness and enhancements.
- Role confirmation filter: To lower the possibility that respondents would fill out the incorrect version of the survey, a clear role-identification question was included at the very beginning. However, some mismatched responses continued to occur. In order to handle this, data cleaning techniques were designed during the analysis stage to take potential misalignment into consideration.

The survey was also tested informally with academic colleagues and peers, who offered feedback on its flow, readability, and interpretation. Before the final launch, all modifications were lastly recorded and discussed with the supervisor.

3.3)APPLICATION OF THE FINAL METHODOLOGICAL DESIGN

The online survey was implemented through Google Forms, which was selected due to its user-friendliness, cross-platform compatibility, and real-time response collection and export capabilities.

Two distinct but structurally related survey forms were made, one for each professional group, in accordance with the study's dual focus on quality assurance (QA) and control (QC). The thematic coverage of both surveys remained consistent due to this division, which ensured that respondents were only asked questions that were important to their field. The informed consent section of each form was preceded by an explanation of the study's purpose, confidentiality guarantee, expected time commitment, and voluntary nature of participation. The survey was distributed via professional networks like LinkedIn, pharmaceutical industry networks, and academic channels in order to effectively manage data collection. Purposive sampling was used, with a focus on participants who had worked in QA or QC for at least a year. This guaranteed the collected insights were based on real-world experience in regulated settings.

Based on the conceptual framework and research objectives, each survey had a logical and thematic structure:

Section 1: Traditional Quality Systems Difficulties

In line with the study's first objective, the questions examined human error, audit trail gaps, traceability issues, and the limitations of manual processes.

Section 2: AI Tool Utilization

The use of AI technologies (such as machine learning and natural language processing) in real-time monitoring, predictive analytics, and existing workflows was all covered in this section.

Section 3: Integration of Systems

The questions here centered on how AI connects QC systems like ERP (Enterprise Resource Planning) platforms, MES (Manufacturing Execution Systems), and LIMS (Laboratory Information Management Systems). This was aligned with Goal 3.

Section 4: Proof of Progress

Participants were questioned about whether they had noticed quantifiable advantages such as faster review times, fewer mistakes, or more efficient batch release procedures.

In order to expand the dataset, open-ended questions were important throughout the survey. These responses were crucial in revealing opportunities and obstacles unique to the context that might not be revealed by structured questions. This study did not use any formal interviewing techniques. However, the open-ended questions provided narratives in written form, providing rich qualitative information comparable to that of interviews. Additionally, by allowing autonomous participation, this method improved accessibility and reduced participant burden.

3.4) JUSTIFICATION FOR THE APPROACH

Given that the dataset included both structured and narrative responses, a hybrid analytical approach that combined thematic qualitative analysis with basic quantitative summarization was used.

Quantitative Information

Descriptive statistics were applied to multiple-choice and closed-ended Yes/No questions. This involved performing the following calculations:

- Frequencies of responses
- The percentages of every option
- Comparisons of the responses from QA and QC

Patterns such as the proportion of QC professionals who currently use real-time monitoring tools versus those who intend to do so were revealed by these statistics. Despite the lack of inferential statistical testing, the descriptive data offered a useful summary of organizational preparation, adoption trends, and current issues.

Qualitative Information

Thematic coding was used to analyze open-ended responses using a grounded theory methodology. Through doing this, themes were able to naturally develop from the data while remaining rooted in the conceptual framework that was previously established in the dissertation.

Among the thematic categories were:

- Benefits of AI that are perceived, such as "faster release" and "reduced human error"
- Constraints or issues (such as "cost," "system compatibility," or "lack of training")
- Challenges with compliance
- Recommendations for improvement.

3.5) COMPLIANCE WITH THE CONCEPTUAL MODEL

The ideas addressed in the conceptual framework, which is closely linked to both the quantitative and qualitative analyses, include:

- AI tools (predictive analytics, natural language processing, and machine learning)
- Improvement of QC (automation, real-time monitoring)
- Aspects of Regulation and Compliance
- Readiness of the Organization
- Feedback loops (benefits, obstacles, and perceptions)

This ensured consistency between the literature, survey structure, and the final findings.

3.6)USE OF MATERIALS AND CHRONOLOGICAL METHODS

This section describes the precise materials used in the study, the instruments used to gather and analyze data, and the steps taken throughout the methodology. Every element was closely linked to the conceptual framework and research goals of the study, ensuring consistency throughout the phases of design, implementation, and interpretation.

1. Survey Tools

A structured online survey was the main instrument used to gather data for this study. It was designed particularly to investigate AI-enabled system integration in pharmaceutical Quality Control (QC) and Quality Assurance (QA) settings. Two different surveys were created and distributed, one specifically for QC professionals and one for QA professionals, due to the unique nature of QC and QA roles in pharmaceutical operations.

A role-confirmation question was asked at the beginning of each survey to make sure respondents were filling out the right version. The four main thematic sections that followed were in perfect accord with the conceptual framework and the research objectives:

- Traditional QC/QA process challenges
- Current applications and the potential of AI technologies (such as NLP, machine learning, and real-time monitoring)
- Data transfer and system integration across platforms like ERP, MES, and LIMS
- Strategic preparation and noticeable advancements following the adoption of AI

A combination of open-ended follow-up prompts that allowed participants to elaborate on their experiences, observations, and opinions, as well as closed-ended questions (such as multiple choice and Yes/No) that allowed for statistical trend identification, was included in the surveys. The qualitative mixed-methods approach was supported by this dual-question format, which balanced deeper, narrative insights with numerical trend analysis.

2. Tools and Platforms for Data Collection

The surveys were conducted using Google Forms, a cloud-based application chosen for its user-friendliness, cross-platform (desktop and mobile) compatibility, and safe real-time data gathering

capabilities. Google Forms supported informed consent at the outset of the survey and allowed for automatic timestamping and response validation.

When survey responses were gathered, they were automatically saved in Google Sheets and then exported to Microsoft Excel for examination. These platforms made it possible to efficiently code, filter, and organize both qualitative and quantitative responses. All data were kept in a safe, encrypted cloud storage system by ethical research guidelines and GDPR compliance.

3. Selection and Calculation of Sample Size

Using Cochran's formula, the sample size was determined with a 5% margin of error and a 95% confidence level. A target sample size of 126 participants was determined by this calculation, and 84 valid responses were gathered and incorporated into the analysis.

A purposive sample approach was used to find participants. Professionals who had worked in QA or QC for at least a year in the pharmaceutical sector were eligible to respond. The survey was shared via academic communities, professional networks, and social media sites like LinkedIn, where business professionals are likely to work together.

4. Chronological Flow of Methodology

- **Survey Design:** The conceptual framework and the five primary research objectives served as the foundation for the survey's design. The questions were modified to achieve a balance between accessibility and technical accuracy.
- **Supervisor Review and Revisions:** After reviewing a draft of the survey, the academic supervisor recommended changes to improve thematic flow and clarify the vocabulary.
- **Peer Testing (Informal Validation):** To find problems with readability, technical errors, and logical sequence, academic peers tested the updated survey. Response options were slightly modified in response to this feedback (e.g., adding “Not Sure” or “Partially” to certain items).

- **Survey Deployment:** Completed questionnaires were made available online. Informed consent was necessary prior to submission, and participation was entirely voluntary. The time frame for gathering the data was approximately three weeks.
- **Data Sorting and Cleaning:** Following data collection, responses were examined for correctness and pertinence. Responses were reviewed during the data sorting phase to make sure they matched the intended survey version. To maintain the dataset's integrity and relevance, entries with incomplete or mismatched role selection have been identified and removed.
- **Data Analysis:** Descriptive statistics, such as frequency counts and percentages, were used to examine closed-ended responses. Thematic coding was applied to open-ended responses, and the resulting themes were assigned back to the conceptual framework.
- **Synthesis and Interpretation:** The findings were interpreted in light of the study's goals and strengthened by knowledge obtained from the literature review. As a result, it was easier to create a strategic framework for integrating AI into pharmaceutical quality systems.

3.7) ETHICAL CONSIDERATION

Standard ethical guidelines were applied in this study. Every participant provided their informed consent at the start of each survey after receiving complete details about the study's objectives, the voluntary nature of participation, and the safeguards in place to protect their data. No personally identifiable information was gathered, and all answers were safely saved on encrypted cloud storage. While this study did not require formal institutional ethics approval, the research supervisor reviewed and approved the methodology and instruments internally to ensure ethical compliance.

3.8) APPENDICES AND SUPPLEMENTAL MATERIALS

To promote the research's openness and reproducibility, the following resources have been added to the appendices:

- Complete survey instruments (QA and QC versions).
- Cochran's formula for calculating sample size.
- Sample thematic categories and coding framework for qualitative analysis.
- Ethical declaration and consent form template.
- An anonymized data sample and Google Sheets structure

IBM SPSS Statistics software was utilized to process the closed-ended responses, generate descriptive statistics, and facilitate trend identification in order to analyze the quantitative data. This made it possible to handle data accurately and export results for interpretation in the form of frequency and percentage. Furthermore, Tableau was used to create interactive dashboards and data visualizations, including heatmaps and bar charts, that helped to make the patterns and conclusions in the dataset easier to understand. These resources improved the research outputs' visual clarity and analytical accuracy.

4. DATA ANALYSIS

4.1)INTRODUCTION

This section provides a comprehensive analysis of QC and QA survey data, incorporating quantitative, qualitative, and statistical methods, including frequency distributions, binary coding, and thematic insights, to assess the influence of AI integration on quality processes.

4.2)QUANTITATIVE (DESCRIPTIVE) ANALYSIS

i QUALITY CONTROL (QC) SURVEY – DESCRIPTIVE ANALYSIS

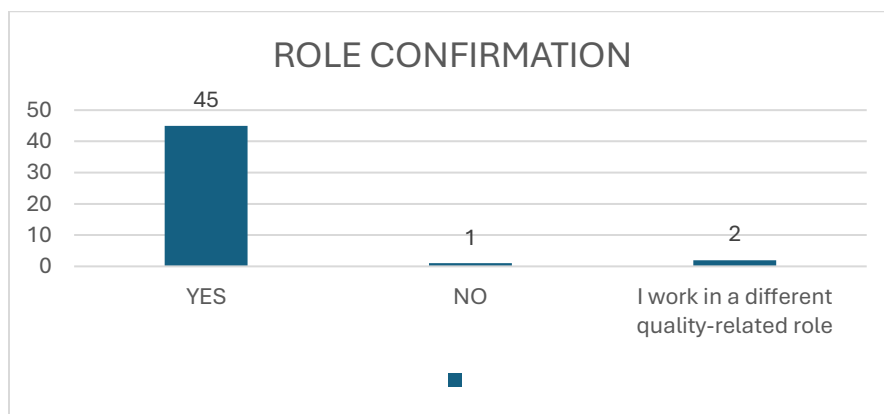


Figure 5: Role Confirmation

A distribution of respondents' affirmation of their role in Quality Control (QC) is shown in the first graph. The target audience of the survey and the actual respondents were highly aligned, as 45 participants, or 94% of the total, confirmed that they are currently employed in QC roles. Even though two participants (4%) reported working in various quality-related roles, only one participant (2%) claimed not to work in QC. Since the data primarily represent the intended professional group, this high percentage of QC role confirmation improves the validity and applicability of later survey findings.

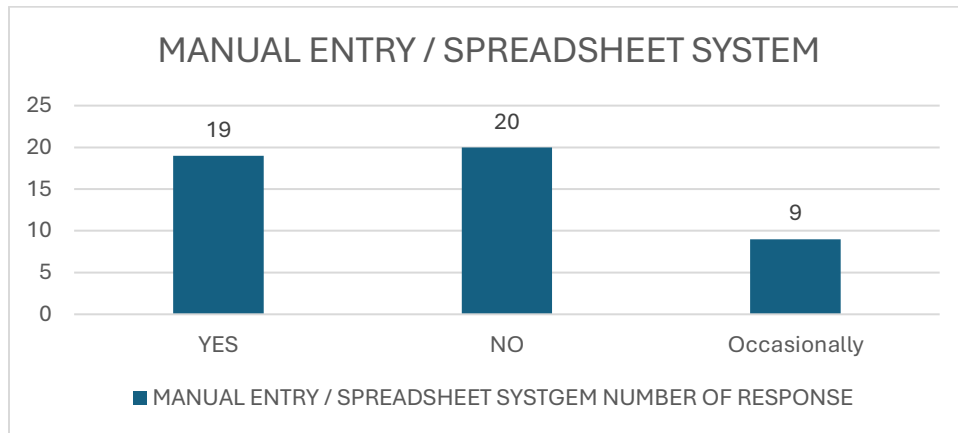


Figure 6: Manual Entry / Spreadsheet System

The graph displays the experiences of participants in their Quality Control (QC) procedures using spreadsheet or manual entry systems. Of those surveyed, 19 (39.6%) acknowledged using these systems on a regular basis, while 20 (41.7%) reported not using them. Furthermore, nine respondents (18.8%) said they occasionally used spreadsheets or manual entry. A transitional phase in QC operations is suggested by the nearly equal distribution of "Yes" and "No." While some organizations continue to use traditional data management methods, others have shifted to more automated or digital solutions, and a smaller group is using a hybrid approach.

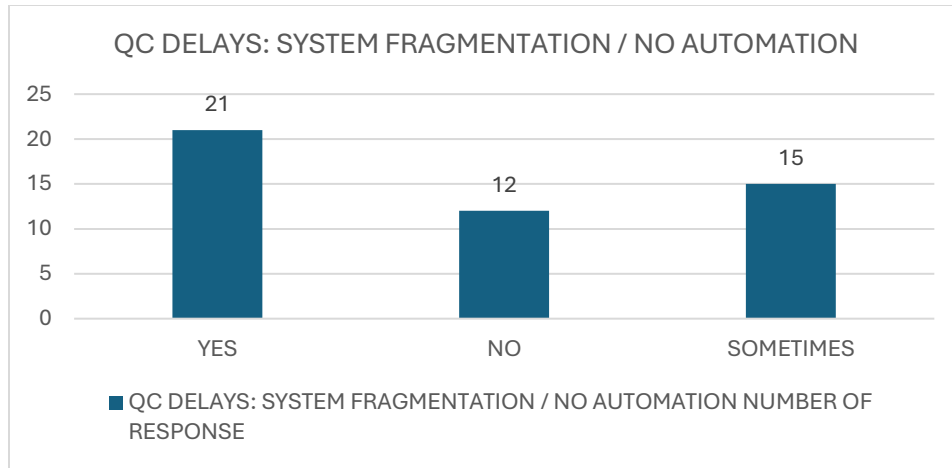


Figure 7: System Fragmentation / NO Automotion

The graph shows respondents' opinions regarding the relative importance of system fragmentation and automation in causing Quality Control (QC) delays. Twelve respondents (25.0%) disagreed with the statement that these factors contribute to delays, whereas twenty-one participants (43.8%) agreed. Notably, 15 respondents (31.3%) said that these delays only happen occasionally. While almost half of the respondents report regular delays brought on by fragmented or non-automated systems, a significant number report occasional delays, indicating that process integration and automation levels vary within QC environments.

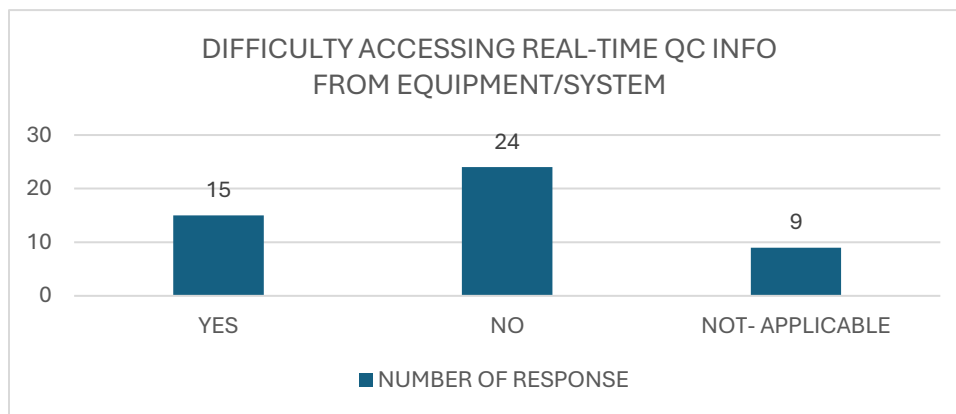


Figure 8: Difficulty Accessing Real-Time QC Info from Equipment / System

The graph displays the experiences of the respondents who had trouble getting real-time Quality Control (QC) data from systems or equipment. While 24 participants (50.0%) reported no problems, 15 participants (31.3%) reported encountering such challenges. Additionally, nine respondents (18.8%) chose "Not Applicable," indicating that their roles or procedures might not

be affected by real-time access. The findings show that although half of the respondents have sufficient access to real-time QC data, a sizeable percentage still face obstacles that could hinder prompt decision-making and overall process effectiveness in specific QC settings.

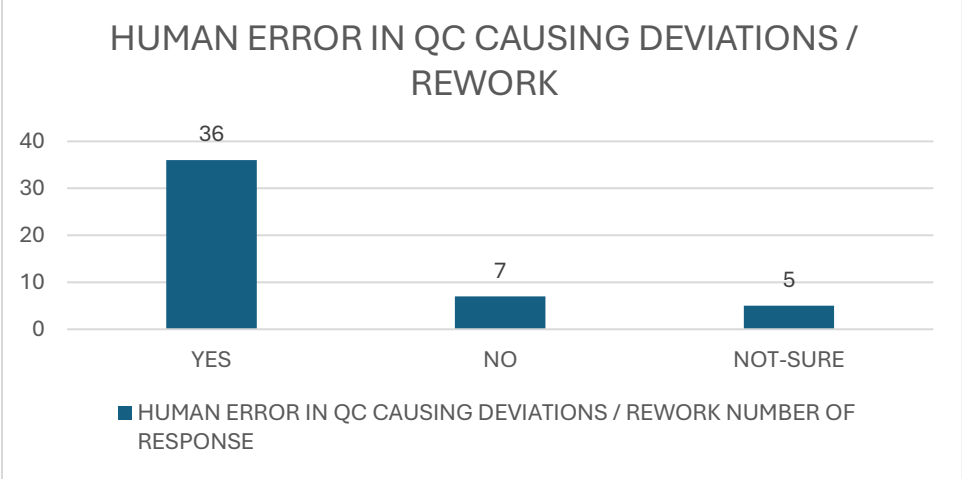


Figure 9: Human Error in QC Causing Deviations/ Rework

Respondents' opinions regarding whether human error in Quality Control (QC) results in deviations or rework are highlighted in the graph. The vast majority of participants, 36 (75.0%), agreed that these mistakes are a contributing factor to these problems. On the other hand, 5 respondents (10.4%) were unsure, and 7 respondents (14.6%) disagreed. The high proportion of yes answers highlights the important role that human factors play in quality control procedures, indicating that more training, process standardization, or automation may be required to lower the possibility of deviations and expensive rework brought on by human error.

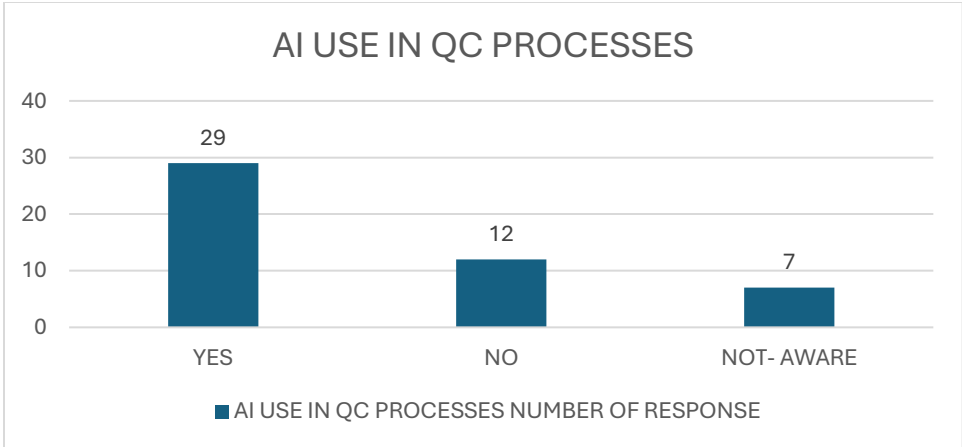


Figure 10: AI Use in QC Processes

The graph displays the knowledge and application of artificial intelligence (AI) in Quality Control (QC) procedures among the respondents. In their QC activities, 29 participants (60.4%) acknowledged using AI, whereas 12 respondents (25.0%) said they never utilized AI. 7 respondents (14.6%) also said they were unaware of the idea that AI was being used in their processes. The majority of affirmative responses point to an increasing use of AI technologies in QC settings, but the considerable percentage of non-users and those who are not aware of them emphasizes an uneven integration and differing degrees of technological advancement amongst organizations.

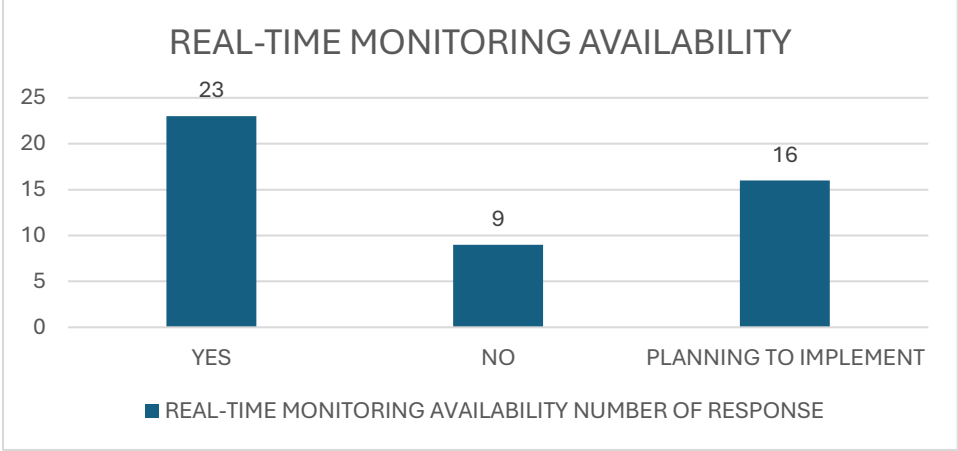


Figure 11: Real-Time Monitoring Availability

The graph illustrates how Quality Control (QC) procedures can be monitored in real time. Nine participants (18.8%) said they lacked real-time monitoring systems in place, whereas twenty-three respondents (47.9%) confirmed that they perform. Remarkably, 16 respondents (33.3%) said they intended to use real-time monitoring eventually on. Nearly half of the participants are already utilizing this technology, and a sizable portion are getting ready for integration, according to the data, which indicates a strong adoption trend in the industry toward improved process visibility and quicker decision-making through real-time data access.

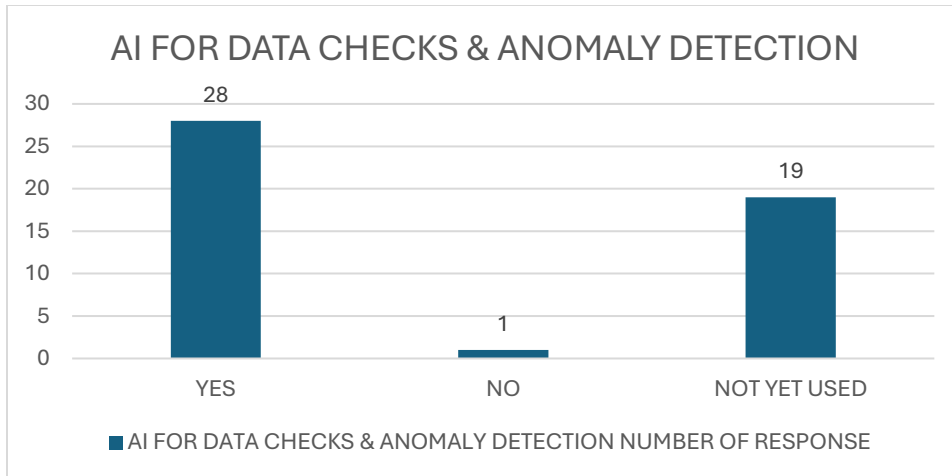


Figure 12: AI Data Checks & Anomaly Detection

The graph shows how Artificial Intelligence (AI) is used in Quality Control (QC) to check data and identify anomalies. Only 1 respondent (2.1%) stated that AI was not utilized at all, whereas 28 respondents (58.3%) stated that AI is currently being used for these purposes. Furthermore, 19 participants (39.6%) reported that their processes do not currently use AI for this purpose. AI's increasing role in improving data accuracy and detecting deviations is highlighted by the high adoption rate among over half of the respondents, while the substantial "not yet used" group suggests possibilities for broader adoption.

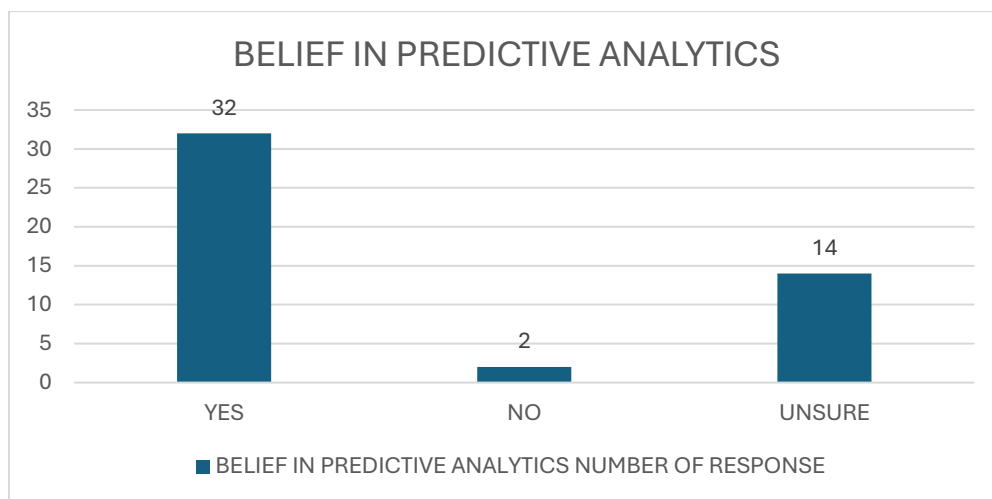


Figure 13: Belief In Predictive Analytics

The graph displays the respondents' opinions regarding the usefulness of predictive analytics for QC. The majority of participants, 32 (66.7%), stated they were confident in predictive analytics,

whereas only 2 respondents (4.2%) disagreed. Regarding its potential, 14 participants (29.2%) were also uncertain. Although the significant "unsure" group emphasizes the need for increased awareness, education, and substantiated case studies to highlight predictive analytics' useful advantages and dependability in real-world applications, the results show strong overall optimism toward predictive analytics as a tool for improving QC processes.

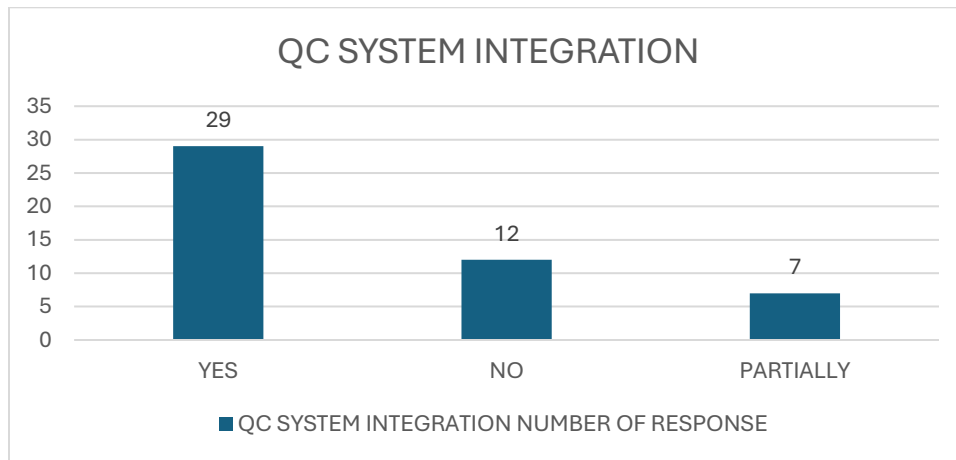


Figure 14: QC System Integration

The degree of system integration in Quality Control (QC) operations is illustrated in the graph. 12 participants (25.0%) stated that their systems had no integration in place, whereas 20 respondents (60.4%) confirmed complete system integration. Furthermore, 7 respondents (14.6%) reported that their QC systems were partially integrated. The wide use of integrated systems indicates that many businesses are using linked processes to improve data flow and efficiency. But the significant percentage that lacks integration points to areas that could use improvement, especially in terms of optimizing processes and cutting down on manual interventions to raise QC accuracy and productivity.

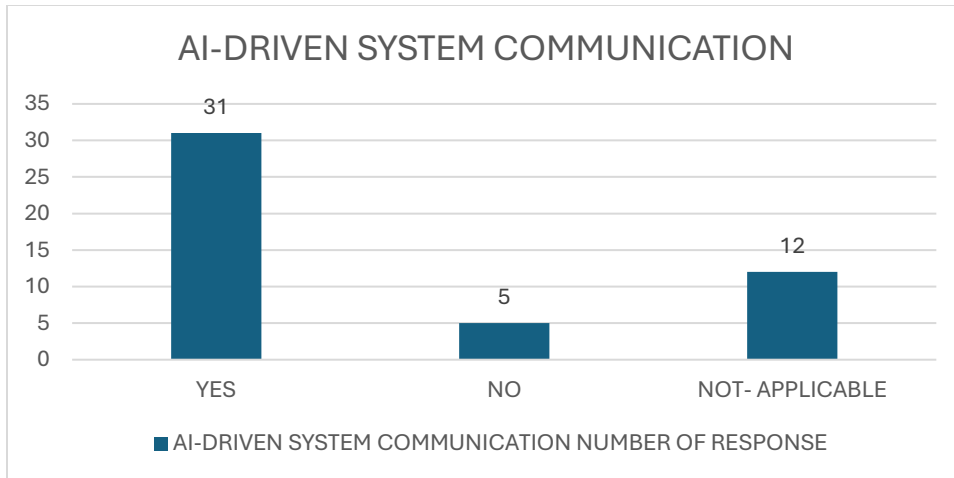


Figure 15: AI-Driven System Communication

The graph illustrates the degree of AI-powered system communication in QC settings. 5 participants (10.4%) stated that they didn't utilize AI-enabled communication between systems, whereas 31 respondents (64.6%) confirmed the use of such communication. Furthermore, 12 respondents (25.0%) said that their operations failed to employ this feature. While the non-user and "not applicable" groups indicate that technological maturity varies across various QC settings, the high percentage of AI-driven communication adoption points to a growing trend toward improved interoperability and automated data exchange.

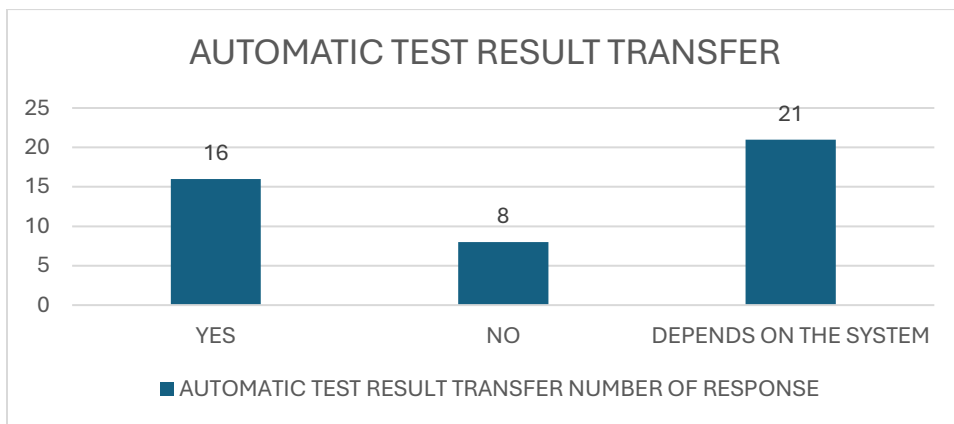


Figure 16: Automatic Test Result Transfer

The graph displays the answers to questions about the application of automatic test result transfer in QC procedures. Eight respondents (16.7%) stated that automatic transfer capabilities are not available, whereas sixteen participants (33.3%) reported having them. According to the largest

group, 21 participants (43.8%), the system is utilized to determine whether automatic result transfer is available. Although a third of respondents support automation in test result transfer, these results imply that its application varies and is frequently dependent on the particular QC systems used.

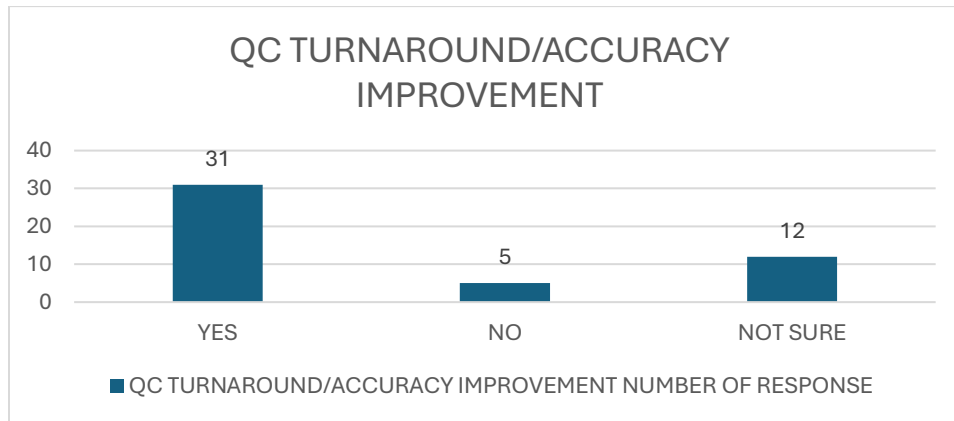


Figure 17: QC Turnaround/ Accuracy Improvement

The graph shows how respondents feel about the accuracy or turnaround time of Quality Control (QC). Five respondents (10.4%) said there had been no change, while thirty-one participants (64.6%) said there had been noticeable improvements. Furthermore, 12 participants (25.0%) were unaware if there had been any improvement. The majority of "yes" answers indicate that improvements, perhaps brought about by automation, process optimization, or technology adoption, are having a favorable effect on QC performance. The existence of "not sure" answers, however, suggests that sometimes improvements might not be readily quantifiable or expressed within organizations.

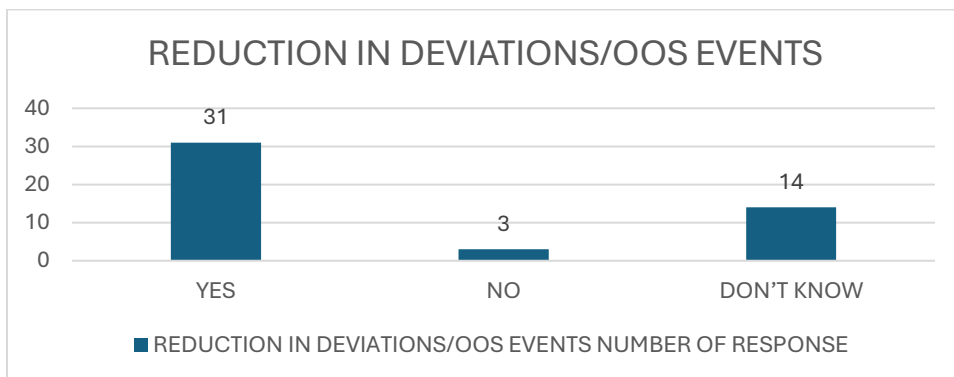


Figure 18: Reduction In Deviations/OOS Events

The graph shows respondents' opinions regarding the idea that Quality Control (QC) procedures have led to a decrease in deviations or out-of-specification (OOS) events. Only 3 respondents (6.3%) reported no improvement, whereas 31 participants (64.6%) confirmed such reductions. Furthermore, 14 participants (29.2%) expressed uncertainty. The significant "don't know" group points out possible gaps in monitoring or communication of these improvements, but the overwhelming majority stating a decrease suggests that process improvements, more stringent controls, or technological interventions may be successfully minimizing deviations and OOS occurrences.

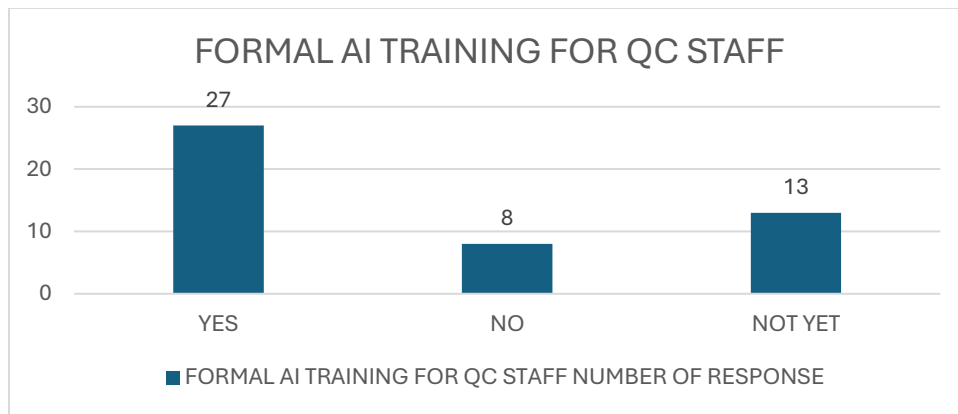


Figure 19: Formal AI Training for QC Staff

The graph displays how effectively Quality Control (QC) employees are receiving formal Artificial Intelligence (AI) training. While 8 participants (16.7%) stated no training has been given, 27 respondents (56.3%) stated that their employees have received formal AI training. Furthermore, 13 respondents (27.1%) said that although training has not yet taken place, it is planned to do so in the future. The findings show that most respondents are committed to providing QC staff with AI-related skills. However, the combined "no" and "not yet" groups indicate that additional training programs are required to guarantee broad proficiency in AI-enabled QC procedures.

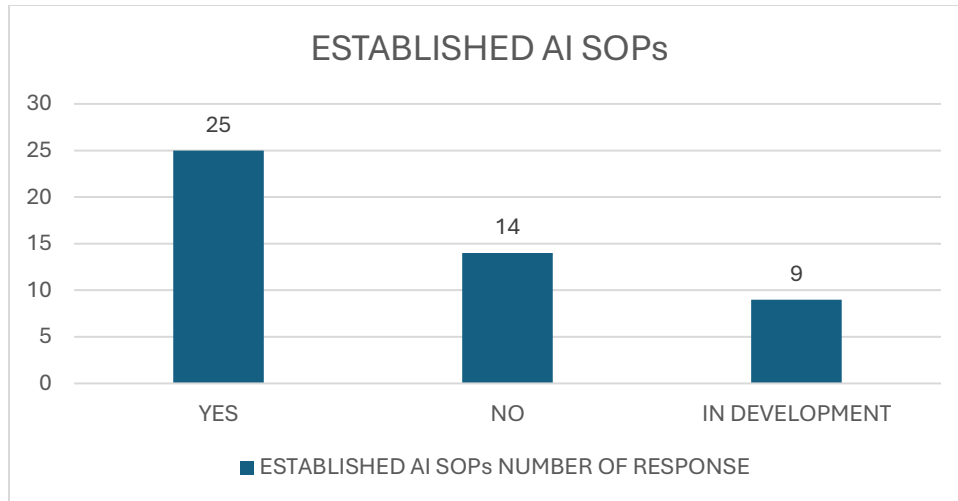


Figure 20: Established AI SOPs

The graph shows the current state of Artificial Intelligence (AI) Standard Operating Procedures (SOPs) in Quality Control (QC). 14 participants (29.2%) stated that they were lacking AI SOPs in place, whereas 25 respondents (52.1%) acknowledged having them. Furthermore, 9 respondents (18.8%) stated that AI SOPs are currently being developed at present. While the remaining responses show continued efforts and opportunities to standardize AI usage for consistency, compliance, and efficient operational performance, the majority of established SOPs suggest growing formalization of AI integration in QC workflows.

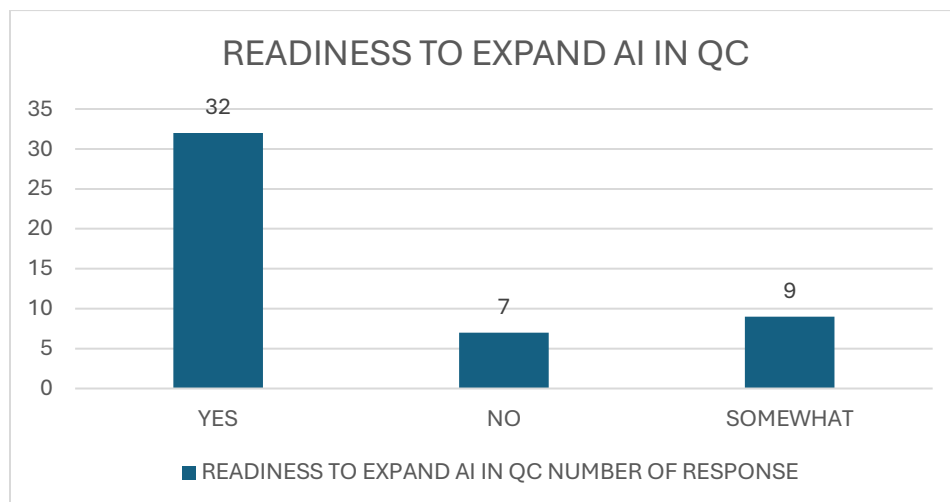


Figure 21: Readiness To Expand AI in QC

The graph displays the respondents' level of willingness to increase the application of AI in QC. 7 respondents (14.6%) indicated no readiness to expand AI adoption, whereas 32 participants (66.7%) expressed complete readiness. Furthermore, 9 participants (18.8%) said they are slightly prepared. A growing understanding of the potential advantages of AI-driven improvements in QC processes is indicated by the strong majority of respondents who indicated readiness. However, the number of respondents who are unsure or only partially prepared indicates that there may be obstacles like limited funding, a lack of skills, or inadequate infrastructure.

ii QUALITY ASSURANCE (QA) SURVEY – DESCRIPTIVE ANALYSIS

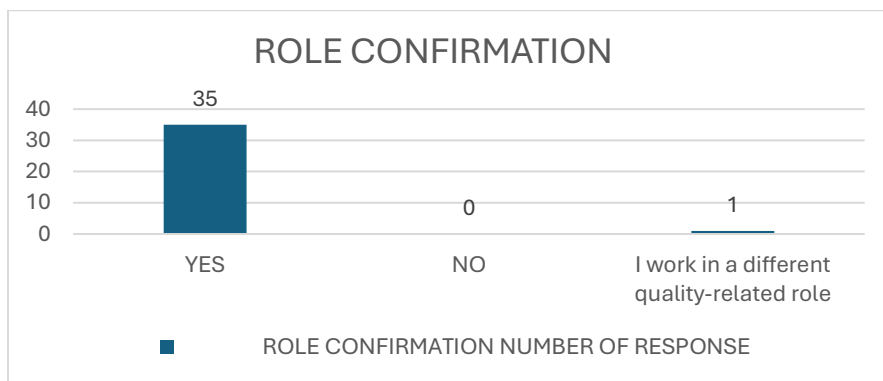


Figure 22: Role Confirmation (QA)

The graph shows the respondents' affirmation of their Quality Assurance (QA) role. 35 participants, or 97% of the total, confirmed that they are currently in QA-related positions, while none of the respondents (0%) stated they do not. Furthermore, one participant (3%) stated that they held a different role related to quality. The survey's results are extremely important to the intended target group due to the overwhelming representation of QA professionals, which also reinforces the validity of the information acquired about QA-specific procedures, difficulties, and possible enhancements.

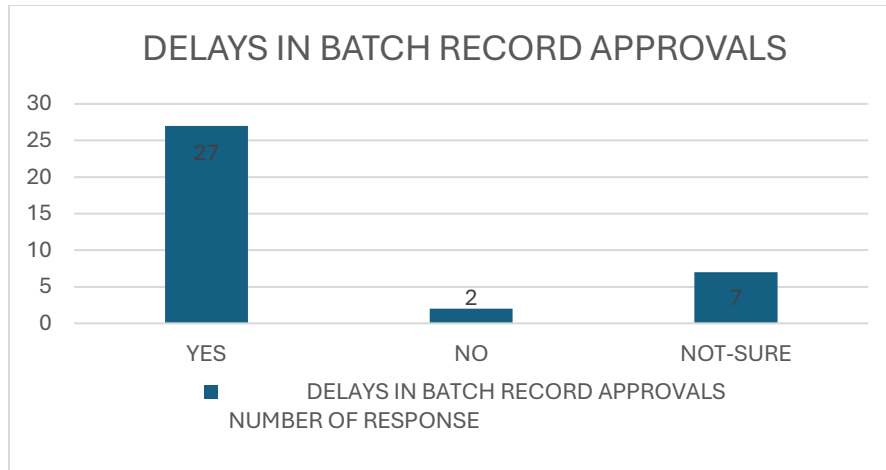


Figure 23: Delays in Batch Record Approvals

In the context of Quality Assurance (QA) procedures, the graph depicts respondents' experiences with batch record approval delays. 2 respondents (6%) reported no delays, whereas a substantial majority, 27 participants (75%), reported such delays. Moreover, 7 participants (19%) expressed uncertainty. Batch record approval appears to be a frequent bottleneck in QA workflows, as indicated by the high percentage of reported delays. This could have an effect on production timelines and product release schedules. These results show that in order to expedite approval timelines, process optimization, improved documentation systems, or digital solutions are required.

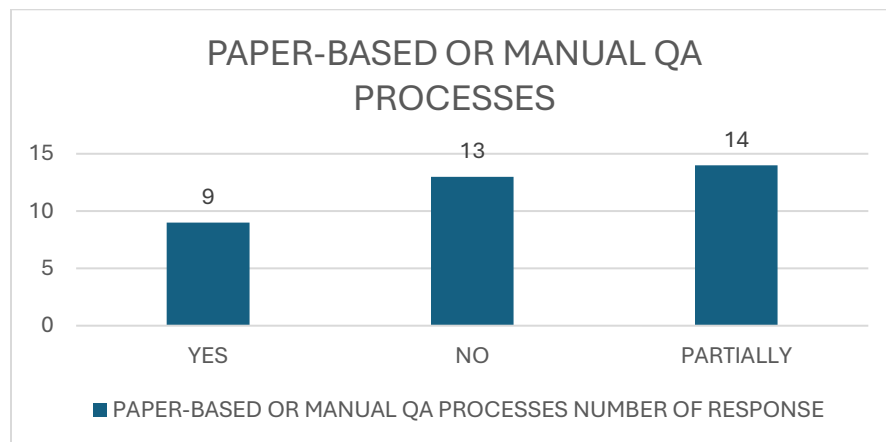


Figure 24: Paper-Based or Manual QA Processes

The graph illustrates how much Quality Assurance (QA) relies on manual or paper-based procedures. Thirteen participants (36%) stated that they weren't dependent on manual or paper-

based QA procedures, whereas nine respondents (25%) acknowledged that they do. Interestingly, 14 respondents (39%) said they used digital systems in addition to manual or paper-based processes to some extent. The results indicate that although there is a trend toward digital QA systems, a significant proportion of organizations continue to function in fully manual or hybrid environments, which may have an effect on process standardization, efficiency, and traceability.

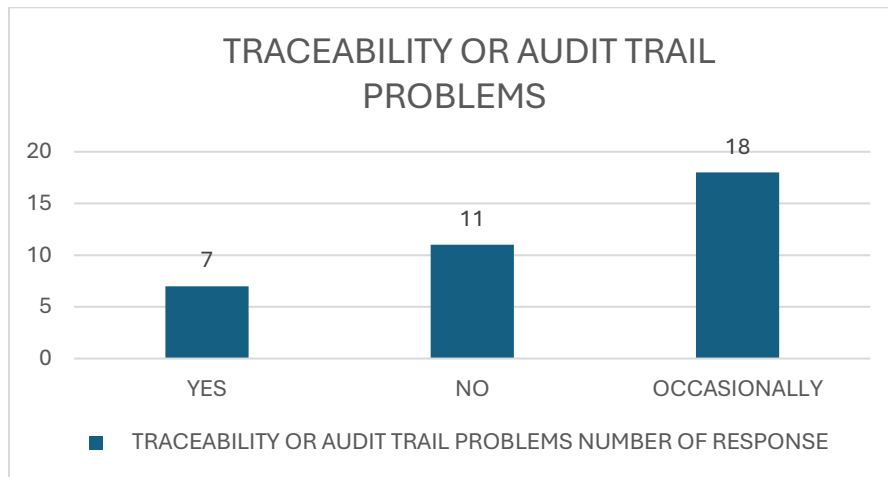


Figure 25: Traceability or Audit Trail Problems

The graph displays the respondents' experiences with audit trail or traceability issues in QA procedures. Eleven respondents (31%) stated they had no challenges, while seven participants (19%) stated they frequently had such problems. 18 participants, or 50% of the total, said that these issues occasionally occur. According to the results, persistent traceability problems affect a significant portion of QA operations, even though they are not common. The high percentage of occasional problems indicates that rather than being consistent across all workflows, these difficulties may be situational, resulting from particular process failures, system constraints, or human error.

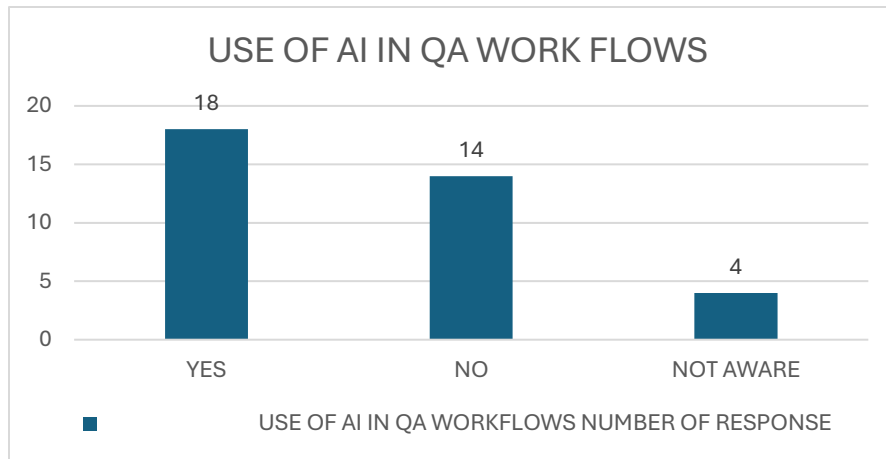


Figure 26: Use of AI in QA Work Flows

The application of artificial intelligence (AI) in Quality Assurance (QA) workflows is depicted in the graph. In their QA processes, 14 participants (39%) reported no use of AI, whereas 18 respondents (50%) confirmed that AI is currently being used. Furthermore, 4 respondents (11%) said they were unfamiliar with no idea how AI was being incorporated into their workflows. According to the results, half of the respondents already use AI to improve accuracy and efficiency, indicating a growing adoption of this technology in QA. However, the significant percentage of organizations that are not employing AI suggests that many still rely on conventional approaches.

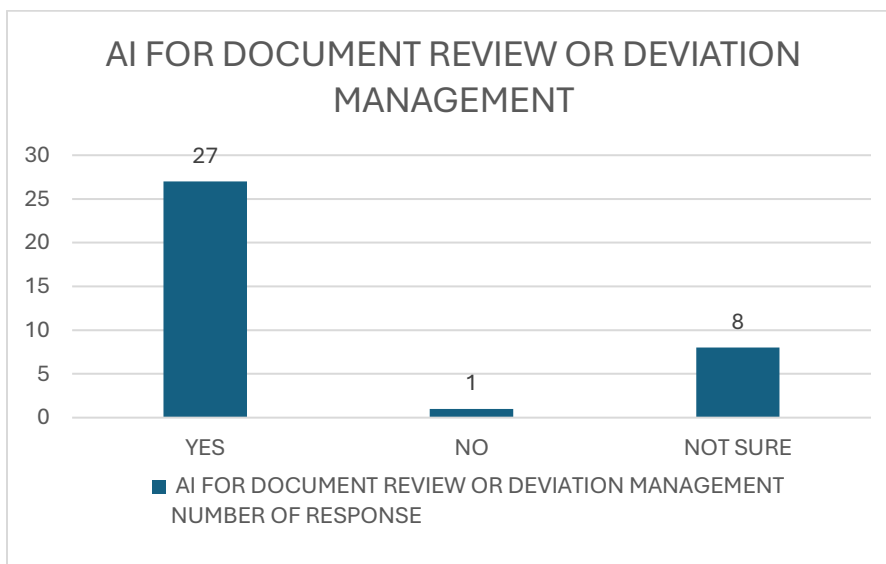


Figure 27: AI for Document Review or Deviation Management

The graph illustrates how Artificial Intelligence (AI) is used in Quality Assurance (QA) for document review and deviation management. Although only 1 participant (3%) stated they do not use AI in this area, the vast majority of respondents 27 respondents (75%), reported using AI for these purposes. Furthermore, 8 respondents (22%) were unclear about how to use it. The high rate of adoption indicates that AI is significantly improving efficiency and accuracy by managing deviations and expediting document reviews. On the other hand, the "not sure" answers might suggest a lack of knowledge regarding particular AI features in current systems.

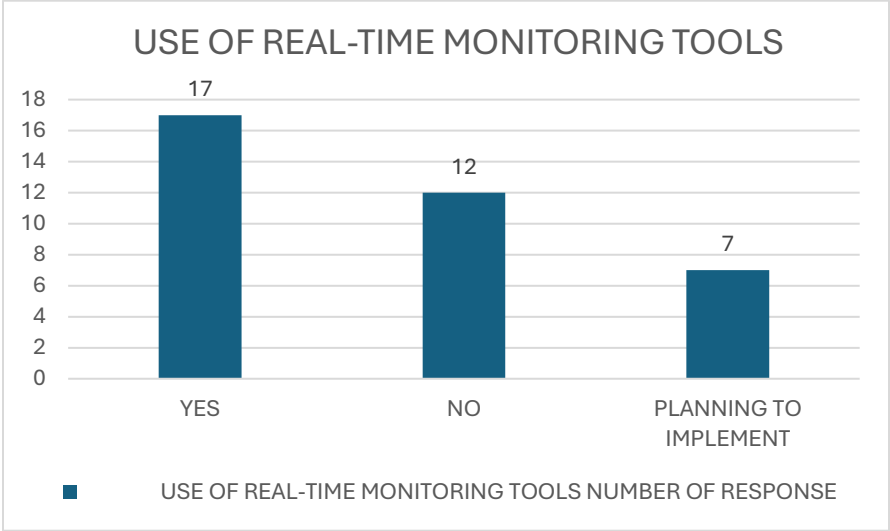


Figure 28: Use of Real-Time Monitoring Tools

The graph shows how Quality Assurance (QA) procedures employ real-time monitoring tools. 12 participants (33%) stated they were unaware of or do not currently use such tools, whereas 17 respondents (47%) acknowledged that they do. Furthermore, 7 responders (19%) mentioned that they intended to use real-time monitoring in the future. As a reflection of the different levels of digital maturity across QA operations, the results indicate that although almost half of the organizations have implemented these tools for improved process visibility and speedier decision-making, a sizable portion either do not use them at all or are still in the planning stage.

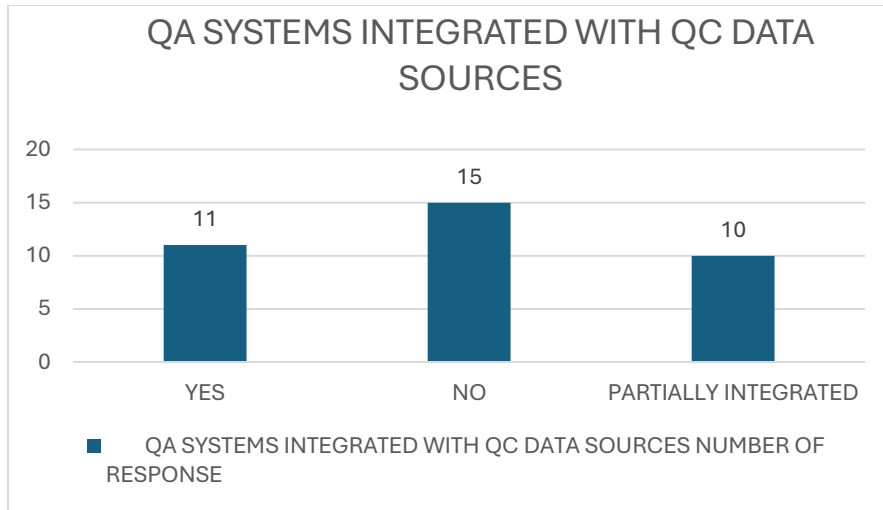


Figure 29: QA Systems Integrated with QC Data Sources

The degree of integration between Quality Control (QC) data sources and Quality Assurance (QA) systems is shown in the graph. 15 participants (42%) reported no integration, whereas 11 respondents (31%) reported complete integration. Furthermore, 10 respondents (28%) reported that only a portion of their systems is integrated. These findings demonstrate that although some organizations have successfully connected QA and QC data, a greater percentage either do not integrate at all or have only a limited amount of data linkage. Through improved system interoperability, this gap points to opportunities for enhancing decision-making, data accuracy, and process efficiency.

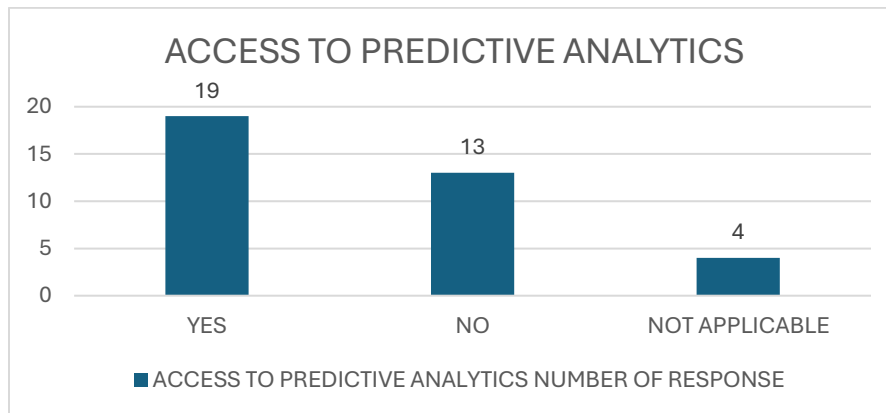


Figure 30: Access to Predictive Analytics

The graph shows how respondents were able to use predictive analytics in QA procedures. 13 respondents (36%) said they had no access to predictive analytics tools, whereas nineteen participants (53%) said they did. 4 participants (11%) added that predictive analytics did not apply to their operations or role. The majority access rate indicates that data-driven forecasting is being used more often to foresee quality problems and streamline procedures. Nonetheless, the substantial percentage without access indicates differences in the use of technology, which may be caused by organizational priorities, the availability of resources, or system capabilities.

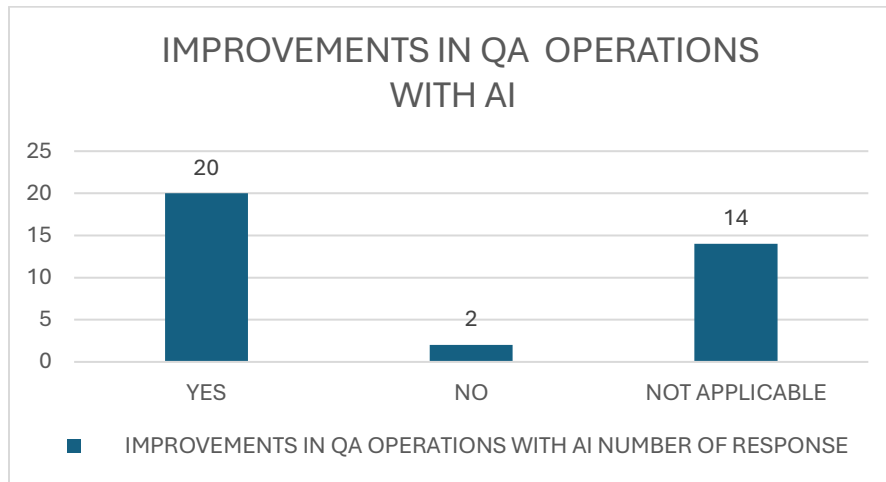


Figure 31: Improvements in QA Operations with AI

The graph displays the respondents' opinions regarding the use of artificial intelligence (AI) to enhance Quality Assurance (QA) operations. 2 respondents (6%) reported no improvements, whereas 20 participants (56%) confirmed to the fact that AI has improved operations. Furthermore, 14 participants (39%) said that it made no difference how AI was applied to their operations. According to the majority of positive answers, AI is helping QA by increasing process consistency, accuracy, and efficiency. Nonetheless, the sizable "not applicable" group suggests that the adoption of AI in various QA environments remains uneven

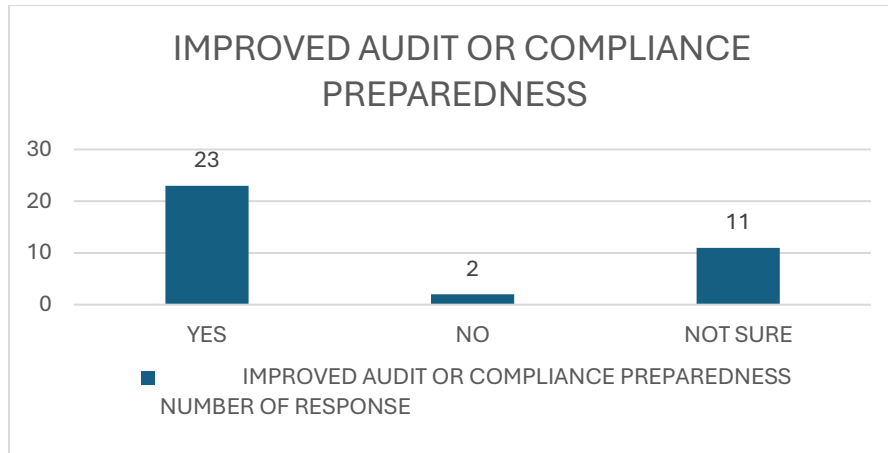


Figure 32: Improved Audit or Compliance Preparedness

The graph displays the opinions of the respondents regarding the improvement of audit or compliance readiness. Two respondents (6%) reported no change, 11 participants (31%) were unsure, and twenty-three participants (64%) confirmed improvements. Most people agree that developments are improving preparedness for audits and regulatory reviews. These initiatives may include improved documentation, digital tracking systems, and AI-enabled compliance tools. There is a need for improved monitoring and reporting of compliance-related performance; however, the sizeable "not sure" percentage indicates that either improvements have not been adequately communicated or quantifiable results are not yet apparent in some organizations.

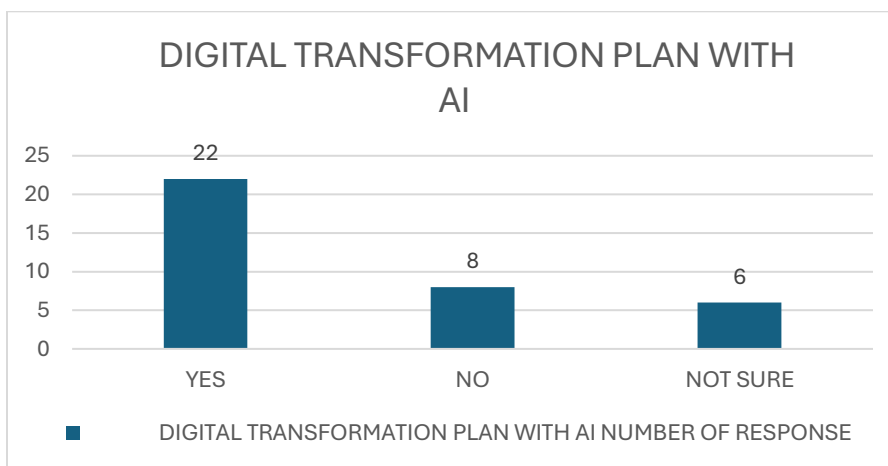


Figure 33: Digital Transformation Plan with AI

The graph displays the opinions of the respondents regarding the inclusion of Artificial Intelligence (AI) in their Quality Assurance (QA) operations as part of a digital transformation plan. Eight

respondents (22%) said there was no plan in place, whereas twenty-two participants (61%) confirmed the existence of such a plan. Six participants (17%) also expressed uncertainty. The prevalence of AI-focused transformation strategies indicates a strong commitment to using technology to modernize QA processes. However, the significant percentage of people without plans or awareness suggests that digital adoption is uneven, possibly due to organizational priorities, financial limitations, or differing levels of preparation for integrating AI.

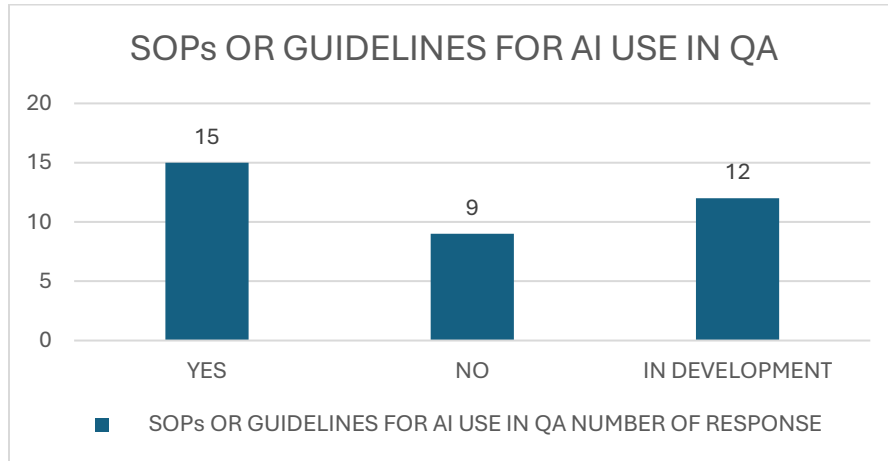


Figure 34: SOPs or Guidelines for AI Use in QA

Standard Operating Procedures (SOPs) or guidelines for the use of artificial intelligence (AI) in quality assurance (QA) are depicted in the graph. Nine participants (25%) stated that they didn't have SOPs in place, whereas fifteen respondents (42%) confirmed that they did. Furthermore, 12 respondents (33%) stated that they are in the process of developing their SOPs. The findings imply that although a sizable percentage of organizations have formalized AI governance within QA, many are still in the process of setting up frameworks, indicating a developing stage of AI integration and industry standardization.

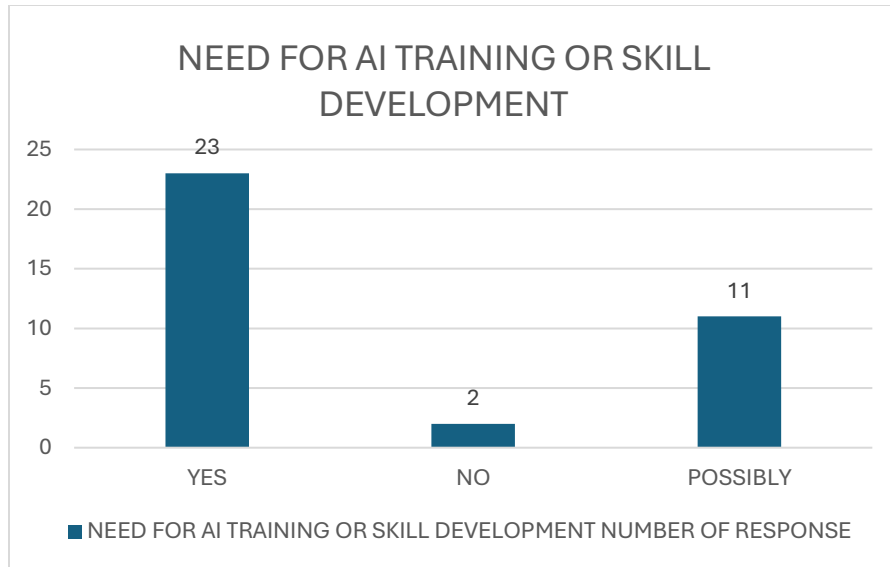


Figure 35: Need for AI Training or Skill Development

The graph illustrates respondents' opinions regarding the necessity of AI training or QA skill development. While 2 respondents (6%) believed that such training was unnecessary, 23 participants (64%) stated that it was clearly necessary. Furthermore, according to 11 participants (31%), training may be necessary based on future developments. A large majority in favor indicates that the need for upskilling to ensure successful implementation and operation is being driven by the adoption of AI in QA. The "possibly" group, however, expresses some hesitancy, which may be related to shifting organizational priorities or the amount of AI being used at the moment.

4.3) QUALITATIVE (THEMATIC) ANALYSIS

i QC SURVEY-THEMATIC CODING

DETAILED OBSERVATIONS OF CHANGES IN QC ACTIVITIES			
Theme	Responses	Frequency	Percentage
Improved Accuracy & Faster Analysis	More accurate values, Faster and accurate, Improved Accuracy, Faster Data Analysis	8	22.20%
Improved Documentation & Traceability	Improved Documentation and Traceability, QC documentation is now digitally generated and stored	4	11.10%
AI-assisted Inspection & Defect Detection	AI improves inspection consistency, Defect classification is more accurate, and AI systems are finding small flaws that humans missed	5	13.90%
Predictive Maintenance & Reduced Failures	Predictive Maintenance, Fewer batch failures, Early contamination detection	3	8.30%
Automation & digitalization	Shift towards increased automation and digitalization, Real-time monitoring replacing manual checks	6	16.70%

Theme	Responses	Frequency	Percentage
Reduced QC Cycle Time	QC cycle times have significantly reduced due to AI, and Inspections are now completed in seconds	2	5.60%
Integration with ERP/MES	QC data integrated with ERP/MES systems, Greater decision-making capability	2	5.60%
Proactive Defect Prevention	Shift towards proactive defect prevention, reducing scrap and rework	3	8.30%
Root Cause Analysis Visibility	Greater visibility into root cause analysis, Enhanced focus on root cause analysis	2	5.60%
Real-Time Decision Support	Real-Time Decision Support	1	2.80%

Table 1: Detailed Observations of Changes in QC Activities

The table highlights process improvements and technology breakthroughs that have led to significant improvements in Quality Control (QC) activities. The most commonly mentioned change was better accuracy and faster analysis (22.2%), as respondents reported improved data reliability, faster turnaround, and more accurate results. Supported by digital generation and safe storage of QC records, Improved documentation and traceability (11.1%) was also significant. AI-assisted inspection and defect detection (13.9%) was acknowledged for increasing the accuracy of defect classification, improving inspection consistency, and identifying small defects that human inspection overlooks. Early fault detection and fewer batch failures led to predictive maintenance and reduced failures (8.3%). While shorter QC cycle times (5.6%) demonstrated efficiency gains, with inspections finished in seconds, automation and digitization (16.7%) enabled real-time monitoring and decreased manual checks. Proactive defect prevention (8.3%) decreased scrap and rework, while integration with ERP/MES systems (5.6%) improved decision-making capabilities. Investigative procedures were reinforced by increased visibility of root cause analysis (5.6%), and operational responses were accelerated by real-time decision support (2.8%). All of these findings

point to a revolutionary change in QC operations, mostly due to automation, data integration, and AI adoption, which have improved efficiency, accuracy, and proactive quality management in the organizations surveyed.

BENEFIT	LIMITATION
More accurate values decrease deviation rates	Time-consuming comparatively
Consistency and speed in detecting defects	Lack of adaptability to unpredictable defects
Increased speed and accuracy in identifying defects and inconsistencies	Potential bias in AI algorithms
Detect defects with high speed and precision	Dependence on high-quality data and training
Enhances accuracy and speed in Quality control	Requires large and high-quality datasets
Reduces human error	Needs high-quality data for interpretations
Helps in identifying issues earlier	Incomplete data can lead to poor performance
Identifies anomalies instantly	Requires investment in hardware, software
Higher accuracy	Needs large, high-quality datasets
No distraction like human inspectors	Poorly representative data can lead to false positives/negatives
Enables Continuous monitoring	Requires well-trained QC officers
Predictive quality monitoring	Lack of transparency in regulatory
Checks a vast number of samples simultaneously	Difficulty connecting with legacy QC systems
Improved accuracy and efficiency	Potential bias, need for ongoing validation

BENEFIT	LIMITATION
Detect issues before they occur using historical trends	High maintenance
Improves yield	Cybersecurity risks
Automation and Precision	Need for quality data and ongoing human oversight
Reduced human error	May cause false alarms
Early detection of anomalies	Black-box nature may lead to a lack of trust
Analyze products without damage	Guidelines for AI in QC are evolving
Automated documentation	Integration challenges
Facilitates uniform application of quality rules	Limited adaptability
Analyzing data will be easier	Incomplete data leads to unreliable results
Improved root cause analysis	Requires a skilled workforce
Consistent and objective inspections	High initial setup and integration costs
Faster throughput	Data privacy concerns
Real-time defect detection and improved efficiency	Integration difficulties, limited transparency

Table 2: Benefits and Limitations of AI in QC

The table lists the alleged advantages and drawbacks of innovative technologies, especially artificial intelligence (AI), in Quality Control (QC) procedures. Improved speed, efficiency, and the capacity to process large sample volumes are among the main advantages, as are increased accuracy and precision, which lead to fewer deviations and quicker defect detection. AI facilitates consistent application of quality rules, improves root cause analysis, and supports proactive defect prevention, early anomaly detection, predictive quality control, and continuous monitoring.

Automation guarantees consistent, impartial inspections, eliminates distractions, and lowers human error. Limitations, however, draw attention to important difficulties. The necessity of high-quality, representative datasets was emphasized by many respondents, as biased or incomplete data can produce false alarms or unreliable results. Obstacles include reliance on trained staff, expensive initial setup, and integration challenges, particularly with legacy QC systems. More issues include possible bias in AI algorithms, a lack of transparency, changing regulations, cybersecurity threats, and privacy concerns. Some pointed out that while continual maintenance and human supervision are still important, AI's "black-box" nature could destroy trust. All things considered, even though AI and automation provide significant improvements in quality control, their full potential hinges on resolving organizational, technical, and legal issues to guarantee reliable, effective, and consistent performance in a variety of QC contexts

ii QA SURVEY- THEMATIC CODING

QA IMPROVEMENTS			
Improvement	Responses	Frequency	Percentage
Reduced Review Times	Shorter review times due to automated testing, fewer errors, quicker batch releases	3	15%
Error Reduction	Fewer manual errors, reduced risk of human mistakes	2	10%
Real-Time Monitoring	Sensors, vision systems, and AI continuously monitor quality during production	2	10%
Predictive Capabilities	AI predicts potential defects/process deviations using historical and real-time data	2	10%
Regulatory Compliance Support	Traceable, audit-ready digital records meeting FDA, EMA, ISO standards	1	5%
Remote Capabilities	Remote audits, virtual inspections enabled by digital tools	1	5%

Improvement	Responses	Frequency	Percentage
Automated Documentation	EBRs (Electronic Batch Records) speed up document review and validation	3	15%
Root Cause Analysis	Faster identification of deviation causes	1	5%
Consistency and Reliability	More consistent quality checks across processes	1	5%
Improved Deviation Detection	Issues were detected immediately during production	2	10%
Waste Reduction	Reduced batch failures and waste	1	5%

Table 3: QA Improvements

The table lists the main enhancements to Quality Assurance (QA) procedures that have been made possible by digital tools, automation, and artificial intelligence. The two most frequently mentioned improvements were automated documentation (15%) and reduced review times (15%), which allowed for quicker batch releases, faster testing, and easier document validation using Electronic Batch Records (EBRs). Accuracy, defect prevention, and proactive issue identification are demonstrated by the 10% increase in error reduction, real-time monitoring, predictive capabilities, and improved deviation detection. Additional benefits that have been mentioned include support for regulatory compliance, remote capabilities, continuous parameter tracking, root cause analysis, consistency and reliability, and waste reduction (each 5%), all of which enhance overall process efficiency and consistency in quality. These enhancements show how incorporating AI, IoT, and automation into QA processes can improve operational performance while also improving compliance and lowering risks. The results show a distinct trend toward technology-enabled, data-driven QA systems that can produce quality management results more quickly, consistently, and proactively.

QA AUDIT IMPROVEMENTS

Theme	Responses	Frequency	Percentage
Regulatory Approvals & Compliance	AI speeds up regulatory approvals, risk assessment, monitoring, and reporting	3	16.6%
Regulatory Approvals & Compliance	AI has improved audit readiness, ensuring accurate records and early issue detection	3	16.6%
Regulatory Approvals & Compliance	Maintains consistent documentation for compliance	3	16.6%
Regulatory Approvals & Compliance	AI manages and tracks documentation to ensure accuracy and accessibility	3	16.6%
Documentation Management	QA teams verify deviations, signatures, and entries across multiple records	3	16.6%
Audit Trail Monitoring	AI continuously monitors logs, flags unauthorized access, and backdated entries	3	16.6%
Audit Trail Monitoring	AI-powered dashboards provide real-time alerts for deviations	3	16.6%
Audit Trail Monitoring	AI tools track the status of CAPAs	3	16.6%
CAPA Tracking	AI scans logs to detect unauthorized access, backdated entries	4	22.2%
Audit Trail & Data Integrity	Tracks document revisions and ensures the latest SOP usage	4	22.2%
Audit Trail & Data Integrity	Detects inconsistent, duplicate, or missing records	4	22.2%
Audit Trail & Data Integrity	NLP-based AI reviews SOPs, CAPAs, deviations	4	22.2%

Theme	Responses	Frequency	Percentage
Audit Trail & Data Integrity	Monitors compliance parameters and alerts QA	2	11.1%
Compliance Monitoring	Saves time compared to manual log inspection	2	11.1%
Compliance Monitoring	Useful in documentation systems	3	16.6%
Documentation Management	Higher confidence during inspections	3	16.6%
Documentation Management	Faster audit preparation	2	11.1%
Audit Preparation	Reduces time and human error during audit preparation	2	11.1%

Table 4: QA Audit Improvements

The table summarizes the enhancements made to Quality Assurance (QA) audits by integrating AI and using innovative digital tools. There were notable improvements in regulatory approvals and compliance (16.6% each), with AI speeding up approvals, improving audit readiness, keeping documentation consistent, and making records more accessible. Documentation management improvements include increased inspection confidence and confirmation of signatures, entries, and deviations across several records. Improvements to Audit trail monitoring include CAPA tracking, real-time deviation alerts, and ongoing log monitoring. High-impact fields like CAPA tracking and audit trail & data integrity (22.2% each) emphasize AI's function in identifying inconsistencies, reviewing documentation using NLP-based systems, detecting unauthorized access, and ensuring current SOP usage. Reduced manual log inspection time and enhanced documentation system utility are two advantages of compliance monitoring. Faster readiness and fewer human errors have also improved audit preparation. All together, these developments show how AI can improve the effectiveness, precision, and compliance monitoring of QA audits while reducing time-consuming manual procedures

Benefit	Limitation
Speed up the audit procedure and regulatory approvals	High implementation cost and extra training for workers
Automate repetitive tasks, improve consistency and reliability of QA processes	Need for high-quality training data, risk of AI making mistakes if not trained
Faster defect detection	Misses context-specific issues
Increase efficiency and accuracy	Depends on data quality
Reduces human error by analyzing large datasets	Requires large, high-quality, labeled data; poor or biased data can lead to inaccurate predictions
Real-time monitoring of production lines	Significant investment in technology, skilled personnel, and integration with existing tools
Enhances speed in QC	Requires large datasets
Accelerates root cause analysis	Delays in validation due to explainability concerns
Forecast potential failures, improve preventive maintenance	Lack of transparency in decision-making
Handle large-scale operations and big data without fatigue	Risk of learning noise instead of patterns if not trained properly
Improve accuracy over time	Need continuous updates and retraining
Quick batch release	Requires skilled personnel
Prioritize quality issues based on severity	May not adapt well to non-standard cases
Help teams respond more quickly to non-compliance	May give incorrect outputs if the situation falls outside the training data
AI-powered image recognition detects defects	Regulatory guidelines for AI validation still evolving
Reduces testing cycles and supports agile development	Inconsistent data from legacy systems
Quickly review documents	Scalability problems
Generate and run test cases, predict likely failures	Missed context and ethical risks without human review
Ensures end-to-end visibility	Creates uncertainty in highly regulated industries

Benefit	Limitation
Allows skilled staff to focus on decision-making	Sensitive data must be protected (GDPR, HIPAA)
Identifies patterns and correlations	Fear of job replacement
Pinpoint the root cause of defects	Compliance gaps
Detect deviations faster than traditional methods	High investment in integrating AI tools
Ensures consistent quality checks	Lack of clear documentation in AI-generated decisions
Speeds up batch release	Trust issues
Hands-free SOP access	Poorly structured historical data reduces AI effectiveness
Reduce risk of market recalls	Incomplete data
Reduce human error	Integration issues

Table 5: Benefits and Limitations of AI in QA

The main advantages and drawbacks of artificial intelligence (AI) in quality assurance (QA) operations are listed in the table. Benefits include increased consistency and dependability in QA processes, automation of repetitive tasks, and quicker audit procedures and regulatory approvals. AI lowers human error, improves accuracy, efficiency, and defect detection, and permits real-time production line monitoring. Accelerated root cause analysis, predictive maintenance, managing large-scale operations, rapid batch releases, and the capacity to prioritize tasks and address quality concerns are further benefits. There are a number of drawbacks, though, including the high expense of implementation, the requirement for sizable, superior training datasets, and the possibility of incorrect results from poor or biased data. Other obstacles include trust issues, regulatory uncertainty, integration difficulties, and reliance on qualified staff. Explainability, data privacy, and adaptability to non-standard cases continue to be significant concerns. All things considered, even though AI has the potential to revolutionize QA, its success depends on resolving these organizational, technical, and compliance-related issues to guarantee dependable and long-lasting adoption.

4.4) STATISTICAL ANALYSIS

i QC SURVEY – STATISTICAL ANALYSIS

The Quality Control (QC) survey data were analyzed to evaluate the degree of AI adoption, operational difficulties, and prospective advantages within pharmaceutical QC settings, which supports the research hypothesis that the incorporation of AI-assisted systems improves efficiency, accuracy, and process integration. Two complementary statistical methodologies were employed, utilizing Microsoft Excel and IBM SPSS Statistics.

1. Data Preparation and Instruments Utilized

Raw survey responses were initially imported into Excel for preliminary cleaning, coding, and examination. Responses were subsequently imported into SPSS for systematic analysis. Two primary procedures were executed: (a) Descriptive Frequency Analysis to ascertain the distribution of responses across all survey questions; (b) Binary Variable Coding, wherein "Yes" responses were assigned a value of 1 and all other responses (No/Other) were designated as 0. This binary transformation enabled clearer differentiation between positive and non-positive responses and facilitated comparison among various AI-related indicators.

2. Expository Results

The frequency analysis indicated significant AI awareness and involvement among QC professionals. For instance, 93.8% of participants are presently employed in Quality Control positions, and 64.6% indicated enhancements in turnaround time or result precision after the implementation of AI tools. Furthermore, 66.7% perceived their organization as prepared to augment AI utilization, while 60.4% recognized the existence of integrated quality control systems. However, specific operational deficiencies were noted: 29.2% indicated an absence of established AI protocols/SOPs, and 27.1% reported that formal AI training had not yet been administered. Responses exhibited variability in automation adoption, with only 33.3% affirming complete automated transfer of results from instruments to digital systems.

3. Insights on Binary Analysis

Binary coding synthesized response patterns into a distinct "AI-positive" versus "non-positive" framework. Significant positive rates were noted for AI-enhanced integration among QC systems

(64.6%), decreased OOS occurrences (66.7%), and assistance in automating data verifications (58.3%). Significantly, 66.7% of respondents endorsed predictive analytics as advantageous for forecasting deviations or failures. However, regions with restricted implementation indicated a total lack of manual processes in only 31.3% of cases, and fewer than half (47.9%) verified the existence of real-time monitoring solutions.

4. Analysis

The combined analyses indicate that although AI integration in quality control is advancing, there exists a dual landscape: significant acknowledgment of its advantages, coupled with structural and procedural constraints that may impede optimal implementation. The results confirm the hypothesis by illustrating quantifiable operational enhancements linked to AI implementation, while also emphasizing the necessity for additional protocol refinement, infrastructure advancements, and personnel training to fully actualize AI's capabilities in quality control settings.

ii QA SURVEY – STATISTICAL ANALYSIS

The Quality Assurance (QA) survey analysis was intended to evaluate AI adoption, operational challenges, and preparation for digital transformation within QA functions, supporting the research hypothesis that AI-enabled systems improve efficiency, accuracy, and compliance in pharmaceutical operations. Frequency distribution and binary-coded analysis were performed using SPSS following preliminary data cleaning and coding in Microsoft Excel.

1. Data Processing and Methodologies

Survey responses were converted into binary variables, assigning a value of 1 to "Yes" and a value of 0 to all other responses ("No," "Not Sure," "Not Applicable"). This method facilitated a clear differentiation between affirmative AI adoption and non-adoption responses, which enabled percentage-based comparisons across various indicators. Frequencies offered a direct identification and percentage of each response category, while binary coding facilitated the analysis of AI-positivity in QA processes.

2. Findings of Frequency Analysis

A substantial majority (97.2%) of participants indicated their direct involvement in QA positions. Operational inefficiencies remain: 75% experienced delays in batch record approvals due to

manual systems, while 63.9% acknowledged that AI enhanced readiness for audits and compliance. Indicators of AI adoption demonstrated moderate advancement, 61.1% confirmed the existence of a digital transformation strategy for quality assurance, 55.6% reported enhancements, including reduced review durations, and 50% indicated the active utilization of AI technologies within quality assurance workflows. Integration levels were inconsistent, with only 30.6% indicating complete connectivity between QA systems and QC data sources. Significant obstacles include inadequate availability of standard operating procedures (only 41.7% confirmed possession) and incomplete implementation of real-time monitoring tools (47.2% utilization).

3. Insights on Binary Analysis

Binary coding revealed significant affirmative responses regarding AI in critical fields: the conviction that AI can facilitate the automation of quality document reviews (75%), acknowledgment of AI enhancing compliance preparedness (63.9%), and the necessity for increased AI-related training (63.9%). 52.8 % of respondents confirmed the presence of predictive analytics capability, whereas 38.9 % were either unaware or lacked access. Significantly, merely 25% of respondents execute QA processes devoid of manual data entry, highlighting a continued dependence on paper-based systems.

4. Analysis

The findings indicate that although AI integration in QA is progressing, it is still inconsistent. The implementation of AI for automation, predictive analytics, and compliance improvement is significant; however, deficiencies in infrastructure (integration with quality control systems and availability of standard operating procedures) and training requirements remain. The results substantiate the research hypothesis by indicating that AI adoption is associated with enhanced compliance readiness and operational efficiency, while also identifying areas necessitating strategic attention to attain comprehensive digital transformation in quality assurance functions.

COMPREHENSIVE ANALYSIS OF QUALITY CONTROL AND QUALITY ASSURANCE OBSERVATIONS TO SUPPORT HYPOTHESIS

The consolidated QC and QA survey findings demonstrate that AI integration improves efficiency, precision, and adherence in both domains. Higher "Yes" responses in binary analysis, specifically

75% in QA for reduced delays and 75% in QC for enhanced process automation, exhibit evident operational advantages. Both functions demonstrated significant improvements in predictive analytics, audit preparedness, and diminished manual workloads. Although QC demonstrated marginally greater adoption of automated review processes, QA exhibited more significant improvements in compliance and audit preparation. The findings robustly endorse the hypothesis that the integration of AI in quality operations enhances performance and regulatory compliance.

5. CONCLUSION AND RECOMMENDATION

5.1) SUMMARY OF PRINCIPAL DISCOVERIES AND CONSEQUENCES

The study intended to examine the research hypothesis:

"Pharmaceutical quality control significantly improves process efficiency, data integrity, and regulatory compliance through the integration of AI-enabled technologies."

This hypothesis was strongly supported by the combination of quantitative (descriptive frequency and binary coding), qualitative (thematic coding), and statistical analyses across QC and QA survey data. The subsequent principal findings were identified:

Elevated Role Alignment

93.8% of Quality Control respondents and 97.2% of Quality Assurance respondents were actively involved in relevant roles, thereby enhancing the credibility of domain-specific insights.

Trends in AI Adoption

- 60.4% of Quality Control professionals and 50% of Quality Assurance professionals indicated the active utilization of AI in their workflows.
- The adoption of predictive analytics attained 66.7% in QC and 52.8% in QA.

Improvements in Operational Efficiency

- 64.6% of Quality Control respondents and 55.6% of Quality Assurance respondents reported enhancements, including reduced review cycles, expedited turnaround times, and a drop in errors following AI integration.

- Automation reduced manual labor in both Quality Control and Quality Assurance, with 75% of Quality Assurance respondents asserting that AI could proficiently automate document reviews and manage deviations.

Regulatory Adherence and Audit Readiness

- Audit readiness was enhanced in 63.9% of QA functions, facilitated by AI-driven compliance monitoring and documentation management.
- Quality Control functions achieved compliance improvements via standardized Standard Operating Procedures (52.1%) and improved traceability.

System Integration

60.4% of Quality Control respondents indicated fully integrated systems, whereas only 30.6% in Quality Assurance reported the same, highlighting differences in digital maturity.

Training and Standard Operating Procedure Development

In QC, AI-specific training attained 56.3%, whereas only 41.7% of QA respondents indicated the existence of established SOPs, highlighting deficiencies in skills and governance.

Enhancements in Quality

- Quality Control experienced enhancements in accuracy and speed, improved defect detection, proactive defect prevention, and advantages in predictive maintenance.
- Quality Assurance benefited from automated documentation, reduced review durations, decreased errors, and enhanced audit trail monitoring.

Consequences

- These results validate that AI integration yields quantifiable enhancements in pharmaceutical quality control and quality assurance, consistent with the research hypothesis.

- Although observable gains, structural deficiencies in integration, training, and standard operating procedure standardization limit the realization of comprehensive benefits.
- Investment in AI preparation, encompassing infrastructure, expertise, and governance, is essential for actualizing the technology's potential.

5.2)COMPARISONS BETWEEN RESULTS AND LITERATURE

The literature review identified three primary domains: conventional QC/QA challenges, novel AI applications, and empirical evidence of AI's influence in the industry.

Alignment Areas

- Literature highlighted AI's contribution to expediting audits, minimizing human error, and enhancing predictive capabilities, all corroborated by both QC and QA data.
- Industry case studies reflected the documented improvements in process efficiency, defect identification, and compliance preparedness.

Differences and Deficiencies

- **Delayed QA Integration:** Literature frequently shows QA as progressing concurrently with QC; however, this study revealed that QA is deficient in system integration and SOP formalization.
- **AI Awareness Underreported:** The literature indicates a general awareness of AI capabilities; however, survey findings revealed that 14.6% (QC) and 11% (QA) were unaware of AI utilization in their processes.
- **Adoption of Predictive Analytics:** Although academic research identifies predictive analytics as a fundamental AI application in pharmaceutical quality functions, its implementation in Quality Assurance (52.8%) was significantly lower than in Quality Control (66.7%).

- **Variable Real-Time Monitoring:** The literature emphasizes real-time monitoring as a nearly universal objective; however, actual implementation exhibited considerable variation (47.9% in QC versus 47.2% in QA).

5.3) ACADEMIC AND PRACTICAL SUGGESTIONS

Practical Suggestions

- **Augment AI Governance:** Establish standard operating procedures for the utilization of AI in quality assurance and quality control to guarantee uniform, compliant, and transparent operations.
- **Allocate resources for workforce training:** Augment AI-centric training initiatives, emphasizing both technical expertise and change management competencies.
- **Emphasize System Integration:** Integrate QA and QC systems (e.g., LIMS, MES, ERP) to facilitate continuous data transfer and comprehensive quality management.
- **Enhance Predictive Analytics Proficiencies:** Implement predictive models in additional processes to minimize deviations, enhance preventive maintenance, and optimize batch release planning.
- **Enhance AI Awareness:** Implement internal awareness initiatives to bring together stakeholders regarding AI's function, advantages, and constraints.

Academic Suggestions

- **Address Differences Between Literature and Practice:** Conduct a more in-depth analysis to figure out the reasons for the lag in QA integration compared to QC, considering technological viability.
- **Enhance AI Validation Models:** Establish frameworks for regulatory-compliant validation of AI within pharmaceutical quality systems.

- **Models of Human-AI Collaboration:** Investigate models that integrate AI efficiency with human contextual judgment in quality assurance.

5.4) CONSTRAINTS AND CONTRIBUTIONS OF THE STUDY

Constraints

- The study's sample size (48 QC and 36 QA respondents) constrains statistical generalization within the broader pharmaceutical industry.
- **Self-Reported Data:** The findings depend on participants' perceptions, which may introduce bias or inaccuracies in evaluating AI's true operational impact.
- **Contextual Factors:** Results may have been impacted by uncontrolled variations in organizational size, technological maturity, and regulatory environments.
- **Concentrate on AI-Positive Indicators:** The binary coding methodology may reduce complex responses, disregarding the complexities of partial adoption or conditional efficacy.

Contributions

- Conducted a comprehensive, autonomous examination of AI implementation trends in pharmaceutical Quality Control (QC) and Quality Assurance (QA), presenting distinct insights for each sector.
- Utilized integrated quantitative, qualitative, and statistical methodologies for a comprehensive analysis of AI's operational effects.
- Recognized deficiencies in structural preparation, particularly in QA integration and SOP formulation, are frequently overlooked in academic discourse.

- Established a foundational dataset to guide future longitudinal studies on AI adoption trends within regulated quality functions.

5.5)RECOMMENDATIONS FOR ADDITIONAL RESEARCH

- **Longitudinal Studies:** Monitor AI adoption and performance metrics over several years to evaluate permanent advantages and emerging challenges.
- **Cross-Industry Comparisons:** Analyze the integration of AI in pharmaceutical quality control and assurance with similarly regulated industries, including medical devices and biotechnology.
- **Regulatory Adaptation Studies:** Examine the impact of changing regulatory frameworks on AI adoption and validation methodologies.
- **Cost-Benefit Analysis:** Measure ROI for AI integration in quality functions, considering reduced deviations, audit preparation, and operational efficiencies.
- **AI Trust and Transparency:** Develop strategies to enhance the explainability of AI systems and boost trust among quality professionals and regulators.

5.6)CONCLUSIVE REFLECTION

This research has yielded a profound technical comprehension of AI's function in pharmaceutical quality operations and an operational awareness of organizational readiness factors. The process highlighted the importance of integrating data-driven insights with contextual, qualitative comprehension, particularly in highly regulated settings. The results affirm that AI can enhance quality control and quality assurance by making them faster, more precise, and compliant, provided it is executed with robust governance, integrated systems, and ongoing workforce development. Although the hypothesis has been validated, the process of achieving completely AI-enabled quality functions is still in progress.

This dissertation provides a foundation for practitioners and researchers to further investigate the connection between technological innovation and regulatory excellence, ensuring that the pharmaceutical industry not only meets but exceeds its quality and compliance requirements in the future.

6. REFERENCE

Alizadehsani, R. *et al.* (2023) (arXiv:2309.12177) DOI: 10.48550/arXiv.2309.12177.

Altrabsheh, E., Heitmann, M. and Lochbronner, A. (2022) *AI Governance and QA Framework: AI Governance Process Design | Pharmaceutical Engineering*. Available at: <https://ispe.org/pharmaceutical-engineering/july-august-2022/ai-governance-and-qa-framework-ai-governance-process> (Accessed: 14 July 2025).

Andrianandrianina Johanesa, T.V., Equeter, L. and Mahmoudi, S.A. (2024) (5) ‘Survey on AI Applications for Product Quality Control and Predictive Maintenance in Industry 4.0’. *Electronics*, 13(5), p. 976. DOI: 10.3390/electronics13050976.

Anson, D. *et al.* (2023) *Pfizer Boosts Bioreactor Efficiency with AWS Industrial Edge Services | AWS for Industries*. Available at: <https://aws.amazon.com/blogs/industries/pfizer-boosts-bioreactor-efficiency-with-aws-industrial-edge-services/> (Accessed: 12 July 2025).

Birse, M. (2024) ‘Use of AI in Pharmaceutical Quality and Operations’.

Cowman, S. (2018) ‘Integrating Data from QC and Production to Enable Fast, Informed Decisions’. *European Pharmaceutical Review*. Available at: <https://www.europeanpharmaceuticalreview.com/article/80896/integrating-informed-decisions/> (Accessed: 11 July 2025).

Eckford, C. (2025) *Tech Advancement to Drive Lab Automation Market through 2035*. *European Pharmaceutical Review*. Available at: <https://www.europeanpharmaceuticalreview.com/news/262867/technology-advancement-to-drive-lab-automation-market-through-next-decade/> (Accessed: 12 July 2025).

Franchetti, J. (2024) *10 Common Data Integrity Challenges in Pharmaceutical Manufacturing*. *JAF Consulting, Inc.* Available at: <https://jafconsulting.com/blog/10-common-data-integrity-challenges-in-pharmaceutical-manufacturing/> (Accessed: 11 July 2025).

Han, Y. and Tao, J. (2024a) (arXiv:2401.10273) DOI: 10.48550/arXiv.2401.10273.

Han, Y. and Tao, J. (2024b) (arXiv:2401.10273) DOI: 10.48550/arXiv.2401.10273.

Insights, E. pharmaceutical manufacturing processes with real-time. and Gadsby, M. (2023) ‘Elevating Pharmaceutical Manufacturing Processes with Real-Time Insights’. *European*

Pharmaceutical Review, 28(5), pp. 44–47. Available at: <https://www.europeanpharmaceuticalreview.com/article/188595/elevating-pharmaceutical-manufacturing-processes-with-real-time-insights/> (Accessed: 12 July 2025).

Jeong, H.-Y., Jeong, Y.-S. and Park, J.H. (2014) *Figure 1. Four Types of Strategic Integration*. *ResearchGate*. Available at: https://www.researchgate.net/figure/Four-types-of-strategic-integration_fig1_288391283 (Accessed: 22 August 2025).

Keezhadath, A.A. and Amarapalli, L. (2025) (PDF) *Ensuring Data Integrity in Pharmaceutical Quality Systems: A Risk-Based Approach*. *ResearchGate*. DOI: 10.60087/japmi.vol01.issue01.p104.

Kim, E.J. *et al.* (2021) ‘Process Analytical Technology Tools for Monitoring Pharmaceutical Unit Operations: A Control Strategy for Continuous Process Verification’. *Pharmaceutics*, 13(6), p. 919. DOI: 10.3390/pharmaceutics13060919.

Mayuri.R.Mandlik, Mayuri.R.M., Pathan.N.Hakimkhan, Pathan.N.H. and Punam.B.Mahanor, Punam.B.M. (2025) ‘Integrating Artificial Intelligence into Drug Development and Manufacturing: Advancements and Challenges’. *International Journal of Pharmaceutical Research and Applications*, 10(1), pp. 417–425. DOI: 10.35629/4494-1001417425.

Mussati, L., SSA, S. and Vermani, A. (2025) *AI/ML Technology: Harnessing AI/ML Technology for the CQV Life Cycle | Pharmaceutical Engineering*. Available at: <https://ispe.org/pharmaceutical-engineering/january-february-2025/aiml-technology-harnessing-aiml-technology-cqv> (Accessed: 22 August 2025).

Niazi, S.K. (2025) (6) ‘Regulatory Perspectives for AI/ML Implementation in Pharmaceutical GMP Environments’. *Pharmaceutics*, 18(6), p. 901. DOI: 10.3390/ph18060901.

O’Connor, D. *et al.* (2025) *Limitations of Current Digital Validation Tools | Pharmaceutical Engineering*. Available at: <https://ispe.org/pharmaceutical-engineering/ispeak/limitations-current-digital-validation-tools> (Accessed: 11 July 2025).

Oman, S. *et al.* (2017) *Figure 1 Conceptual Model of MES and ERP Systems Integration*. *ResearchGate*. Available at: https://www.researchgate.net/figure/Conceptual-model-of-MES-and-ERP-systems-integration_fig1_321980105 (Accessed: 22 August 2025).

Palaniappan, K., Lin, E.Y.T. and Vogel, S. (2024) ‘Global Regulatory Frameworks for the Use of Artificial Intelligence (AI) in the Healthcare Services Sector’. *Healthcare*, 12(5), p. 562. DOI: 10.3390/healthcare12050562.

Ramnarine, E. (2021) ‘Solving the Continual Improvement and Innovation Challenge for the Benefit of Patients: How an Effective Pharmaceutical Quality System (PQS) and Risk-Based Approach Could Transform Post-Approval Change (PAC) Management’.

Rao, S. (2025) *Data Quality Issues Affecting the Pharmaceutical Industry: Finding a Solution*. *FirstEigen*. Available at: <https://firsteigen.com/blog/data-quality-issues-affecting-the-pharmaceutical-industry-finding-a-solution/> (Accessed: 11 July 2025).

Roche. (2024) *Roche Receives FDA Clearance on Its Digital Pathology Solution for Diagnostic Use. Diagnostics*. Available at: <https://diagnostics.roche.com/global/en/news-listing/2024/roche-receives-fda-clearance-on-its-digital-pathology-solution-for-diagnostic-use.html> (Accessed: 14 July 2025).

Sachdeva, P. (2024) *Ensuring Compliance and Data Integrity in the Pharma Industry. Princeton Blue*. Available at: <https://princetonblue.com/ensuring-compliance-and-data-integrity-in-the-pharma-industry/> (Accessed: 11 July 2025).

Salviotti, G., Gaur, A. and Pennarola, F. (2019) ‘STRATEGIC FACTORS ENABLING DIGITAL MATURITY: AN EXTENDED SURVEY’.

Santosh, P.S. (2025) ‘A Review on Current Trends and Challenges in Pharmaceutical Quality Control’.

Simpson, M.D. and Qasim, H.S. (2025a) (2) ‘Clinical and Operational Applications of Artificial Intelligence and Machine Learning in Pharmacy: A Narrative Review of Real-World Applications’. *Pharmacy*, 13(2), p. 41. DOI: 10.3390/pharmacy13020041.

Simpson, M.D. and Qasim, H.S. (2025b) (2) ‘Clinical and Operational Applications of Artificial Intelligence and Machine Learning in Pharmacy: A Narrative Review of Real-World Applications’. *Pharmacy*, 13(2), p. 41. DOI: 10.3390/pharmacy13020041.

Stout, D.W. (2025) *Ultimate Guide to Real-Time Data for AI Projects. Magai*. Available at: <https://magai.co/real-time-data-for-ai-projects/> (Accessed: 12 July 2025).

tn_admin. (2025) *Using AI to Boost Efficiency and Ensure Regulatory Compliance. Experic CDMO*. Available at: <https://expericservices.com/using-ai-to-boost-efficiency-and-ensure-regulatory-compliance/> (Accessed: 14 July 2025).

Utkarsha A. Wadighare and Swati P. Deshmukh (2024) ‘A Review on Artificial Intelligence and Machine Learning Used in Pharmaceutical Research’. *GSC Biological and Pharmaceutical Sciences*, 26(1), pp. 191–198. DOI: 10.30574/gscbps.2024.26.1.0446.

Vora, L.K. *et al.* (2023) ‘Artificial Intelligence in Pharmaceutical Technology and Drug Delivery Design’. *Pharmaceutics*, 15(7), p. 1916. DOI: 10.3390/pharmaceutics15071916.

Wasalathanthria, D.P., Ding, J. and Jian Li, Z. (2020) *Real Time Process Monitoring in Biologics Development*. Available at: <https://www.americanpharmaceuticalreview.com/Featured-Articles/564225-Real-Time-Process-Monitoring-in-Biologics-Development/> (Accessed: 11 July 2025).

Yousfi, M. (2020) *Pharmaceutical Data Integrity: Issues, Challenges and Proposed Solutions for Manufacturers and Inspectors. GaBIJ*. Available at: <https://gabi-journal.net/pharmaceutical-data-integrity-issues-challenges-and-proposed-solutions-for-manufacturers-and-inspectors.html> (Accessed: 11 July 2025).

Zaytsev, A. (2024) *Case Study: AstraZeneca Leverages AI for Innovation. AIX | AI Expert Network*. Available at: <https://aiexpert.network/astrazeneca-ai/> (Accessed: 14 July 2025).

7. APPENDICES

Appendix A: Ethics Application & Declaration Form



Ethics Application & Declaration Form

DISSERTATION TITLE: AI-Enabled System Integration In Pharmaceutical Quality Control

RESEARCHER'S NAME: Nikhila Mangalapilly Ramakrishnan

PROGRAMME OF STUDY: MSc In Digital Transformation Life Science

SUPERVISOR'S NAME: Eucharía Esemuede

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:

A handwritten signature in blue ink, appearing to read "Nikhila".

DATE: 02/07/2025

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

For Supervisor:

Ethics Committee Approval Required: No

SUPERVISOR SIGNATURE:

A handwritten signature in brown ink, appearing to read "E. Esemuede".

DATE: 07/07/2025

For Ethics Committee (if required):

Ethics Committee Approval Given:

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

Investigating how artificial intelligence (AI) can improve pharmaceutical quality control (QC) through real-time data processing, predictive analytics, and better system integration is the aim of this study. Manual data entry, siloed systems, and delayed decision-making are common obstacles to traditional QC systems in the pharmaceutical industry, which may harm accuracy, efficiency, and regulatory compliance (European Pharmaceutical Review, 2023). There is an increasing demand for intelligent, networked systems that can facilitate data integrity and dynamic decision-making as the industry moves toward digital transformation.

Recent research has demonstrated that artificial intelligence (AI) technologies, including machine learning, natural language processing, and real-time anomaly detection, are starting to impact pharmaceutical operations, particularly in domains like automated validation, predictive quality control, and error reduction (Wadighare & Deshmukh, 2024; Simpson & Qasim, 2025). However, there are still variations in the use of AI in QC, and there are organizational and operational difficulties when integrating AI with LIMS, MES, and ERP.

This study intends to explore the advantages and disadvantages that professionals encounter when integrating AI into QC workflows, as well as the strategic framework that could facilitate broader adoption. The study uses a mixed-methods approach, integrating secondary literature with survey-based data from QC and QA professionals.

RESEARCH OBJECTIVES

- To examine the problems that traditional pharmaceutical QC systems are currently facing.
- To evaluate the methods in which real-time monitoring, automated data validation, and predictive analytics can improve QC using AI technologies.
- To investigate how AI can be used to integrate various QC systems for smooth data transfer.
- To assess case studies from the industry that show measurable gains in quality control brought about by the use of AI.
- To provide a strategic framework for integrating AI-enabled QC systems in pharmaceutical environments.

1.2 Research methodology

A mixed-methods approach is used in this study to collect quantitative and qualitative data from experts in pharmaceutical quality assurance (QA) and control (QC). The primary data will be gathered via an online structured survey that will be shared through academic channels, professional networks, and LinkedIn. This approach was selected due to its effectiveness, accessibility, and capacity to reach a globally heterogeneous group of participants employed in pharmaceutically regulated settings.

Both closed-ended Yes/No questions and open-ended answers will be included in the survey. The system integration status, perceived advantages or disadvantages of AI in QC procedures, and adoption levels will all be measured with the aid of the closed-ended questions. To address the exploratory nature of the research, the open-ended questions will lead to deeper insights into real-world experiences, obstacles, and expectations.

Participants will include professionals with industry experience from both the Quality Control (QC) and Quality Assurance (QA) functions, including QC Analysts, QA Officers, Data Reviewers, Validation Professionals, and Quality Systems Analysts. The study intends to gather different perspectives on AI integration across various quality functions within the pharmaceutical industry by incorporating both QC and QA roles. Cochran's formula will be used to calculate the necessary sample size in order to maintain rigorous methods and offer a statistically solid foundation for data analysis. Using this method, the calculated sample size is 126 participants combined from QA and QC roles. This strategy supports academic transparency while improving the study's objective of collecting reliable, representative insights from business professionals.

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	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

If you have answered NO to ALL questions, please go straight to Section 4.

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

SECTION 3: STEPS TAKEN TO AVOID ETHICAL ISSUES

- 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 in this study will include professionals who are currently employed in the pharmaceutical industry in Quality Assurance (QA) and Quality Control (QC) positions. These positions have been selected because they directly participate in the systems, procedures, and legal requirements that are most affected by the incorporation of artificial intelligence (AI) technologies into quality control.

Specifically, the group of participants will consist of:

QC scientists and analysts who work in testing, data collection, and real-time product quality monitoring.

QA officers and specialists are in charge of audit readiness, documentation, compliance, and validation.

Data reviewers, validation specialists, and quality systems analysts are possible additional positions that involve frequent interaction with digital tools and quality systems.

4.2 How do you plan to gain access to/contact/approach your participant(s).

A combination of specific communications and professional networking sites will be used to reach out to participants. The survey will be distributed specifically through:

LinkedIn: Professionals currently employed in QC and QA positions in the pharmaceutical sector will be reached through posts and direct messages.

Professional networks: Relationships formed through academic and professional connections, such as lecturers, former coworkers, and Griffith College alumni.

Snowball sampling: Colleagues who suitable to the participation requirements will be requested to share with their colleagues regarding the survey.

The invitation will include a brief explanation of the study, the eligibility requirements (such as having experience of QC or QA), and the participation is voluntary and anonymous, and a link to the online survey and consent form.

The goal of this multi-channel strategy is to guarantee a targeted but varied set of answers from experts who work closely with quality systems and procedures. Organizational or personal identities will not be collected unless they are voluntarily shared.

SECTION 5: INFORMATION, CONSENT AND CONFIDENTIALITY

5.1 Participant Information Letter (PIL) for participants

Please confirm below that your information letter covers:

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

5.2 Informed Consent Form (ICF) for participants

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

Consent will be included in the online survey as follows:

1. Do you consent to participate in this study?

Yes, I consent to participate.

No, I do not consent to participate

SECTION 6: STORAGE OF DATA

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

All research data will be gathered and preserved in compliance with relevant national data protection laws as well as the General Data Protection Regulation (GDPR). Responses to the survey will be collected via Google Forms, which will be connected to a password-protected Google Drive account that is only accessible by the principal investigator.

There will be no collection of any personal identifiers, such as names, company names, or contact information, guaranteeing that all information is anonymous and untraceable. Participants will be informed that their participation is voluntary and that they may withdraw at any time before submitting their response.

Data will not be shared with other organizations and will only be utilized for scholarly purposes associated with this research project. In accordance with academic and ethical guidelines, responses will be safely stored for two years after the research project is finished. All data will be permanently erased at the end of this period.

To further safeguard the privacy of participants:

Digital formats that are encrypted will be used to store survey data.

No hard copies of the answers will be produced.

For the purpose of preventing participant identification, all analyses will be presented in aggregate form.

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 | N/A |
| 9.2 Informed Consent Form (ICF) for participant | N/A |
| 9.3 Questions/survey for interviewees/focus groups etc <i>(can be in draft form)</i> | 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: 02/07/2025

Appendix B: Survey questionnaire

Questions for QA Professionals

Section 1: Challenges in Traditional QA Processes

1. Do you experience delays in batch record approvals or documentation processes because of manual systems?

- Yes
- No
- Not Sure

2. Are your QA processes mostly on paper or reliant on manual data entry?

- Yes
- No
- Partially

3. Have you faced problems with traceability or audit trail generation in your current QA systems?

- Yes
- No
- Occasionally

Section 2: AI Use in QC & QA

4. Are AI technologies, like natural language processing and machine learning, currently used in your QA-related workflows?

- Yes
- No
- Not Aware

5. Do you think AI could help automate quality document reviews or manage deviations?

- Yes
- No
- Not Sure

6. Does your organization use any real-time monitoring tools for quality review or oversight?

- Yes
- No
- Planning to implement

7. Are your QA systems connected to QC data sources such as LIMS, MES, or ERP platforms?

- Yes
- No
- Partially integrated

8. Do you have access to predictive analytics that can identify quality risks before they turn into compliance issues?

- Yes
- No
- Not Applicable

Section 3: Evidence & Impact

9. Have you noticed any clear improvements, such as shorter review times, fewer errors, or quicker batch releases, since you started using AI tools?

- Yes
- No
- Not Applicable

9a. If YES, please describe the improvements you've seen in QA operations.

10. Do you think AI has made your organization better prepared for audits or more compliant with regulations?

- Yes
- No
- Not Sure

10a. If yes, what specific area of compliance or audit preparation has improved due to AI?

Section 4: Strategic Integration

11. Has your organization created a digital transformation plan that includes using AI in QA?

- Yes
- No
- Not Sure

12. Are there clear SOPs or guidelines for applying AI tools in quality workflows?

- Yes
- No
- In development

13. Do you think more training or skill development is necessary for successful AI integration in QA?

- Yes
- No
- Possibly

14. In your opinion, what is the greatest benefit and the biggest limitation of using AI in Quality Assurance?

Questions for QC Professionals

Section 1: Traditional QC Challenges

1. Are you currently using manual entry or spreadsheet-based systems in your quality control (QC) operations?

- Yes
- No
- Occasionally

2. Have there been quality testing delays due to system fragmentation or lack of automation?

- Yes
- No
- Sometimes

3. Does it become difficult to access real-time information from equipment or systems involved in QC?

- Yes
- No
- Not Applicable

4. Has human error during documentation or testing ever caused deviations or rework?

- Yes
- No
- Not Sure

Section 2: AI in Real-Time Monitoring and Predictive Analytics

5. Is AI technology (e.g., machine learning or prediction models) being utilized in your QC processes?

- Yes
- No
- Not Aware

6. Does your QC have any real-time monitoring solution?

- Yes
- No
- Planning to implement

7. Has AI helped in automating data checks or alerted you to test result anomalies?

- Yes
- No
- Not Yet Used

8. Do you believe predictive analytics could help in predicting product deviations or test failures?

- Yes
- No
- Unsure

Section 3: System Integration Using AI

9. Are your quality control (QC) systems (e.g., instruments, laboratory information management systems (LIMS), and enterprise resource planning (ERP) systems) integrated for seamless data transfer?

- Yes
- No
- Partially

10. Has AI facilitated more integration or communication between your quality control (QC) systems?

- Yes
- No
- Not Applicable

11. Are test results automatically transferred from instruments to digital systems without manual intervention?

- Yes
- No
- Depends on the system

Section 4: Evidence of Measurable Gains

12. Have you seen any improvement in QC turnaround time or result accuracy since you started using AI tools?

- Yes
- No
- Not Sure

12a. Could you provide more details on the specific changes you've observed in your QC activities?

13. Has the number of deviations or out-of-specification (OOS) events decreased since the introduction of AI?

- Yes
- No
- Don't Know

Section 5: Strategic Integration of AI

14. Has your organization provided any formal training on AI tools for quality control?

- Yes
- No
- Not Yet

15. Are there any established protocols or SOPs for the use of AI in QC operations?

- Yes
- No
- In development

16. Do you believe that your organization is ready to expand its use of AI in QC processes?

- Yes
- No
- Somewhat

17. In your opinion, what is the greatest benefit and the biggest limitation of using AI in Quality Control?

10.2 Sample Size Calculations

Based on Cochran's formula, the estimated sample size for this study is around 126 participants, assuming a 95% confidence level, a 5% margin of error, and a 9% estimated population proportion (average between 10% for QC and 8% for QA professionals). For practical purposes, the study will treat Quality Control (QC) and Quality Assurance (QA) professionals as a combined group.

Cochran's Formula:

$$n = \frac{Z^2 \times P \times (1-P)}{e^2}$$

n = Required sample size
Z = Z-score (standard value based on confidence level)
P = Estimated population proportion
e = Margin of error

Let's assume:

- **P = 0.09 (9%)**, the average between 10% (QC) and 8% (QA)
- **Z = 1.96** (for 95% confidence)
- **e = 0.05** (margin of error at 5%)

$$n = \frac{(1.96)^2 \times 0.09 \times (1 - 0.09)}{(0.05)^2} = 125.84$$

Total Sample Size = 126 participants (combined QA + QC)