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Assignment Type:	**Individual: Yes**	**Group: No**	
Course:	**Pharmaceutical business and technology**	**Stage/year:**	**1**
Module:	**Dissertation**		
Study Mode:	Full time		
Supervisor Name:	**Dr. Victor David Vendrell**		
Assignment Title:	**Evaluating the Role of ICH Q9-Based Quality Risk Management in Reducing CAPA Recurrence Rates: A Study of GMP-Regulated Pharmaceutical Companies in Ireland**		
No. of pages: 69			
Uploaded to Moodle:	Yes		
Additional Info:			
Date due: 25/08/2025			
Date submitted: 24/08/25			

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Evaluating the Role of ICH Q9-Based Quality Risk Management in Reducing CAPA Recurrence Rates: A Study of GMP-Regulated Pharmaceutical Companies in Ireland

GRIFFITH COLLEGE DUBLIN

A thesis submitted in partial fulfilment of the Requirements for the degree of

Msc in pharmaceutical business and technology

Innopharma Faculty of Pharmaceutical Sciences

Griffith College Dublin

September 2025

Name of the Supervisor: Dr. Victor David Vendrell

Name of the Researcher: Cladissophiya George

CANDIDATE DECLARATION

Candidate name: **CLADISSOPHIYA GEORGE**

I certify that the dissertation entitled:

"Evaluating the Role of ICH Q9-Based Quality Risk Management in Reducing CAPA Recurrence Rates: A Study of GMP-Regulated Pharmaceutical Companies in Ireland"

submitted in partial fulfilment of the requirements for the degree, MSc in Pharmaceutical Business and Technology is the result of my own work and that where reference is made to work of others, due acknowledgment is given.

Candidate

Signature: G. Cladissophiya Date: 20/08/2025

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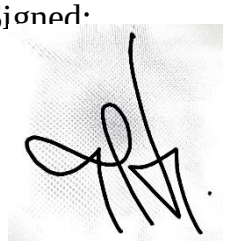
21/08/2025



ACKNOWLEDGEMENT

First and foremost, I would like to express my sincere gratitude to **Dr. Victor David Vendrell**, my supervisor, for their invaluable guidance, constructive feedback, and encouragement throughout the course of this dissertation. Their expertise and support have been instrumental in shaping the direction and quality of this research.

I would also like to thank the faculty and staff of **Griffith college** for providing the resources, academic support, and learning environment that enabled me to complete this work successfully.

My appreciation extends to all the **industry professionals and survey participants** who generously contributed their time and insights, without which this research would not have been possible.

A special thanks goes to my better half **Mark Skymanee** for his continuous support and for helping me relieve stress during challenging times.

I am deeply grateful to my **family and friends** for their patience, understanding, and unwavering support during this academic journey. Their encouragement has been a constant source of strength and motivation.

Finally, I would like to acknowledge my peers and colleagues who shared valuable discussions and feedback, which enriched both my learning and this dissertation.

EVALUATING THE ROLE OF ICH Q9-BASED QUALITY RISK MANAGEMENT IN REDUCING CAPA RECURRENCE RATES: A STUDY OF GMP-REGULATED PHARMACEUTICAL COMPANIES IN IRELAND

Table of Contents

List of figures

List of tables

Abstract

This research examines the contribution that Quality Risk Management (QRM) under the ICH Q9 framework can make to resolving the long-standing problem of recurring Corrective and Preventive Actions (CAPAs) in Irish pharmaceutical manufacturing. Even with good regulatory management that is seen with EU GMP, the repeated occurrence of problems within many sites remains to be a source of disappointment to product quality and efficiency within the operations. This research study conducted a systematic survey of 109 quality professionals to investigate the maturity of QRM practices in use, perceived utility of QRM tools, and the degree to which regulatory alignment can be used to impact the results of CAPAs.

The results point out that greater QRM maturity is strongly linked to increased CAPA success and lower recurrence. The respondents in the locations that have high integration of QRM practices gave higher ratings to the effectiveness of CAPA processes and those with low levels documented recurring issues. The regression analysis also showed that the alignment of regulatory practices to the EU GMP and ICH Q9 regulations significantly affected the decline of CAPA recurrence, but the actual presence of formal QRM policies did not cause significant difference.

The work has academic and practical contributions by highlighting the importance of a better integration of QRM into CAPA investigations, as opposed to policy-based adoption. Practitioner recommendations to the industry, as well as academic recommendations on the longitudinal effects, are given.

CHAPTER 1: INTRODUCTION

1.1 Background of the Study

Corrective and Preventive Action (CAPA) is a fundamental quality assurance tool used across regulated industries, particularly in the pharmaceutical sector. It refers to a structured process aimed at identifying, investigating, and resolving quality issues by implementing corrective measures to fix existing problems and preventive strategies to avoid recurrence (FDA, 2006; EMA, 2023). CAPA is a mandatory requirement under international Good Manufacturing Practice (GMP) standards and forms a critical component of pharmaceutical Quality Management Systems (QMS), as outlined in ICH Q10: Pharmaceutical Quality System.

CAPA is employed by pharmaceutical manufacturers, contract manufacturing organisations (CMOs), and quality departments to handle quality-related incidents such as production deviations, audit findings, product complaints, equipment malfunctions, and regulatory observations. Regulatory authorities such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) require robust CAPA systems as part of GMP inspections and compliance assessments. Failures in CAPA processes are among the leading causes of FDA warning letters issued to pharmaceutical companies (ISPE, 2019).

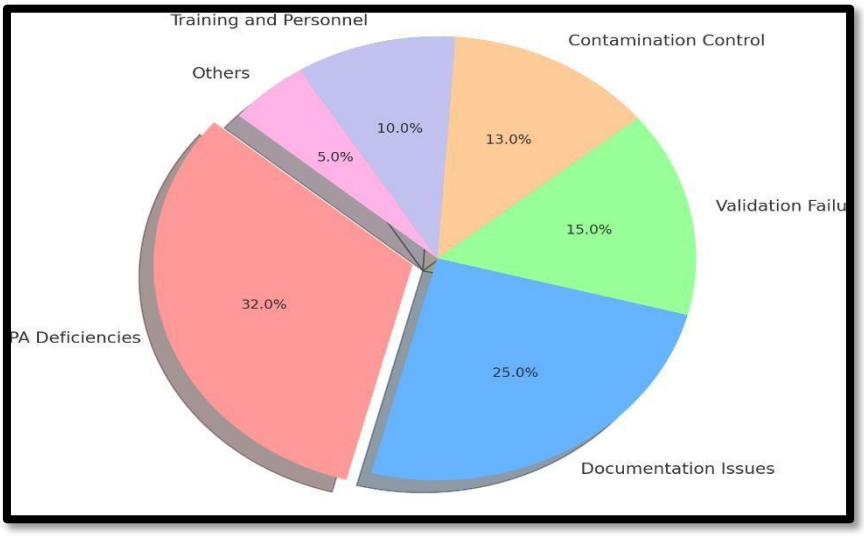


Figure 1: Common Causes of FDA Warning Letters 2018–2023 (ISPE, 2019; FDA, 2023).

In practical terms, the CAPA process involves several stages, including:

- **Problem identification and reporting:** This stage includes capturing deviations, audit findings, or non-conformances.
- **Investigation and root cause analysis**: Using techniques such as the 5 Whys, Fishbone diagrams, or Failure Mode and Effects Analysis (FMEA) to determine the underlying causes.
- **Corrective actions**: Actions taken to eliminate the root cause of a detected deviation or problem.
- **Preventive actions**: Measures implemented to prevent potential issues that have not yet occurred but are likely based on risk assessment.
- **Effectiveness checks**: Validation to ensure the actions taken have resolved the issue and prevented recurrence.
- **Closure:** Final documentation, including sign-off by QA and cross-functional stakeholders (MHRA, 2015; PDA, 2021).

CAPA is deeply embedded in other pharmaceutical quality systems such as change control, deviation management, complaint handling, and product recall procedures. Its effective implementation contributes to continuous improvement, supports regulatory compliance, and enhances product quality and patient safety.

Key components of a CAPA system includes Documentation and traceability of all steps, Root cause analysis (RCA) methodology, Defined timelines and responsible persons, Risk-based prioritisation of actions, Monitoring of implementation, Final review and effectiveness check.

ICH Q9 is an international guideline titled *Quality Risk Management*, developed by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). Officially introduced in 2005, the guideline provides a structured, science-based approach for identifying, assessing, controlling, and reviewing risks that may impact pharmaceutical product quality and patient safety throughout the entire product lifecycle—from development and manufacturing to packaging, distribution, and post-marketing surveillance (ICH, 2005).

ICH Q9 is primarily used by pharmaceutical manufacturers operating in Good Manufacturing Practice (GMP)-regulated environments, as well as by regulatory agencies such as the European Medicines Agency (EMA), U.S. Food and Drug Administration (FDA), and Health Canada. It is designed to support the pharmaceutical industry in making consistent, risk-based decisions and to help regulatory bodies ensure product safety and compliance.

In pharmaceutical quality systems, **ICH Q9** is applied to several core processes to ensure product quality and regulatory compliance. These include **Corrective and Preventive Actions (CAPA)**, **change control**, **deviation and incident management**, **equipment and process validation**, **supply chain risk management**, and **technology transfer**.

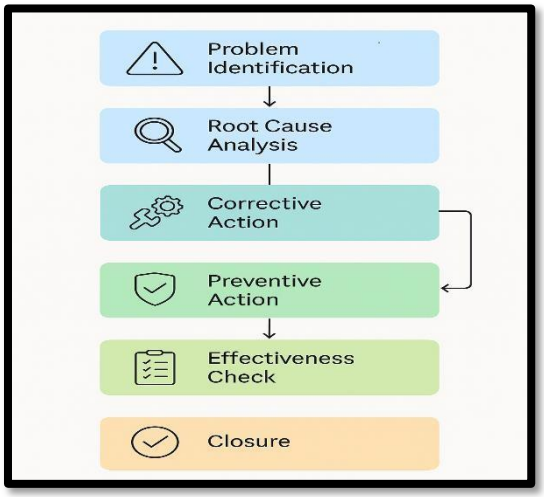


Figure 2: Standard CAPA Process Flow (PDA, 2021; MHRA, 2015)

The guideline provides a systematic approach to managing risks through four main components: **risk assessment**, which involves identifying potential hazards and evaluating their likelihood and severity; **risk control**, which determines actions to reduce or mitigate those risks; **risk review**, which ensures continuous monitoring and updates of risk profiles; and **risk communication**, which promotes effective sharing of risk information across departments and stakeholders (ICH, 2005). To support these activities, ICH Q9 encourages the use of various risk management tools, including **Failure Mode and Effects Analysis (FMEA)**, **Hazard Analysis and Critical Control Points (HACCP)**, **Risk Ranking and Filtering**, and **Fault Tree Analysis (FTA**). By applying these tools, companies can enhance process understanding, improve regulatory compliance, prioritize resources, and minimize the recurrence of quality issues (Teasdale and Elder, 2018).

Figure 3: Core Elements of ICH Q9 Quality Risk Management (ICH, 2005)

In essence, ICH Q9 encourages a shift from reactive problem-solving to proactive, risk-based decision-making, supporting continuous improvement in pharmaceutical operations while maintaining patient safety and product reliability.

1.2 Research Problem

Despite the critical role that CAPA (Corrective and Preventive Action) systems play in maintaining regulatory compliance and driving continuous improvement in pharmaceutical manufacturing, many companies continue to experience recurring quality issues even after CAPAs have been officially closed. This persistent recurrence reveals serious underlying gaps in how CAPA systems are implemented and managed, particularly in relation to root cause analysis (RCA), application of risk management tools, staff training, and quality culture (Waldron, 2017). Investigations into CAPA failures often show that companies do not probe deeply enough into the true root causes of deviations, and instead rely on superficial or incomplete assessments. In many cases, actions taken are corrective only at a surface level, without addressing systemic or process-level weaknesses that could prevent similar issues in the future.

A major factor contributing to these inefficiencies is the inconsistent and often cosmetic application of Quality Risk Management (QRM) as outlined in ICH Q9. While QRM is widely recognized as essential to pharmaceutical quality systems and is expected by regulators, many companies treat QRM as a formal requirement rather than an operational strategy. That means while QRM might be documented in SOPs or included in deviation reports, it is not genuinely integrated into daily decision-making or quality improvement processes. This disconnect

weakens the potential of ICH Q9 to drive proactive quality management, especially within CAPA systems where proper risk-based thinking should guide both the investigation and the preventive strategy design.

The core problem is the mismatch between the theoretical framework provided by ICH Q9 and the practical reality of CAPA execution on the ground. ICH Q9 promotes the use of structured tools like FMEA (Failure Mode and Effects Analysis), HACCP, and risk matrices, but these tools are often underutilized, misunderstood, or applied too late in the deviation lifecycle. As a result, pharmaceutical companies continue to operate in a reactive mode, dealing with deviations after they occur rather than designing processes that anticipate and prevent them.

1.3 Purpose of the study

This research seeks to examine whether stronger and more mature integration of ICH Q9-based QRM principles into CAPA systems can reduce the recurrence of quality issues. Specifically, it explores the Irish GMP pharmaceutical manufacturing landscape, where the industry is well-developed and regulatory expectations are high. The study aims to identify the current challenges companies face in implementing QRM effectively and whether those that apply ICH Q9 more rigorously experience lower CAPA recurrence rates, better compliance, and enhanced product quality. Understanding this relationship can help build a practical framework that improves both CAPA effectiveness and the overall quality risk culture within pharmaceutical organisations.

1.4 Rationale for Choosing Ireland as the Study Location

Ireland has a globally recognised pharmaceutical sector, with more than 85 pharmaceutical companies operating within its borders, including nine of the top ten global pharmaceutical firms (IDA Ireland, 2023). The country serves as a major hub for drug manufacturing, quality control, and regulatory operations in the European Union. As a result, GMP compliance and alignment with ICH guidelines, including ICH Q9, are core expectations in Irish pharma operations.

Figure 4: Ireland's Pharmaceutical Footprint in the EU (IDA Ireland, 2023)

Despite its advanced infrastructure and regulatory maturity, recurring quality issues and CAPA inefficiencies continue to challenge even top-tier pharmaceutical companies. This suggests that regulatory alignment does not always translate into effective operational risk management, particularly in the consistent application of QRM tools like FMEA or HACCP during CAPA investigations.

Moreover, there is limited academic literature exploring how Irish GMP-regulated companies apply ICH Q9 specifically within CAPA systems, creating a clear research gap. Ireland's strong culture of regulatory adherence, combined with its global pharmaceutical relevance, makes it a strategically valuable setting to assess how QRM maturity impacts CAPA recurrence.

By focusing on Ireland, this study aims to generate real-world, data-driven insights that can inform continuous improvement strategies not only within the country but also in other regulated pharmaceutical environments with similar operational frameworks.

1.5 Significance of the Study

This research is significant for the following reasons:

1. Enhances Regulatory Compliance: The study supports alignment with global regulatory expectations such as those from the EMA and FDA.
2. Strengthens Root Cause Analysis: Embedding QRM tools can improve the accuracy of investigations and reduce superficial CAPA closures.

3. Improves Operational Efficiency: A proactive QRM strategy can help allocate resources more effectively and reduce rework.
4. Reduces Financial and Quality Risks: Recurring CAPAs increase inspection risk and cost; reducing these adds business value.
5. Fills a Research Gap in the Irish Pharmaceutical Industry: There is limited published research specifically evaluating QRM-CAPA integration in Ireland.
6. Supports Continuous Improvement: Promotes a learning culture within pharmaceutical organisations.

1.6 Research Objectives

- To assess current practices of integrating ICH Q9-based QRM principles into CAPA systems in GMP-regulated pharmaceutical companies in Ireland.
- To evaluate whether mature QRM implementation correlates with reduced CAPA recurrence.
- To identify the challenges and gaps in applying QRM tools during CAPA lifecycles.
- To propose a practical framework for enhancing CAPA outcomes through improved QRM integration.
- To provide recommendations to support continuous improvement in pharmaceutical quality systems.

1.7 Research Questions

- To what extent does the integration of ICH Q9-based QRM reduce recurring CAPAs in Irish pharmaceutical manufacturing?
- What are the practical barriers to implementing effective QRM systems that prevent CAPA recurrence in Ireland's GMP-compliant pharma sector?
- How do Quality Assurance professionals in Irish pharmaceutical companies assess the effectiveness of QRM in managing recurring deviations?

1.8 Hypothesis

Pharmaceutical companies in Ireland that demonstrate mature implementation of ICH Q9-based QRM principles will exhibit lower CAPA recurrence rates and enhanced quality system performance compared to companies with less integrated QRM practices.

Chapter 2: LITERATURE REVIEW

2.1 Literature Map of Thematic Areas in QRM and CAPA

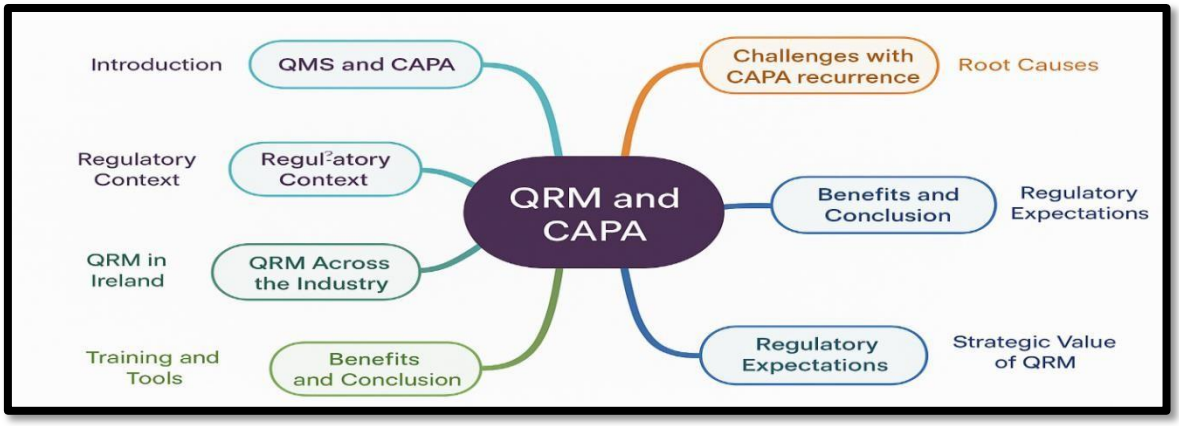


Figure 5: Literature Map of Thematic Areas in QRM and CAPA (George, 2025)

2.2 Introduction to Quality Management Systems and CAPA in Pharmaceuticals

In the highly regulated pharmaceutical industry, Quality Management Systems (QMS) serve as the backbone for ensuring that medicinal products are consistently produced and controlled to the standards required for their intended use. These systems are designed not only to meet regulatory expectations but also to uphold patient safety, therapeutic efficacy, and manufacturing reliability. Global health authorities including the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) mandate adherence to Good Manufacturing Practice (GMP) regulations, which require that companies establish, document, and maintain robust QMS frameworks that include structured mechanisms for identifying and managing quality risks (Charoo & Ali, 2013; Niazi, 2021).

Within these QMS frameworks, one of the most critical components is the Corrective and Preventive Action (CAPA) system. CAPA is a structured, science-based process designed to investigate non-conformities and deviations, determine their root causes, and implement corrective actions to eliminate the causes of existing issues, as well as preventive actions to mitigate the potential for recurrence (O'Donnell et al., 2012). The importance of CAPA is emphasized across numerous regulatory guidelines and inspection programs because effective CAPA systems are closely linked to continuous improvement, product quality, and regulatory compliance.

In theory, a well-functioning CAPA system should lead to a significant reduction in repeat deviations, customer complaints, product recalls, and adverse event reports. However, persistent CAPA recurrence remains a widespread issue in the pharmaceutical industry, indicating that many CAPA programs may fall short in practice. This recurrence defined as the re-emergence of the same or similar deviations despite previous CAPA closure reflects deep-rooted challenges in root cause analysis, risk prioritization, and systematic follow-through (Rompicherla et al., 2020). Many organisations continue to take a reactive approach to CAPA, implementing short-term fixes rather than conducting comprehensive investigations that can drive sustainable change (PDA, 2012).

This challenge is further compounded by a lack of structured integration between CAPA and Quality Risk Management (QRM) frameworks, such as those defined in ICH Q9. In many cases, CAPAs are initiated and closed without adequate application of risk assessment tools like Failure Mode and Effects Analysis (FMEA), Hazard Analysis and Critical Control Points (HACCP), or risk ranking matrices. This disconnect prevents companies from effectively prioritising risks or tailoring preventive actions based on their likelihood and potential impact (Charoo & Ali, 2013).

Moreover, the culture of compliance in some organisations tends to focus on closing CAPAs rapidly to meet audit or inspection deadlines rather than ensuring that the actions taken truly address systemic vulnerabilities (Niazi, 2021). This behaviour can lead to documentation-heavy but effectiveness-light CAPA processes, undermining their intended function as a driver of improvement.

Therefore, understanding how CAPA operates within QMS, the extent to which QRM tools are applied during CAPA execution, and identifying the gaps that lead to recurrence are essential for strengthening pharmaceutical quality systems. When properly implemented, CAPA is not just a compliance requirement but a strategic mechanism to prevent patient harm and build trust in the safety and reliability of pharmaceutical products.

2.3 Regulatory Context: GMP, ICH Guidelines, and QRM

The global pharmaceutical industry operates within a complex and highly regulated environment where compliance with quality standards is non-negotiable. At the heart of this regulatory structure lies Good Manufacturing Practice (GMP), a universally recognised quality assurance framework designed to ensure that pharmaceutical products are consistently

produced and controlled to quality standards appropriate to their intended use. Regulatory authorities such as the European Medicines Agency (EMA), the U.S. Food and Drug Administration (FDA), and the Health Products Regulatory Authority (HPRA) in Ireland enforce GMP principles through regular inspections, licensing, and compliance monitoring (EMA, 2022; FDA, 2006; HPRA, 2023).

While GMP sets the baseline for quality system expectations, the International Council for Harmonisation (ICH) adds a harmonised and strategic dimension to regulatory compliance. The introduction of ICH Q9: Quality Risk Management in 2005 marked a significant advancement in how pharmaceutical companies are expected to assess and manage quality risks. ICH Q9 complements GMP by embedding a structured, science-based approach for quality risk assessment and decision-making throughout the pharmaceutical product lifecycle—from development and manufacturing to distribution and post-market surveillance (ICH, 2008).

The core pillars of ICH Q9 are risk identification, risk analysis, risk control, risk communication, and risk review. These stages work in a continuous cycle to facilitate real-time risk mitigation and support proactive quality management (Teasdale & Elder, 2018). The guideline encourages the use of formal risk assessment tools such as Failure Mode and Effects Analysis (FMEA), Hazard Analysis and Critical Control Points (HACCP), and Risk Ranking and Filtering, depending on the nature of the process and the severity of the potential impact on product quality or patient safety (Kartoglu & O'Donnell, 2024).

Despite the conceptual clarity and global acceptance of ICH Q9, the operationalisation of Quality Risk Management (QRM) principles in pharmaceutical companies remains inconsistent. Many organisations, particularly those operating in smaller or resource-constrained environments, face challenges in fully embedding risk-based decision-making into their standard operating procedures (Butler et al., 2020). This situation is evident even in highly regulated and mature pharmaceutical markets like Ireland. According to McDermott et al. (2022), while most Irish pharmaceutical companies acknowledge the importance of QRM and have formal systems in place, there are notable discrepancies in how these principles are applied across different departments and functions.

In practice, QRM is sometimes viewed as a regulatory checkbox rather than a decision-making framework that drives strategic quality improvements. Some companies apply risk tools only in preparation for audits, rather than integrating them into day-to-day quality operations,

leading to missed opportunities for identifying and preventing systemic risks (Mulholland, 2024). Furthermore, the variability in QRM maturity across the sector contributes to uneven performance in Corrective and Preventive Action (CAPA) systems, deviation handling, and change control processes.

In conclusion, while GMP and ICH Q9 together provide a robust regulatory and operational framework, the effectiveness of these systems depends heavily on how well pharmaceutical organisations translate theory into practice. Ireland, despite being a pharmaceutical hub, reflects the broader industry challenge: the need for deeper integration of QRM principles to ensure not just compliance, but sustained quality performance and risk minimisation.

2.4 Understanding CAPA Recurrence: Causes and Consequences

Corrective and Preventive Action (CAPA) systems are critical to pharmaceutical quality management. They serve not only to resolve current deviations but also to prevent future occurrences by addressing the root causes of non-conformities. However, CAPA recurrence—the reappearance of similar deviations after a CAPA has been officially closed—remains a persistent challenge in GMP-regulated environments. Recurrence of CAPAs typically indicates systemic weaknesses in quality processes, which may reflect a company's failure to implement a robust and integrated Quality Risk Management (QRM) approach (Waldron, 2017; Arunagiri, Kannaiah & Vasanthan, 2024).

A major contributor to CAPA recurrence is the superficiality of investigations. Instead of conducting in-depth Root Cause Analysis (RCA), companies often settle for addressing symptoms rather than underlying issues. For example, human error is frequently cited as a root cause without investigating contributing factors such as inadequate training, poor system design, or unclear procedures (Waldron, 2017). This kind of investigation leads to weak corrective actions that treat the immediate issue but fail to prevent its reoccurrence. Studies show that when CAPAs are closed without implementing true preventive strategies, companies are likely to face repeat deviations, which escalate into broader compliance risks (Butler et al., 2020).

Another prominent issue is the underutilisation or poor integration of QRM tools, such as Failure Mode and Effects Analysis (FMEA), Hazard Analysis and Critical Control Points (HACCP), and Fault Tree Analysis (FTA). These tools, when properly applied, offer structured methods for evaluating risks, prioritising actions, and implementing system-wide preventive

measures. However, literature and inspection reports suggest that in many cases, these tools are either not used at all or are applied only superficially—primarily to satisfy audit requirements rather than to enhance decision-making and quality outcomes (Arunagiri, Kannaiah & Vasanthan, 2024; Guilfoyle et al., 2013).

The consequences of recurring CAPAs are substantial. From a regulatory perspective, repeated deviations raise red flags during inspections and may result in Form 483 observations, Warning Letters, or even Consent Decrees from agencies such as the FDA or EMA. These findings can cause production halts, delays in product approvals, or restrictions on exports (Guilfoyle et al., 2013). Financially, CAPA failures may necessitate expensive product recalls, re-inspections, and remediation efforts, all of which erode profitability and shareholder confidence. In some documented cases, recurring CAPA issues have led to multi-million-dollar penalties and long-term damage to company reputation (Lexchin et al., 2003).

From a patient safety perspective, unresolved or poorly managed deviations can compromise product quality, resulting in adverse drug events or therapeutic failures. This not only affects public health but also undermines trust in healthcare systems and pharmaceutical providers. Furthermore, the reputational damage incurred through poor CAPA performance often takes years to repair and may have knock-on effects on market share and brand equity.

In summary, CAPA recurrence is a signal of inadequate quality governance and highlights the urgent need for more effective root cause investigations, risk-based thinking, and integration of QRM methodologies. Addressing these gaps is not merely a compliance requirement—it is a business and ethical imperative.

2.5 ICH Q9: Framework and Applicability to CAPA

The International Conference on Harmonisation (ICH) Q9 guideline, titled *Quality Risk Management*, provides a robust and structured framework for incorporating risk-based thinking into pharmaceutical quality systems. First published in 2005 and reinforced in subsequent regulatory documents, ICH Q9 aims to standardise and formalise the application of science-based risk assessment across the pharmaceutical product lifecycle—from development through distribution and post-marketing surveillance (ICH, 2008). One of the critical areas where ICH Q9 offers immense value is in enhancing Corrective and Preventive Action (CAPA) systems, a vital component of Good Manufacturing Practice (GMP) compliance.

The guideline outlines five key elements of an effective Quality Risk Management (QRM) system: risk assessment, risk control, risk communication, risk review, and risk acceptance. Each of these components plays a vital role in ensuring that pharmaceutical manufacturers not only react to quality issues but also proactively mitigate potential risks (Gupta et al., 2014).

Risk assessment serves as the starting point for evaluating hazards or process vulnerabilities that may compromise product quality or patient safety. It involves three sub-elements: risk identification, risk analysis, and risk evaluation. Tools such as Failure Mode and Effects Analysis (FMEA) and Fault Tree Analysis (FTA) are widely recommended in this stage for their ability to break down complex processes and assess both the probability and impact of failure modes (Teasdale & Elder, 2018). For instance, FMEA allows organisations to prioritise risks based on a combination of severity, occurrence, and detectability scores, ensuring that the most critical issues are addressed first.

Risk control involves identifying and implementing measures to reduce identified risks to acceptable levels. When integrated into CAPA processes, risk control mechanisms allow organisations to design more targeted corrective and preventive actions, tailored to the root causes identified during investigation (Ramnarine & O'Donnell, 2018). This ensures that responses are both effective and efficient, reducing the likelihood of recurrence and improving regulatory outcomes.

Risk communication is another important element, ensuring that insights and decisions made during risk assessments are shared across departments and stakeholders. Effective communication fosters transparency and cross-functional collaboration, which is essential for CAPA systems that often require input from quality assurance, manufacturing, and regulatory affairs.

Risk review supports continuous monitoring of known risks and effectiveness of implemented CAPAs. It ensures that actions taken are having the desired impact and that new risks are identified as processes evolve or new data emerges. Lastly, risk acceptance is the decision-making point where risks deemed tolerable—based on scientific evidence and organisational risk appetite—are formally documented and monitored.

The integration of ICH Q9 QRM tools into CAPA processes has been shown to enhance root cause accuracy, reduce superficial investigations, and increase the effectiveness of preventive actions (Ramnarine & O'Donnell, 2018). This structured approach transforms CAPA from a reactive compliance activity into a forward-looking, risk-driven quality improvement engine.

It aligns with global regulatory expectations and supports a quality culture that prioritises patient safety, product integrity, and operational excellence.

2.6 Empirical Evidence Supporting QRM-Based CAPA

The effectiveness of ICH Q9-based Quality Risk Management (QRM) in reducing CAPA (Corrective and Preventive Action) recurrence is increasingly supported by empirical research. A number of studies across global and local pharmaceutical contexts have demonstrated a measurable impact when structured risk management tools and principles are embedded within CAPA processes.

Shah and Ferguson, as referenced in Charoo and Ali (2013), observed that pharmaceutical companies implementing structured Failure Mode and Effects Analysis (FMEA) within their CAPA workflows experienced a 35% reduction in CAPA recurrence. This study highlights the strength of proactive risk assessment tools in identifying failure modes before they evolve into recurring deviations. The reduction suggests not only better control over known issues but also a systemic improvement in the organisation's ability to prevent future non-conformances through targeted preventive actions.

Similarly, evidence from an Ireland-specific context reinforces these findings. Jones et al. (2020) conducted a study involving 23 GMP-compliant pharmaceutical manufacturing sites in Ireland and found that organisations with higher levels of QRM maturity demonstrated significantly lower recurrence of quality deviations. QRM maturity in this context was measured by how well risk-based decision-making had been integrated into daily operations, training, documentation, and cross-functional quality culture. The study suggested that companies at the higher end of the QRM maturity spectrum had formalised systems for tracking risk performance, consistent use of tools like FMEA and Risk Ranking and Filtering, and demonstrated leadership engagement in risk governance.

Ramnarine and O'Donnell (2018) also contributed to this body of evidence by examining how QRM supports continuous improvement in pharmaceutical quality systems. They argue that QRM, when applied with scientific rigour, acts as a mechanism for both compliance and performance enhancement. By systematically documenting risk decisions and aligning them with performance outcomes, companies can detect early warning signs of quality issues, thereby reducing the likelihood of CAPA recurrence. Their findings support the notion that QRM is not just a compliance obligation but a strategic enabler of operational excellence.

Taken together, these studies confirm that structured QRM implementation especially when aligned with ICH Q9 has a significant positive effect on CAPA effectiveness. The data not only validate regulatory expectations but also strengthen the case for greater adoption of QRM tools as part of routine CAPA system practices.

2.7 Barriers to Effective Integration in Irish Pharma

Despite Ireland's global reputation as a hub for pharmaceutical excellence—with over 85 pharmaceutical facilities and many top multinational companies operating in the country—challenges remain in effectively embedding Quality Risk Management (QRM) principles, especially within Corrective and Preventive Action (CAPA) systems. The Health Products Regulatory Authority (HPRA), Ireland's national regulatory body, has frequently highlighted these challenges in their Good Manufacturing Practice (GMP) inspection reports spanning from 2015 to 2021. These inspections have consistently reported deficiencies in how companies perform risk assessments and define preventive actions following quality deviations (EMA, 2022). Rather than fully integrating risk-based thinking, many organisations demonstrate a compliance-driven mentality that limits the potential of QRM tools and processes.

A key issue reported in both academic and regulatory literature is the persistence of organisational silos that prevent the free flow of risk-related information across departments. According to McDermott et al. (2022), limited cross-functional collaboration between quality assurance (QA), manufacturing, engineering, and regulatory teams leads to fragmented implementation of QRM. This lack of integration means that learnings from past deviations are not always translated into effective preventive actions, leading to increased CAPA recurrence. Cross-functional engagement is a cornerstone of successful QRM, as outlined by ICH Q9, and its absence greatly limits the scope of risk-based decisions within pharmaceutical operations.

Another significant challenge is cultural resistance to change. As noted by Mulholland (2024), while Irish pharmaceutical professionals often express theoretical support for QRM principles, many still cling to traditional reactive approaches to quality management. This resistance is especially pronounced in smaller and mid-sized pharmaceutical firms where resource limitations, lack of training, and perceived administrative burden discourage active engagement with QRM tools. In such cases, QRM is often treated as a bureaucratic task—merely satisfying regulatory requirements rather than informing strategic decision-making.

Waldron et al. (2017) echo this sentiment in their benchmarking survey, which found that smaller firms in Ireland are more likely to implement QRM superficially. These organisations tend to rely on templated risk assessments that lack specificity and depth. Furthermore, QRM tasks are frequently siloed within the Quality Department, rather than embedded organisation-wide, thereby reducing the potential for meaningful impact on CAPA outcomes.

Compounding these structural and cultural barriers is the lack of formalised performance metrics to evaluate QRM efficacy. According to Greene et al. (2018), organisations that do not measure the outcomes of risk-based decisions are less able to demonstrate improvement or identify gaps in CAPA effectiveness. Without clear indicators, such as reduced deviation recurrence or faster CAPA closure times, QRM initiatives risk becoming stagnant and losing stakeholder buy-in.

In conclusion, while Ireland boasts a strong pharmaceutical infrastructure and regulatory framework, the translation of QRM theory into practical, effective CAPA management remains a challenge. Addressing organisational silos, fostering a proactive quality culture, and investing in QRM training and metrics are essential steps toward ensuring that QRM principles are not just formally adopted but actively operationalised across the Irish pharmaceutical sector.

2.8 Role of Training, Culture, and Technology

The successful implementation of Quality Risk Management (QRM) within Corrective and Preventive Action (CAPA) systems is not solely a matter of regulatory compliance or technical proficiency it is deeply rooted in organisational culture and workforce capability. An increasing body of literature supports the notion that employee behaviour, interdepartmental communication, and ongoing education significantly influence the effectiveness of pharmaceutical quality systems.

Oktaviani et al. (2020) demonstrate that voluntary behaviour, such as taking initiative in reporting deviations or participating in risk assessments, plays a substantial role in the success of Quality Management Systems (QMS). Their research indicates that quality culture, reinforced by knowledge sharing across functions, is a key determinant of sustained compliance and CAPA effectiveness. This cultural element encourages staff to go beyond routine checklists and engage meaningfully with QRM tools.

In practice, this means pharmaceutical professionals must be competent in applying advanced risk assessment methodologies such as Hazard Analysis and Critical Control Points (HACCP)

and Design of Experiments (DoE). These tools demand both conceptual understanding and practical expertise to accurately identify risk points and optimise process variables (Chordiya, Gangurde & Sancheti, 2019). Without sufficient training, the use of these tools becomes superficial, weakening the link between risk analysis and actionable outcomes.

To address this competency gap, McDermott et al. (2022) argue for stronger university-industry collaboration in Ireland. They recommend joint training programmes, internships, and continuous professional development schemes tailored to QRM application in GMP-regulated environments. Such initiatives can foster a workforce that not only understands regulatory expectations but is also empowered to innovate within risk-based frameworks.

Alongside human capital development, digital transformation of pharmaceutical quality systems presents a significant opportunity to enhance CAPA tracking and QRM execution. According to Pharmaceutical Technology (2024), the integration of digital platforms that offer automated risk scoring, deviation lifecycle management, and real-time dashboards enables organisations to move from reactive compliance to proactive decision-making. These platforms improve data visibility, standardise documentation, and allow Quality Assurance teams to identify trends and emerging risks more efficiently than paper-based systems.

In summary, embedding QRM into CAPA systems requires more than tools and policies—it depends on equipping people with the right skills, cultivating a proactive quality culture, and leveraging digital technologies to enhance transparency and responsiveness. These combined efforts are critical to realising the full potential of QRM and ensuring long-term quality resilience in pharmaceutical manufacturing.

2.9 Regulatory Trends Driving QRM-CAPA Integration

As global regulatory bodies evolve toward more proactive oversight, pharmaceutical manufacturers are under growing pressure to not only adopt Quality Risk Management (QRM) frameworks but to demonstrate their practical integration into core quality systems, especially CAPA. Regulatory expectations have shifted from merely having QRM policies in place to ensuring that risk-based thinking is embedded in day-to-day operations and decision-making.

The European Medicines Agency (EMA) provides a structured QRM framework through its EU Guidelines for Good Manufacturing Practice Chapter 1: Pharmaceutical Quality System, which mandates the use of risk-based strategies across the product lifecycle (EMA, 2022). In particular, the guideline stresses that all investigations, including CAPA, must be guided by

scientifically sound risk assessments, and that the effectiveness of corrective and preventive actions should be linked to the level of risk posed by the quality issue.

Similarly, the U.S. Food and Drug Administration (FDA) has reinforced this approach through its Quality Metrics Initiative, which seeks to quantify a firm's quality maturity and its commitment to continual improvement by evaluating indicators such as CAPA effectiveness, deviation frequency, and risk control mechanisms (Kartoglu & O'Donnell, 2024). The initiative encourages firms to provide objective evidence that QRM tools are being used consistently to prioritise and mitigate risks.

Within Ireland, the Health Products Regulatory Authority (HPRA) increasingly scrutinises the degree to which pharmaceutical companies align their CAPA documentation and deviation investigations with the principles of ICH Q9. According to Greene, Barry and Brennan (2018), Irish inspectors now request to see not only the investigation outcomes but also the risk rationale behind CAPA selection and implementation. For example, CAPA records that omit structured risk evaluations or fail to justify the chosen preventive strategy are likely to attract regulatory concern.

Additionally, the Parenteral Drug Association (PDA) has published guidelines and maturity models that align with both EMA and FDA perspectives, urging manufacturers to adopt a holistic and evidence-based approach to QRM (PDA, 2012). These models advocate for transparent documentation of risk scoring, tool selection (e.g., FMEA, HACCP), and the linkage between identified risks and specific CAPA actions.

In summary, regulators now demand not only the presence of QRM frameworks but measurable, auditable proof of their operational application, especially in relation to CAPA. Companies failing to demonstrate this integration risk regulatory action, reputational damage, and missed opportunities for process optimisation.

2.10 Strategic Benefits of QRM-Based CAPA

The adoption of ICH Q9 principles has reshaped how pharmaceutical companies approach Corrective and Preventive Action (CAPA), transforming it from a reactive compliance task to a proactive quality enabler that supports continuous improvement and operational excellence. Traditionally, CAPA systems were often seen as a necessary procedural response to regulatory non-conformances or audit findings. However, with the formalisation of Quality Risk Management (QRM) through ICH Q9, organisations are encouraged to embed risk-based

thinking at every stage of the CAPA lifecycle—from deviation identification to preventive action and effectiveness verification (ICH, 2008).

This paradigm shift enables companies to conduct deeper, data-driven root cause analyses, rather than relying on superficial or "quick-fix" investigations. Mature QRM cultures apply structured risk evaluation tools such as Failure Mode and Effects Analysis (FMEA), Fault Tree Analysis (FTA), and Risk Ranking and Filtering to determine the significance of each deviation and guide proportionate responses (Teasdale & Elder, 2018; Gupta et al., 2014). As a result, preventive actions are no longer generic or administrative, but targeted and prioritised based on actual risk exposure to product quality and patient safety.

Butler et al. (2020) emphasise that QRM-integrated CAPA systems are a hallmark of advanced pharmaceutical quality cultures. Their research indicates that companies with high QRM maturity are more likely to align CAPA activities with strategic goals, achieve consistency in process control, and reduce variation across manufacturing lines. Similarly, Calnan, O'Donnell and Greene (2013) assert that embedding QRM fosters cross-functional accountability, enhances knowledge sharing, and enables the creation of robust decision-making frameworks, thus improving organisational resilience to future quality challenges.

The benefits of QRM in CAPA are not just theoretical. Real-world studies show that companies with integrated risk-based approaches report significantly fewer product recalls, faster batch release timelines, and improved regulatory outcomes (Poli et al., 2014). Waldron, Ramnarine and Hartman (2017) highlight that such companies also demonstrate better documentation practices, traceability, and audit readiness—attributes increasingly favoured by regulators like the EMA and FDA.

In essence, the integration of QRM transforms CAPA into a strategic asset, enabling pharmaceutical companies to reduce repeat deviations, mitigate compliance risks, and strengthen patient trust. This positions CAPA not just as a response mechanism but as a forward-looking process for sustainable quality excellence.

2.11 Gap Analysis and Research Need

While the global pharmaceutical industry increasingly recognises the value of integrating Quality Risk Management (QRM) into Corrective and Preventive Action (CAPA) systems, there remains a significant gap in region-specific research, particularly concerning implementation practices in Ireland. Despite Ireland's status as a prominent hub for

pharmaceutical manufacturing home to over 85 pharmaceutical companies, including nine of the top ten global firms there is limited empirical literature examining how effectively Irish Good Manufacturing Practice (GMP)-regulated sites embed QRM principles into their CAPA frameworks (IDA Ireland, 2023; Mulholland, 2024).

The existing body of international research underscores the benefits of QRM in reducing CAPA recurrence, improving process understanding, and supporting regulatory compliance (Teasdale & Elder, 2018; Ramnarine & O'Donnell, 2018). However, these findings are often based on multinational trends or case studies from broader geographies like the United States, United Kingdom, or continental Europe. The extent to which these findings are applicable to Ireland remains unclear without targeted research focused on local operational practices, regulatory interactions, and cultural influences.

Mulholland (2024), in a doctoral study on risk-based decision-making in pharmaceutical quality, notes that while Irish companies often report having QRM systems in place, variability in implementation maturity is a persistent concern. Some firms demonstrate advanced integration across quality systems, whereas others treat QRM more as a documentation formality than a decision-making tool. This discrepancy limits the realisation of QRM's preventive potential and perpetuates a reactive culture in CAPA handling. Furthermore, the Health Products Regulatory Authority (HPRA) in its inspection reports between 2015 and 2021, observed recurring issues such as weak root cause analysis, inconsistent use of risk tools, and poor documentation of preventive actions underscoring systemic gaps in QRM-CAPA alignment (EMA, 2022; McDermott et al., 2022).

Another significant gap lies in guidance on the selection and application of QRM tools. Although ICH Q9 provides a menu of risk assessment methods such as Failure Mode and Effects Analysis (FMEA), Hazard Analysis and Critical Control Points (HACCP), and Fault Tree Analysis (FTA), it does not specify contexts or scenarios in which each tool is most appropriate (ICH, 2008; Teasdale & Elder, 2018). This lack of prescriptive detail often leads to either underutilisation or misapplication of tools, especially in settings where training and cross-functional coordination are limited.

Training deficiencies and cultural resistance further complicate QRM adoption. Many Irish pharmaceutical organisations, particularly small-to-medium enterprises, lack structured training programs on QRM methodologies, and quality systems remain siloed within QA departments (McDermott et al., 2022). Oktaviani et al. (2020) stress that voluntary behaviour,

collaborative culture, and knowledge sharing are pivotal to successful QMS implementation qualities that require active nurturing beyond compliance mandates.

This dissertation seeks to fill these research gaps by conducting a survey-based study targeting Quality Assurance professionals in Irish GMP-regulated pharmaceutical companies. The goal is to assess the maturity of QRM practices, understand practical barriers to tool integration, and correlate these findings with CAPA recurrence trends. By offering evidence-based insights specific to the Irish pharmaceutical context, this research aims to contribute both academically and practically to the enhancement of QRM-CAPA frameworks within Ireland's highly regulated manufacturing environment.

2.12 Conceptual framework

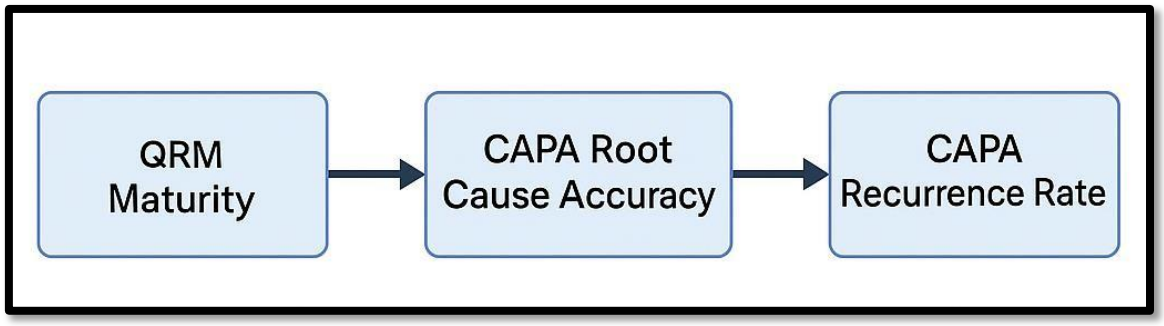


Figure 6: conceptual framework (George, 2025)

2.13 Summary of Key Literature on QRM and CAPA in Pharmaceutical Industry

Author(s)	Year	Methodology	Key Findings	Relevance to Study
Charoo & Ali	2013	Literature Review	Emphasized importance of QRM in early development to ensure product quality.	Highlights foundational QRM principles aligned with ICH Q9.
O'Donnell et al.	2012	Conceptual Analysis	Advocated prioritizing GMP controls when applying QRM.	Reinforces importance of integrating QRM into CAPA for compliance.
Ramnarine & O'Donnell	2018	Case Studies	QRM supports continual improvement and evidence-based decision-making.	Validates QRM as a quality enabler in CAPA recurrence prevention.
Rompicherla et al.	2020	Case-Based Study	Identified quality metrics as indicators of CAPA effectiveness.	Supports use of performance indicators in CAPA monitoring.

	Gupta et al.	2014	Review	Described risk tools (FMEA, FTA) in structured QRM applications.	Provides technical foundation for risk tool integration in CAPA.
	Kartoglu & O'Donnell	2024	Industry Commentary	Addressed Q9 revision updates and maturity models.	Offers context for evaluating QRM maturity in Irish pharma sites.
	Greene et al.	2018	Empirical Study (Ireland)	Showed that incomplete risk documentation leads to recurring deviations.	Irish case study evidence of risk process weaknesses in CAPA.
	McDermott et al.	2022	Qualitative Study	Found barriers in QRM implementation include training gaps and silos.	Identifies practical challenges for embedding QRM in CAPA systems.
	Waldron	2017	Doctoral Thesis	Noted formal but ineffective QRM application is common in industry.	Underscores the problem of compliance vs. operational QRM.
	Teasdale & Elder	2018	Implementation Guide	Provided best practices for integrating ICH Q guidelines.	Used to frame the best-practice expectations in your study.
	Arunagiri et al.	2024	Empirical Analysis	Demonstrated that well-structured CAPA systems reduce recurrence.	Supports the value of well-implemented CAPA frameworks.
	Lexchin et al.	2003	Systematic Review	Showed how quality shortcomings affect public trust and safety.	Broadens the discussion to external impacts of weak CAPA/QRM.
	Oktaviani et al.	2020	Quantitative Study	Found link between behaviour, knowledge sharing, and QMS success.	Highlights importance of training and cultural engagement in CAPA.
	Butler et al.	2020	Survey & Analysis	Described issues of formality and culture in QRM deployment.	Directly relevant to maturity assessment in Irish companies.
	PDA	2012	Technical Reports	Introduced QRM maturity models and metrics for implementation.	Framework supports your QRM maturity evaluation methodology.

CHAPTER 3: METHODOLOGY

This chapter outlines the methodology and methods employed in this study. The research investigates the role of ICH Q9-based Quality Risk Management (QRM) in reducing the recurrence of Corrective and Preventive Actions (CAPAs) within GMP-regulated pharmaceutical manufacturing companies in Ireland. The selected methodological approach is closely aligned with the study's aim of evaluating how QRM maturity influences CAPA outcomes, and identifying the challenges and enablers encountered in practical implementation.

A robust and structured methodology was adopted to ensure the research objectives were achieved, and that valid, reliable insights could be drawn from industry stakeholders. This study employs a quantitative research approach to measure relationships between QRM maturity and CAPA recurrence, as well as to identify recurring barriers, perceived benefits, and improvement opportunities.

Data was collected through a structured questionnaire survey targeting professionals involved in Quality Assurance (QA), Compliance, and Operational Excellence across Irish GMP pharmaceutical sites. These respondents were chosen for their direct involvement in QRM implementation and CAPA investigations. The survey explored key themes including QRM policy adoption, maturity level, tool usage (e.g., FMEA, HACCP), CAPA frequency, root cause analysis effectiveness, and perceived challenges in aligning QRM with CAPA systems.

Additionally, insights from relevant regulatory guidance (e.g., ICH Q9, EU GMP), peer-reviewed literature, and industry white papers were used to inform the conceptual framework and shape the interpretation of primary data. A structured analysis was then conducted using descriptive and cross-tabulation methods to identify trends and correlations. This analytical approach helped interpret how QRM maturity may contribute to CAPA recurrence reduction and provided evidence for practical recommendations.

Throughout this chapter, the justification for the research philosophy, sampling strategy, instrument design, data collection and ethical considerations are discussed. The chapter concludes by describing the analysis plan and limitations, ensuring alignment with the conceptual model and research objectives.

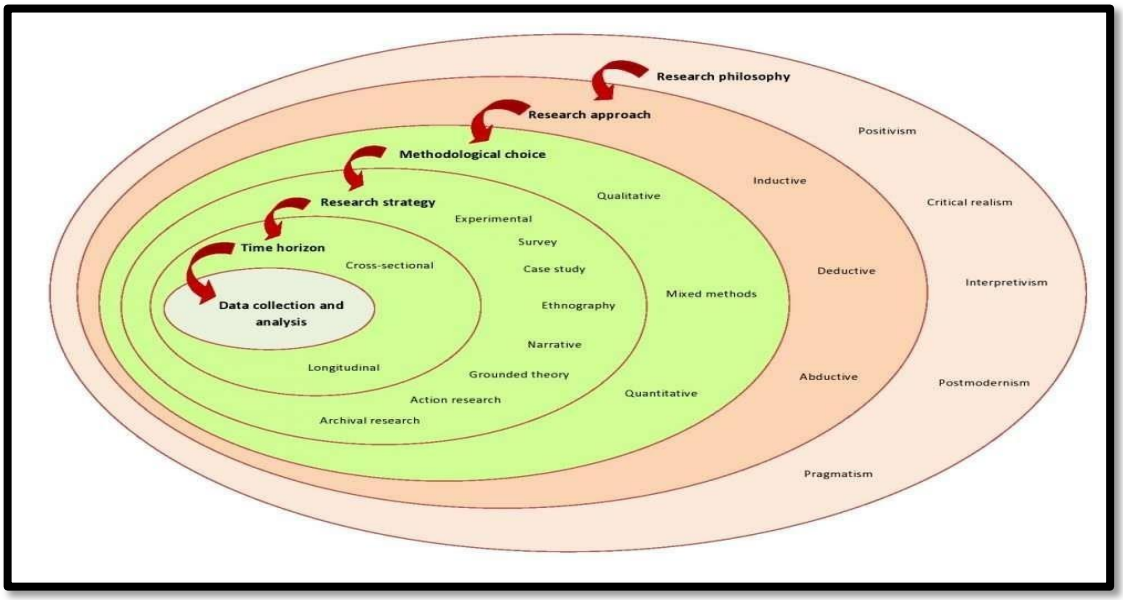


Figure 7: Research Onion (Saunders et al., 2012)

3.1 Research Philosophy

This research adopts an Interpretivist philosophy, which is grounded in the belief that reality is socially constructed through human interaction, shared meanings, and subjective interpretation (Saunders et al., 2012). Interpretivism rejects the notion that complex organisational and behavioural phenomena can be fully understood through purely objective, measurable data. Instead, it focuses on understanding the lived experiences, professional insights, and subjective viewpoints of individuals who operate within a specific context.

In this study, the context is the implementation of Quality Risk Management (QRM) and Corrective and Preventive Actions (CAPA) within GMP-regulated pharmaceutical companies in Ireland. Quality professionals, regulatory specialists, and operational managers often interpret QRM guidelines, such as those outlined in ICH Q9, in ways shaped by their organisational culture, leadership style, regulatory pressures, and available resources. An interpretivist stance enables the researcher to capture these subjective realities and explore how they influence QRM maturity and CAPA recurrence in practice.

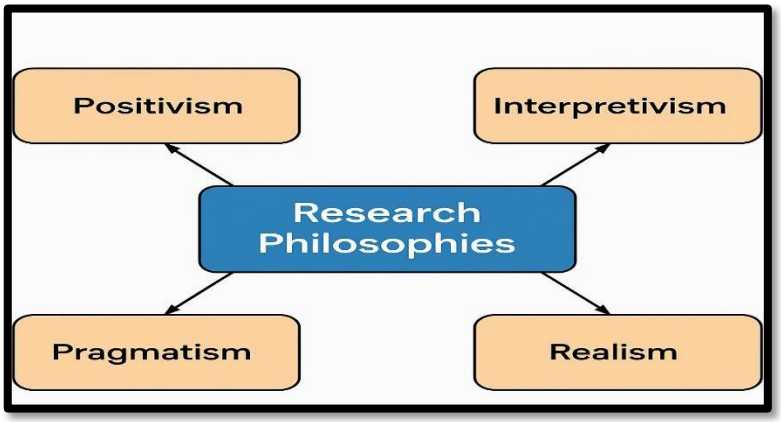


Figure 8: Research philosophies (Saunders et al., 2012)

Interpretivism is particularly appropriate for this study because QRM and CAPA effectiveness are not solely determined by formal systems, written procedures, or audit findings. While quantitative indicators such as the number of repeated CAPAs or compliance scores provide valuable metrics, they do not reveal the underlying organisational behaviours, decision-making processes, or cultural factors that drive these outcomes. Through an interpretivist lens, the research can examine deeper themes such as:

- How quality teams perceive the maturity and robustness of their QRM framework.
- How effectively risk-based thinking is embedded into CAPA investigations.
- The role of leadership engagement and staff training in sustaining CAPA improvements.
- The organisational challenges, such as siloed communication or resource constraints, that hinder the consistent application of ICH Q9 principles.

By focusing on the meanings, perceptions, and contextual barriers experienced by professionals, the study aims to generate insights that are relevant to both theory and practice. This philosophical approach supports the research objective of linking QRM maturity with CAPA recurrence in a way that recognises the complexity and human factors inherent in pharmaceutical quality management systems. Ultimately, interpretivism allows the findings to go beyond compliance checklists and reveal actionable strategies for building more resilient and effective quality systems in the Irish pharmaceutical industry.

3.2 Research Approach

This study adopts a quantitative research approach, underpinned by a deductive strategy, to investigate the relationship between Quality Risk Management (QRM) maturity and

Corrective and Preventive Action (CAPA) recurrence within GMP-regulated pharmaceutical companies in Ireland. A deductive strategy was deemed appropriate as it allows the research to begin with established theories—such as the ICH Q9 quality risk management framework—and test their applicability in predicting and influencing CAPA outcomes in real-world settings.

The decision to employ a quantitative methodology reflects the study's aim of producing structured, statistically analysable data that can be generalised across a wide range of GMP pharmaceutical environments. By relying on numerical data and statistical analysis, the research can objectively measure the extent to which QRM maturity correlates with reductions in CAPA recurrence rates. This enables the validation or rejection of hypotheses derived from the literature review, providing a more empirical basis for conclusions and recommendations.

Data was collected using a standardised online questionnaire specifically designed for professionals in quality assurance, regulatory compliance, operational excellence, and related quality management functions. The survey was distributed to a diverse sample of respondents across multiple pharmaceutical companies to capture a representative view of practices in Ireland.

The structured nature of the survey allowed for the collection of data on a range of variables relevant to the research objectives, including:

- **QRM maturity level** – measured through indicators such as policy integration, risk assessment frequency, and decision-making practices.
- **QRM tools in use** – such as Failure Mode and Effects Analysis (FMEA), Hazard Analysis and Critical Control Points (HACCP), risk ranking and filtering, and fault tree analysis.
- **CAPA recurrence frequency** – including both minor and major deviations.
- **Barriers to QRM application** – such as insufficient training, lack of leadership support, and resource constraints.

A quantitative approach was favoured over qualitative methods because it facilitates a broader reach, enabling data collection from a larger number of participants across different organisational settings. This not only increases statistical reliability but also enhances the generalizability of the findings. By applying statistical techniques such as correlation and regression analysis, the research aims to identify patterns, relationships, and predictive factors

linking QRM maturity to CAPA outcomes. Ultimately, this approach provides a robust evidence base for developing targeted recommendations to strengthen risk management practices in Ireland's pharmaceutical sector.

3.3 Research design

The research design serves as the blueprint for guiding the study, ensuring that all processes remain aligned with the research objectives and that the investigation follows a coherent and systematic path. For this study, a **descriptive research design** was selected to examine the relationship between the maturity of Quality Risk Management (QRM) systems and the recurrence of Corrective and Preventive Actions (CAPA) within GMP-regulated pharmaceutical companies in Ireland.

A descriptive design is appropriate in this context because it enables the systematic documentation and analysis of existing QRM practices, their level of integration into CAPA processes, and the associated barriers and enablers affecting effectiveness. According to Newman and Gough (2020), descriptive research is valuable for providing a factual and objective account of current practices and for identifying common trends, challenges, and opportunities within a specific industry.

In line with Ma et al. (2020), performance within pharmaceutical quality systems can be assessed through measurable indicators such as deviation recurrence rates, regulatory compliance, investigation cycle times, and the robustness of risk assessments. Within this study, QRM maturity functions as a key independent variable influencing CAPA outcomes, with factors such as leadership engagement, training quality, and tool utilisation serving as contributing elements.

Furthermore, Cooksey et al. (2019) highlight that descriptive designs are well-suited for quantitative survey approaches, as they allow researchers to collect structured data using standardised questionnaires, ensuring comparability and reliability. This study applies such a method to capture data from quality professionals across multiple pharmaceutical manufacturing sites in Ireland, thereby ensuring that the findings reflect industry-wide trends rather than site-specific conditions.

Overall, the descriptive design facilitates the identification of patterns in QRM application, the detection of common causes for CAPA recurrence, and the recognition of best practices that can inform future regulatory and operational improvements. The results generated will provide

a factual evidence base to support recommendations for enhancing QRM integration and reducing CAPA recurrence across the Irish pharmaceutical sector.

3.4 Research Strategy

This research adopted a survey strategy as the primary means of data collection, implemented through a cross-sectional design using a self-administered online questionnaire created in Google Forms. A survey strategy was chosen due to its suitability for gathering data from a large and geographically dispersed sample within a relatively short period of time. In the context of Ireland's pharmaceutical sector, where professionals are spread across multiple manufacturing sites and functions, an online survey enabled efficient access to participants without disrupting operational activities.

The survey instrument was structured to align closely with the research objectives and comprised three main sections:

- **Section 1: Consent and Demographics** – This section collected informed consent from participants and gathered background data such as job role, years of experience, and familiarity with Good Manufacturing Practice (GMP) and the International Council for Harmonisation's Q9 (ICH Q9) guideline. These demographic variables allowed for subgroup analysis to explore whether QRM maturity and CAPA performance varied according to role or experience.
- **Section 2: QRM Implementation** – This section focused on measuring the **maturity of QRM systems** within participants' organisations. Items assessed the existence of formal QRM policies, frequency of risk assessments, integration of QRM into CAPA processes, and utilisation of common tools such as Failure Mode and Effects Analysis (FMEA) and Hazard Analysis and Critical Control Points (HACCP).
- **Section 3: CAPA Outcomes and Barriers** – This section explored the frequency and nature of CAPA recurrence, the perceived effectiveness of root cause analysis (RCA), and the role QRM plays in preventing repeat deviations. Participants were also asked to identify **key barriers** to effective QRM application, such as lack of training, inadequate leadership support, or resource limitations.

The questionnaire comprised multiple-choice and Likert-scale items, facilitating both descriptive and correlational statistical analysis. The use of closed-ended formats ensured

consistency in responses, making it easier to identify trends and compare results across different respondent groups.

Prior to full deployment, a pilot survey was conducted with a small group of experienced quality professionals. Their feedback was used to refine question wording, adjust response options, and ensure alignment with the study's objectives. This step helped enhance the content validity of the instrument, ensuring that all items were clear, relevant, and free from ambiguity.

All responses were anonymised to protect participant confidentiality. Data was analysed using descriptive statistics to summarise patterns and inferential techniques, such as correlation analysis, to examine relationships between QRM maturity levels and CAPA recurrence rates. This approach provided a robust basis for identifying trends, challenges, and potential areas for improvement in the Irish pharmaceutical industry's approach to risk management.

3.5 Ethical Issues and Considerations

Ethical considerations were rigorously followed throughout the research process. The study received formal approval from the Griffith College Ethics Committee. Participants were provided with a clear **Participant Information Leaflet (PIL)** and **Informed Consent Form (ICF)** embedded at the beginning of the online survey.

The research adhered to the following ethical principles, adapted from Bassey (1999):

- **Democracy** – All participants voluntarily contributed and had the right to withdraw at any stage. Input was gathered without coercion, and no personally identifiable data was collected.
- **Truthfulness** – The survey provided full transparency about the study's aims, how the data would be used, and its academic purpose.
- **Respect for persons** – Confidentiality and anonymity were ensured. Participants were not required to disclose employer names or sensitive operational details.
- **Trustworthiness** – Data was stored securely, and responses were handled with integrity. No misleading information was given, and findings will be reported honestly.

Inclusion Criteria:

- Quality professionals (QA, Compliance, Operational Excellence, etc.)
- Actively working in GMP-regulated pharmaceutical companies in Ireland

- Familiar with CAPA systems and QRM principles
- Aged between 25–65 years

Exclusion Criteria:

- Individuals not working in pharmaceutical GMP settings
- Those without involvement in QRM or CAPA-related activities
- Participants outside the defined age range
- Incomplete or non-consenting responses

3.6 Sample

This study employed a purposive sampling strategy to engage Quality Assurance (QA) professionals with direct experience in the implementation and oversight of Quality Risk Management (QRM) and Corrective and Preventive Action (CAPA) systems within GMP-regulated pharmaceutical companies in Ireland. The participants were selected based on their roles in quality systems, regulatory compliance, and operational excellence, ensuring they possessed in-depth knowledge of QRM frameworks aligned with ICH Q9 and their practical application in CAPA investigations.

The sample aimed was 70 professionals and consisted of 110 professionals, including:

- QA Managers
- Quality Compliance Officers
- Operational Excellence Leads
- QC Analysts
- And other relevant roles within quality-related functions.

The participants were drawn from a mix of multinational pharmaceutical companies, contract manufacturing organizations (CMOs), and medium-sized enterprises, reflecting the diversity of the Irish pharmaceutical manufacturing sector.

To ensure diversity in perspectives and experience, inclusion criteria required participants to:

- Have 1 or more years of experience in a GMP-compliant pharmaceutical environment.
- Be actively involved in CAPA review, QRM planning, or deviation management processes.

- Work within companies that adhere to EU GMP and have at least partial implementation of ICH Q9-based QRM systems.

The age range of participants spanned 25 to 65 years, representing early-career to senior-level professionals. This range was intended to ensure inclusion of both fresh perspectives and seasoned insights into recurring CAPA issues, QRM maturity, and practical implementation challenges.

This study aims to generate multi-dimensional insights into:

- The effectiveness of QRM in reducing CAPA recurrence.
- The barriers to implementing robust risk-based CAPA systems.
- The maturity of QRM frameworks in real-world settings in Ireland.

The purposive approach ensures the relevance and richness of the data collected, directly supporting the study's aim to evaluate the role of ICH Q9-based QRM in reducing CAPA recurrence in GMP-regulated pharmaceutical companies in Ireland.

3.7 Conclusion

The primary research for this study involved a survey which was distributed to Quality Assurance managers, Quality Control analysts, compliance officers, operational excellence leads, and other professionals working in GMP-regulated pharmaceutical companies in Ireland. The survey was made up of 13 structured questions. The philosophy of the research in this case was that of positivism, chosen to ensure that deductions from all facts gathered from the survey and literature review were analysed objectively.

All information from Chapter 2 (Literature Review) of the study and data from the survey was properly examined and combined to determine the role of ICH Q9-based Quality Risk Management (QRM) in reducing CAPA recurrence rates within the Irish pharmaceutical sector. The analysis focused on evaluating the maturity of QRM implementation, its integration into CAPA processes, and the factors influencing its effectiveness.

A proper analysis of the survey findings will be presented in the next chapter, with results interpreted alongside industry literature to provide practical recommendations for enhancing CAPA effectiveness and minimising recurrence rates.

CHAPTER 4: FINDINGS AND ANALYSIS

4.1 Introduction

In this study, the first research goal is to determine how Quality Risk Management (QRM) based on ICH Q9 can help in lowering the rates of Corrective and Preventive Action (CAPA) recurrence in pharmaceutical organisations that operate under GMP in Ireland. This chapter demonstrates the findings provided by the survey and discusses this data by referring to the aims and research questions of the study.

The statistical data analysis that was conducted in this chapter will attempt to measure the correlation between QRM maturity and CAPA recurrence without overlooking patterns in the use of tools, level of integration, and obstacles to successful implementation. In pursuit of this, descriptive statistics, correlation, and regression analysis of the collected survey data was revised. I used descriptive statistics to summarise respondent demographics and QRM practices, frequencies of CAPA recurrence and perceived barriers. The values of those relationships between QRM maturity scores as well as tool utilisation with the rate of CAPA occurrence were analysed through the method of correlation analysis. Regression analysis took place in order to decide upon the level to which QRM maturity could project CAPA outcomes, when other contributing factors were held constant; these were training, leadership support, and the quality of the examination of roots.

The discussion interpretation of these findings comparing them to the available literature that was reviewed in Chapter 2 is presented in the discussion section. This will involve the evaluation of the congruence or inconsistency between the findings and that of the past related to QRM implementing, CAPA performance, and quality culture with the regulated pharmaceutical manufacturing.

By combining statistical analysis with critical discussion, this chapter seeks to provide a clear understanding of how QRM maturity impacts CAPA recurrence rates, identify industry-wide challenges, and highlight best practices that can enhance compliance, efficiency, and continual improvement in pharmaceutical quality systems.

4.2 Findings

4.2.1 Frequency analysis

4.2.1.1 Current Role of Respondents

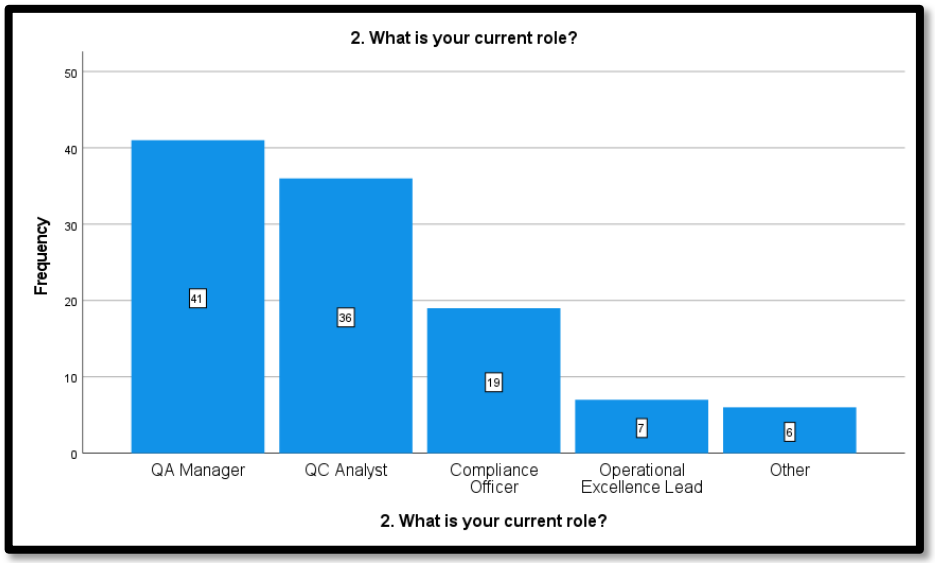


Figure 9: Bar chart showing Current Role of Respondents

The results of the survey point to the professional distribution of respondents. Most of them were QC Analysts (36) and QA Managers (41) respectively. The least represented were Operational Excellence Leads (7), Compliance Officers (19) and respondents in other roles (6). This distribution indicates that the survey reached the views of the people who witnessed quality assurance and control closely.

4.2.1.2 Years of Experience in the Pharmaceutical Industry

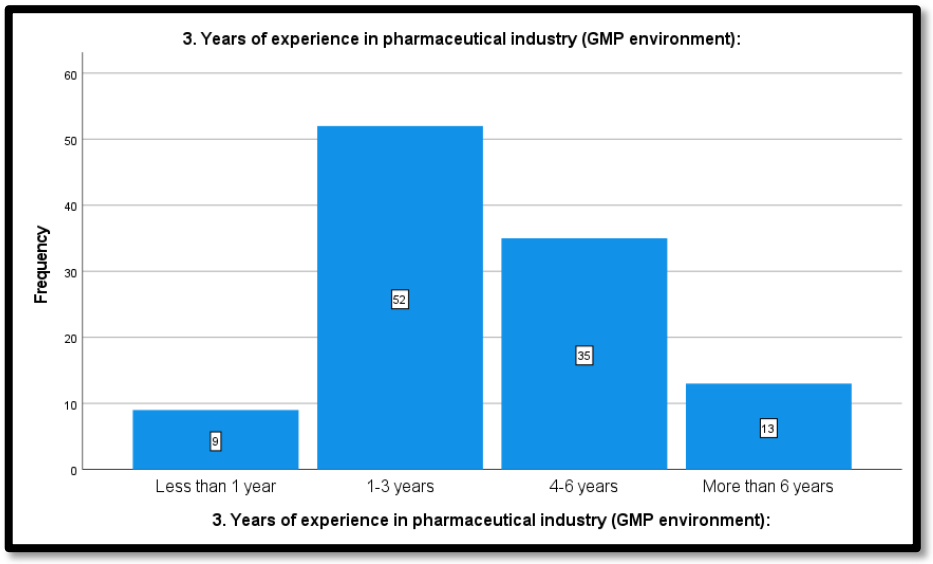


Figure 10: Bar chart for Years of Experience in the Pharmaceutical Industry

The respondents had different levels of experience in the industry but the most with experience were between 1-3 years (52), followed by 4-6 years (35). The number of respondents with over 6 years of experience was 13, whereas those with less than a year were nine. This shows that there is a relative proportional distribution with most of them possessing early- to mid- career views.

4.2.1.3 Compliance with EU GMP and ICH Q9 Guidelines

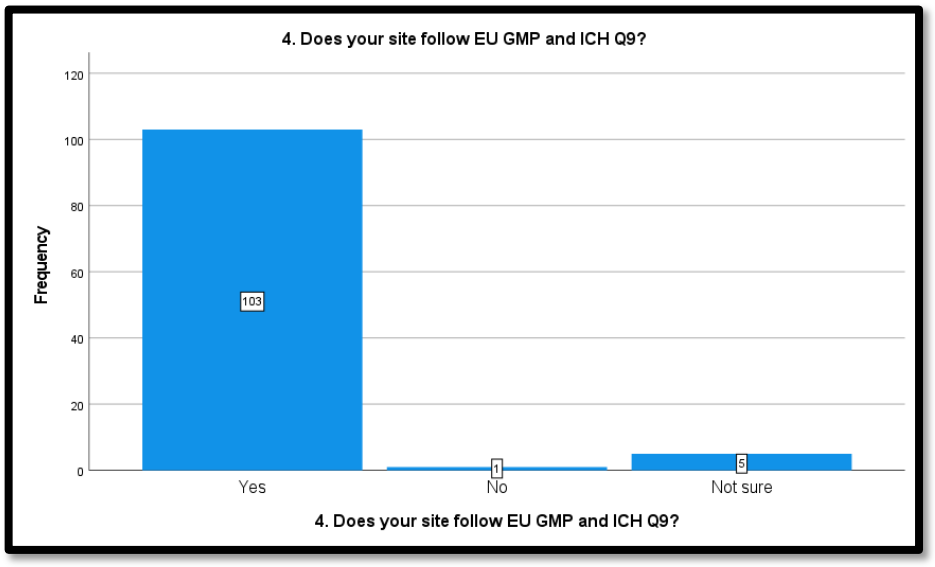


Figure 11: Compliance with EU GMP and ICH Q9 Guidelines

Most of the respondents (103) reported that their sites are EU GMP and ICH Q9 compliant, and only one participant reported they were not. Five respondents were not sure about

adherence. Such preponderance of compliance confirms high regulatory conformity in the surveyed organizations. The minimal percentage of uncertainty indicates the possible communication lapses as far as site-level compliance policies are concerned.

4.2.1.4 Existence of Formal QRM Policies

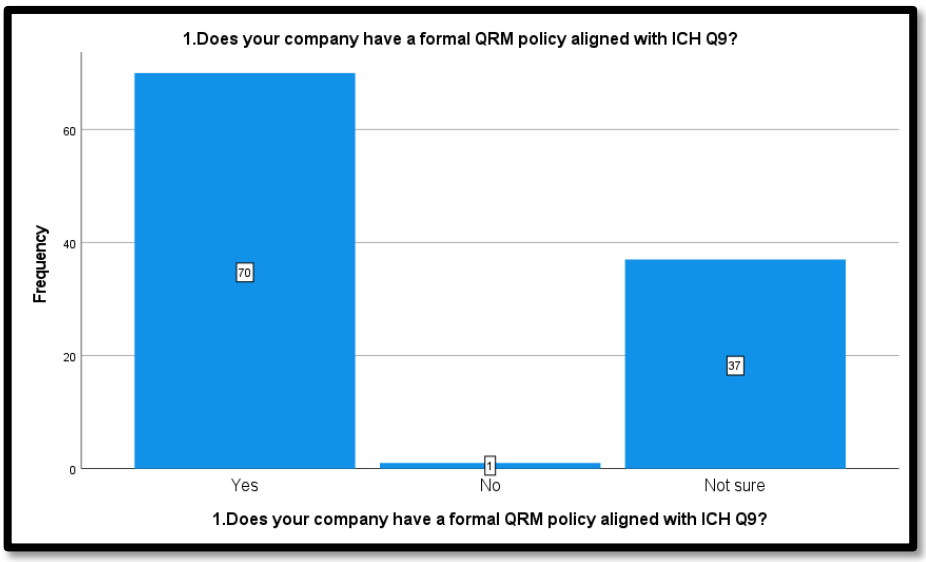


Figure 12: Bar chart for Existence of Formal QRM Policies

As to the question of whether their company has formal QRM policy which is in line with ICH Q9, 70 participants answered it positively, and only one stated that there was no such policy. Interestingly, 37 of them were not sure. These results indicate that QRM policies have been institutionalized in most companies, however, a large proportion of them have not heard of these policies. This can be indicative of internal communication lapses or the insufficient involvement of the staff in the discussion of policies.

4.2.1.5. Perceived Maturity of QRM Practices

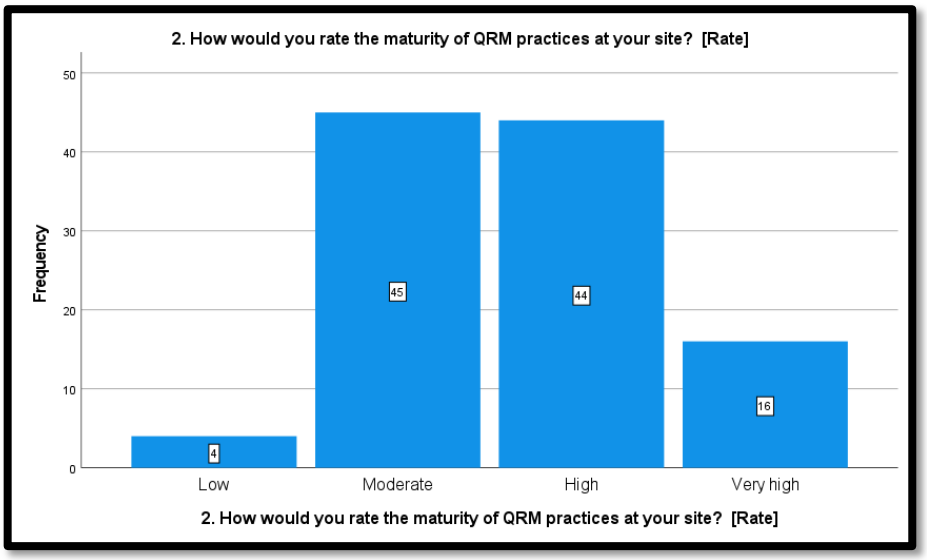


Figure 13: Perceived Maturity of QRM Practices

The respondents at their sites rated the maturity of the practises of QRM differently. The majority of them characterized maturity as moderate (45) or high (44), whereas 16 subjects indicated very high maturity. Four respondents in terms of practices only expressed low rating. This distribution points to the fact that organizations are, on the whole, doing quite well in adopting QRM, but are yet to reach the stage of full maturity consistently. The prevalence of the moderate and high ratings is an indicator of a good trend, but the variability identifies the areas where improvement is needed.

4.2.1.6 QRM Tools Commonly Used

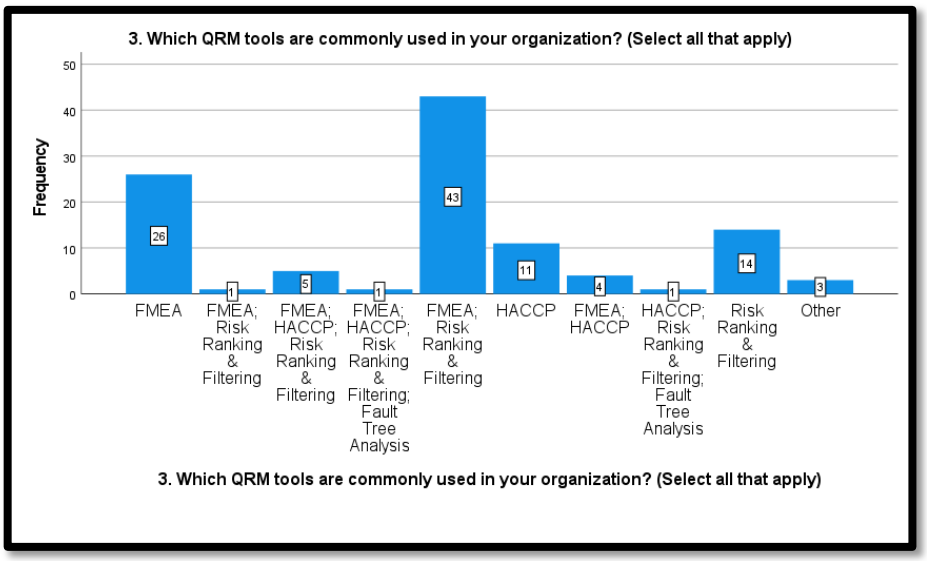


Figure 14: QRM Tools Commonly Used

The data shows that FMEA with Risk Ranking & Filtering is the most widely adopted QRM tool (43 responses), then FMEA (26). Risk Ranking is also important by itself (14), whereas HACCP is moderately utilized (11). Other mixtures are uncommon. This means that they prefer more structured tools that can help in the identification of risk and prioritization, which implies that organizations are more dominated by holistic frameworks than stand-alone tools, with the use of more comprehensive tools such as Fault Tree Analysis being very low.

4.2.1.7 QRM Use in CAPA Investigations

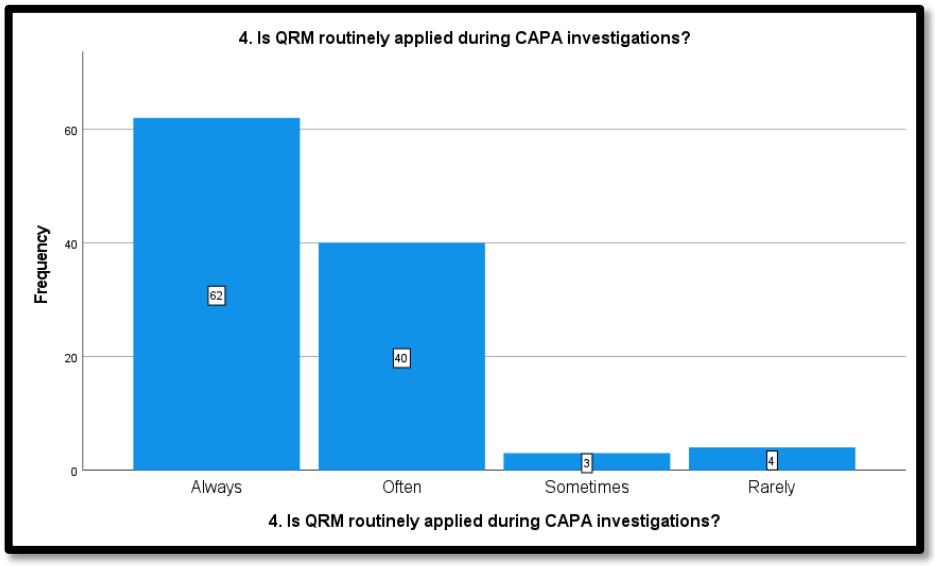


Figure 15: QRM Use in CAPA Investigations

Most of the respondents use QRM frequently in CAPA investigations, with 62 choosing “Always” and 40 choosing “Often.” A very few number of respondents answered either Sometimes (3) or Rarely (4). This indicates a high degree of institutionalization of QRM in CAPA practices and in this way, most organizations are appreciating the importance of risk assessment in both corrective and preventive measures. Nevertheless, the small minority shows that integration difficulties or disparities in organizational culture can still inhibit consistent application in every case.

4.2.1.8 Recurrence of CAPA Issues

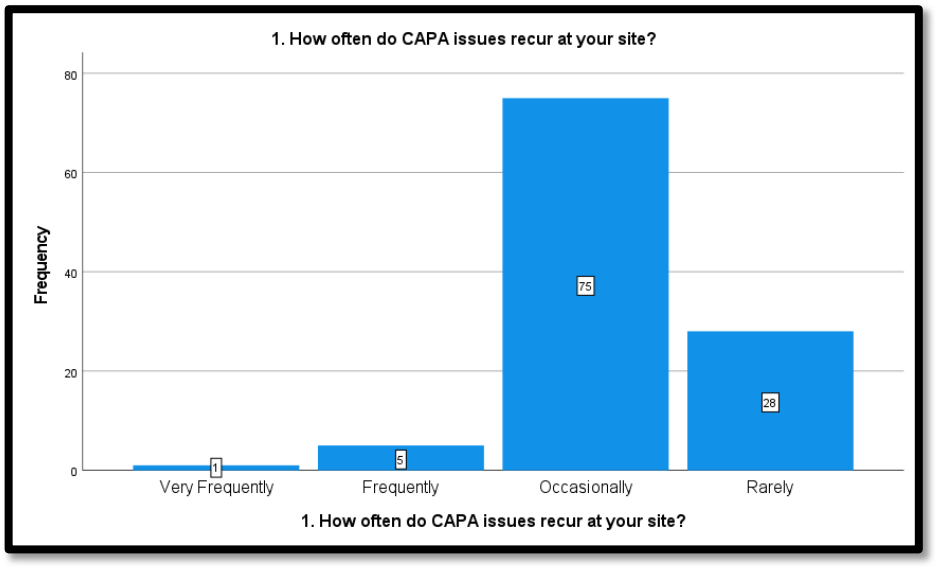


Figure 16: Bar chart showing Recurrence of CAPA Issues

According to the results of surveys, the CAPA issues are most frequently recurring (75), and then rarely (28). Infrequent (2), occasionally (3) and rare (1) were the most common responses with only a handful of respondents reporting frequent (5) and very frequent (1) recurrence. This trend indicates that although the CAPA systems work fairly well in most organizations, there are still instances of failure, which means that there is a lapse in the root cause analysis or follow-up aspects.

4.2.1.9 Reasons for CAPA Recurrence

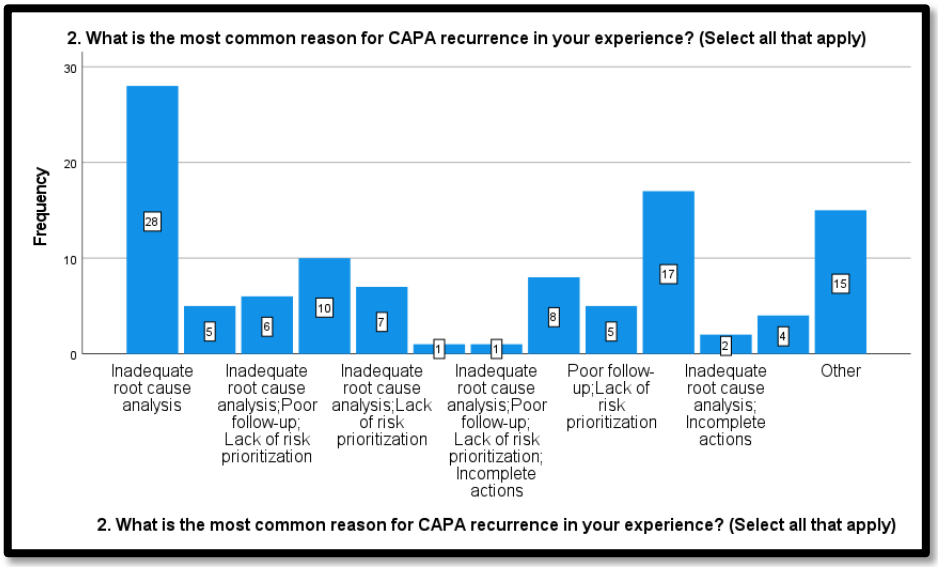


Figure 17: Reasons for CAPA Recurrence

The most cited reason for recurrence is inadequate root cause analysis (28), followed by poor follow-up and lack of risk prioritization (17). Other reasons include incomplete actions and absence of systematic prioritization, although each was less frequent. These findings emphasize weaknesses in investigation rigor and follow-through. Most organizations are yet to manage to get out of the shallow solutions.

4.2.1.10 QRM Tools and CAPA Effectiveness

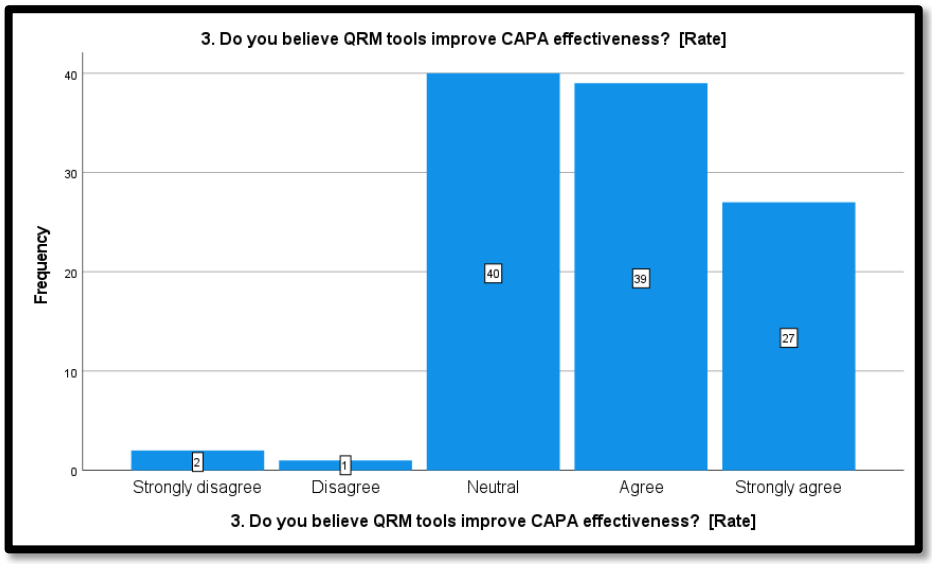


Figure 18: QRM Tools and CAPA Effectiveness

Twenty-seven percent strongly agreed (27) and another 39 percent agreed (39) that QRM tools enhance the effectiveness of CAPA, whereas 40 percent were neutral. There were very few dissenters (3). This agreement indicates that risk-based methods are seen as useful in the process of improving both the corrective and preventive activities. Nonetheless, the high neutrality value can reflect a lack of exposure to outcomes that can be measured or difficulties in showing an improved picture. In general, the findings confirm that QRM can reinforce CAPA practices.

4.2.1.11 Challenges in Applying QRM in CAPA

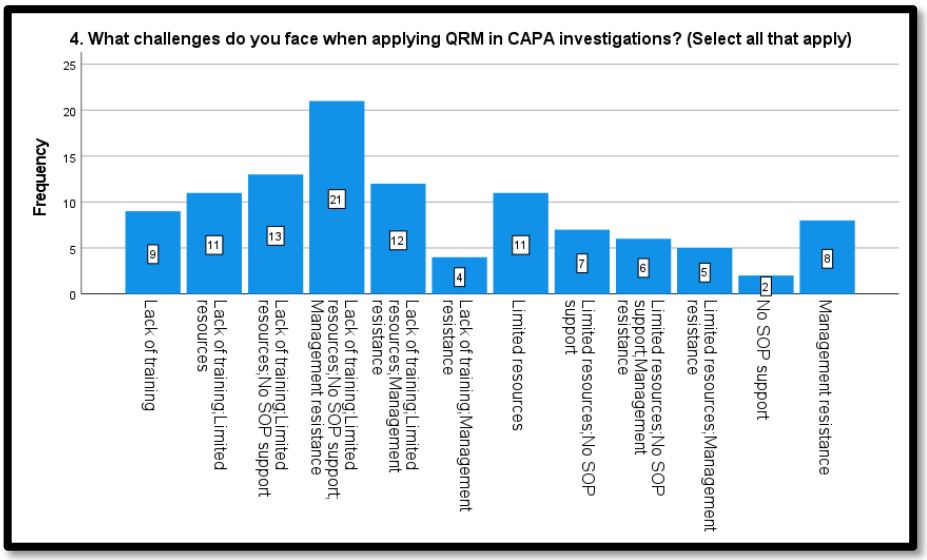


Figure 19: Challenges in Applying QRM in CAPA

The greatest challenge identified is lack of training combined with limited resources (21), followed by lack of SOP support and management resistance. Standalone barriers such as limited resources (11) and lack of training (9) were also reported. The results underscore system-level deficiencies in organizational preparedness, particularly, in resource distribution, planned processes, and management commitment. The issues need to be resolved through more solid institutional backing, investment in education, and management involvement to establish sustainable QRM application.

4.2.2 Crosstabulation and Chi square test

4.2.2.1 Impact of QRM Policy on CAPA Recurrence: Crosstabulation and Chi-Square Analysis

Table 1: crosstabulation for Impact of QRM Policy on CAPA Recurrence

Count

		1.Does your company have a formal QRM policy aligned with ICH Q9?			
		Yes	No	Not sure	Total
1. How often do CAPA issues recur at your site?	Very Frequently	0	0	1	1
	Frequently	1	1	3	5
	Occasionally	52	0	22	74
	Rarely	17	0	11	28
Total		70	1	37	108

The crosstabulation indicates the correlation between the recurrence of the CAPA issues and the existence of a formal QRM policy in compliance with ICH Q9. Findings show that most

organizations having QRM policy report CAPA recurrence occurrences occasionally (52 cases) or rarely (17 cases) implying that structured QRM helps to reduce frequent recurrences. Conversely, those respondents who were uncertain about QRM policy alignment indicated a higher frequency in the case of occasional (22 cases) and rarely (11 cases) cases. Only a few stated that they had frequent or very frequent recurrence.

Table 2: Chi square test table

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	26.088[a]	6	<.001
Likelihood Ratio	12.253	6	.057
Linear-by-Linear Association	.431	1	.512
N of Valid Cases	108		

a. 8 cells (66.7%) have expected count less than 5. The minimum expected count is .01.

The Chi-square test highlights a significant association between CAPA recurrence and the presence of a QRM policy ($\chi^2 = 26.088$, df = 6, $p < .001$). This implies that the implementation of a formal QRM policy will greatly decrease the frequency of recurrence. But the expected count of 66.7 percent cells was less than 5 which means that there was a limitation in the distribution of data. Nonetheless, findings suggest that well-planned QRM deployment improves CAPA performance and minimizes the possibility of a repeat.

4.2.2.2 Relationship Between QRM Application in CAPA Investigations and Issue Recurrence

Table 3: Crosstabulation for Relationship Between QRM Application in CAPA Investigations and Issue Recurrence

Count

		4. Is QRM routinely applied during CAPA investigations?				
		Always	Often	Sometimes	Rarely	Total
1. How often do CAPA issues recur at your site?	Very Frequently	1	0	0	0	1
	Frequently	1	4	0	0	5
	Occasionally	43	28	1	3	75
	Rarely	17	8	2	1	28
Total		62	40	3	4	109

The crosstabulation analyzed the connection between the recurrence rates of CAPA issues and the level of QRM regularly used in the course of CAPA investigation. The information found out that the organizations that implemented QRM regularly (Always or Often) were less prone to CAPA concerns. As an example, 43 respondents who had reported that recurring CAPA

issues were “Occasionally” also reported that QRM was being applied “Always” whereas 28 reported that QRM was applied “Often.” On the contrary, when QRM was not implemented in the same way (“Sometimes” or “Rarely”), CAPA issues were seen to repeat at the same or even greater levels.

Table 4: Chi square test table

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	7.950[a]	9	.539
Likelihood Ratio	7.957	9	.538
Linear-by-Linear Association	.002	1	.967
N of Valid Cases	109		

a. 12 cells (75.0%) have expected count less than 5. The minimum expected count is .03.

The chi-square test result ($\chi^2 = 7.950$, df = 9, p = 0.539) showed no statistically significant association between QRM application and CAPA recurrence. This implies that although descriptive patterns prove that a possible relationship exists between the increased use of QRM and decreased recurrence, the statistical data is insufficient to support this. Future findings might be enhanced in terms of their sample size.

4.2.3 Anova analysis

4.2.3.1 Perceptions of QRM Tools in Enhancing CAPA Effectiveness: ANOVA Analysis

Table 5: Anova table

3. Do you believe QRM tools improve CAPA effectiveness? [Rate]

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	17.618	3	5.873	9.157	<.001
Within Groups	67.336	105	.641		
Total	84.954	108			

ANOVA test was used in order to analyze whether there are significant differences in the perceptions about effectiveness of QRM tools in enhancing CAPA outcomes. According to the results, the variation between groups is statistically significant ($F = 9.157$, $p < .001$). This implicates that the ratings of the effectiveness of the QRM tools by respondents vary significantly among groups, proving that not every participant has the same view of their influence.

Having the between-groups sum of squares (17.618) in comparison to within-groups (67.336) indicates that a significant amount of the variance in the responses is captured by the group differences other than random variation. This strengthens the conclusion that perceptions of QRM effectiveness differ significantly according to organizational practices, experience levels, or QRM principle awareness.

4.2.3.2 Assessment of QRM Maturity Across Sites: ANOVA Analysis

Table 6: ANOVA Analysis

2. How would you rate the maturity of QRM practices at your site? [Rate]

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	7.743	3	2.581	4.780	.004
Within Groups	56.698	105	.540		
Total	64.440	108			

The ANOVA analysis of the question concerning the maturity of QRM practices at the sites of the respondents indicates the statistically significant difference between groups ($F = 4.780$, $p = .004$). This implies that there is a wide variation in the perception of QRM maturity by organizational context or the background of respondents. The difference between the groups

sum of squares (7.743) and within-groups (56.698) indicates that the variance is not only caused by the random error but it is also significantly affected by the group-level differences.

The relatively small within-group variance (0.540) implies homogeneity within each group in their responses, and higher between-group variance indicates dissimilarity in how maturity is lived or put into practice between sites. Such results indicate that certain organizations already established more organized and mature QRM systems whereas others are less mature.

4.2.4 Correlation analysis

4.2.4.1 Correlation between QRM Maturity and CAPA Effectiveness

Table 7: Correlation analysis

		3. Do you believe QRM tools improve CAPA effectiveness ? [Rate]	2. How would you rate the maturity of QRM practices at your site? [Rate]
3. Do you believe QRM tools improve CAPA effectiveness? [Rate]	Pearson Correlation	1	.444**
	Sig. (2-tailed)		<.001
	N	109	109
2. How would you rate the maturity of QRM practices at your site? [Rate]	Pearson Correlation	.444**	1
	Sig. (2-tailed)	<.001	
	N	109	109

**. Correlation is significant at the 0.01 level (2-tailed).

The correlation analysis helps one have significant information regarding the correlation between perceived maturity of Quality Risk Management (QRM) practices and the effectiveness of Corrective and Preventive Actions (CAPA). The Pearson correlation coefficient was 0.444 and this value is significant at 0.01 level ($p < 0.001$). This positive moderate correlation indicates that the more mature QRM practices at a site are, the more effective the CAPA processes become in the perception.

Such an association shows that QRM is an inseparable part of organizational learning, preventing errors and controlling risks. The more mature sites in QRM practices are bound to use structured approaches, evidence-based choices, and proactive risk analyses. These components enhance CAPA systems because the root causes are completely recognized and handled thereby lessening the repetition of the problems. On the other hand, the sites with less mature QRM practices can resort to reactive approaches resulting in a poor CAPA effectiveness.

4.2.4.2 Correlation between QRM Maturity and CAPA Recurrence

Table 8: Correlation table

		2. How would you rate the maturity of QRM practices at your site? [Rate]	1. How often do CAPA issues recur at your site?
2. How would you rate the maturity of QRM practices at your site? [Rate]	Pearson Correlation	1	.241*
	Sig. (2-tailed)		.011
	N	109	109
1. How often do CAPA issues recur at your site?	Pearson Correlation	.241*	1
	Sig. (2-tailed)	.011	
	N	109	109

*. Correlation is significant at the 0.05 level (2-tailed).

The correlation analysis has been conducted to test the correlation between the maturity of the Quality Risk Management (QRM) practices and the frequency of the occurrence of the Corrective and Preventive Action (CAPA) issues. Pearson correlation coefficient was 0.241 and this correlation is statistically significant at 0.05 level ($p = 0.011$). It is a positive relationship which means that there is a weak relationship between maturity of QRM practices and the occurrence of CAPA issues whereby the higher the maturity of the QRM practices the more some association is also present.

This observation might appear contradictory, because mature QRM systems are usually supposed to decrease CAPA recurrence. Nevertheless, it could indicate that those organizations whose QRM practice is more advanced detect, record, and report the issues of CAPA better, resulting in an increased observed recurrence rate. Instead, it might imply that the effect of QRM maturity is positive, but other variables, including cultural adoption, resource allocation or implementation consistency, are also essential to minimize CAPA repeat.

Altogether, the finding underscores the importance of organizations not only to develop their QRM systems but also to have a strong implementation and execution in CAPA systems to improve their quality in a sustainable way.

4.2.5 Regression analysis

Table 9: Model summary table

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.382[a]	.146	.113	.522

a. Predictors: (Constant), 4. Does your site follow EU GMP and ICH Q9?, 1.Does your company have a formal QRM policy aligned with ICH Q9?, 2. How would you rate the maturity of QRM practices at your site? [Rate], 4. Is QRM routinely applied during CAPA investigations?

The regression analysis was used to study the predictors that affected the recurrence of CAPA problems at the sites. The model summary shows a value of 0.382 in a correlation coefficient (R) which means that there is a moderate positive correlation between the predictors and the dependent variable. The R Square value of 0.146 indicates that the variance of the CAPA recurrence is explained by the considered predictors to the tune of 14.6%. Even though the explanatory power is low, it emphasizes the fact that some of the practices related to QRM have a great impact.

Table 10: Anova table

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	4.804	4	1.201	4.401	.003[b]
	Residual	28.112	103	.273		
	Total	32.917	107			

a. Dependent Variable: 1. How often do CAPA issues recur at your site?

b. Predictors: (Constant), 4. Does your site follow EU GMP and ICH Q9?, 1.Does your company have a formal QRM policy aligned with ICH Q9?, 2. How would you rate the maturity of QRM practices at your site? [Rate], 4. Is QRM routinely applied during CAPA investigations?

The ANOVA table demonstrates that the regression model is statistically significant ($F = 4.401$, $p = 0.003$), which proves that the chosen predictors are linked to the variance of CAPA recurrence as a whole. It underlines the relevance of QRM maturity and regulatory compliance variables as factors that affect the effectiveness of CAPA.

Table 11: Coefficients table

Model		Unstandardized Coefficients B	Unstandardized Coefficients Std. Error	Standardized Coefficients Beta	t	Sig.
1	(Constant)	2.283	.298		7.666	<.001
	1.Does your company have a formal QRM policy aligned with ICH Q9?	-.036	.054	-.062	-.671	.504
	2. How would you rate the maturity of QRM practices at your site? [Rate]	.158	.066	.220	2.398	.018
	4. Is QRM routinely applied during CAPA investigations?	-.012	.071	-.016	-.169	.866
	4. Does your site follow EU GMP and ICH Q9?	.374	.119	.291	3.149	.002

a. Dependent Variable: 1. How often do CAPA issues recur at your site?

The coefficients table presents more information about the role of single predictors. Having a formal QRM policy as per ICH Q9 (0.062, p = 0.504) and the routine use of QRM in CAPA investigations (0.016, p = 0.866) did not show any statistically significant effects on a CAPA recurrence. Nevertheless, QRM practices maturity at the site (beta = 0.220, p = 0.018) was identified as a significant factor and thus, it can be argued that the higher the maturity, the less likely the CAPA recurrence. Moreover, the compliance with EU GMP and ICH Q9 (b = 0.291, p = 0.002) also produced a very strong statistical significance indicating that the compliance with the international guidelines is a very important factor that determines the effectiveness of CAPA management.

4.3 Analysis

4.3.1 Impact of QRM Tools on CAPA Effectiveness

4.3.1.1 Differences in Perceptions Across Respondent Groups

The analysis indicated significant variations in the perception of the role played by the Quality Risk Management (QRM) tools in boosting the effectiveness of the Corrective and Preventive Action (CAPA) by different respondent groups. Most of them admitted that QRM could greatly reinforce the systematic risk assessment, but the level of agreement was different in demographic and professional groups. As an example, the respondents in management or supervisory jobs evaluated QRM tools more positively, which can be explained by the fact that they directly participate in decision-making activities and therefore can notice the effect of structured risk evaluation most vividly. On the other hand, there were more moderate responses

given by some operational-level employees indicating there are QRM frameworks but their use may not be consistent and not entirely embedded in everyday CAPA activities.

Such variations point to the possible disconnect between the policy aspiration and the reality. The difference in perceptions can also be an indication of the differences in terms of exposure to QRM methodologies, training difference, or maturity of an organization in the process of entrenching the risk-based thinking. Notably, the differences reflect on the necessity of more standardized dissemination of the QRM principles and similar reinforcement at every level of the organization. The solution to these perceptual gaps would likely enhance engagement and ownership of CAPA processes, and, thus, the overall effectiveness.

4.3.1.2 Implications for Strengthening CAPA Processes

The results highlight a number of important implications of improving the strength of the CAPA processes by the systematic use of Quality Risk Management (QRM). Those companies with greater maturity in QRM practices also recorded reduced cases of recurrent CAPA problems. This implies that risk-based thinking incorporated with non-conformities not only ensures that the non-conformities are solved, but also goes ahead to eliminate the re-occurrence of non-conformities by identifying weaknesses in the system. An adequately integrated QRM system allows companies to prioritize on corrective measures according to the severity of the risk and hence dedicating resources that are most likely to make significant impacts.

In addition, the findings indicate the need to conduct a regular use of QRM principles during CAPA investigations instead of confining them to the policy levels. Data-driven decision-making is more possible when QRM is used regularly, traceability is increased and accountability between departments. Notably, regulatory compliance is also facilitated by the implementation of QRM, that is, organizational practices are streamlined with international recommendations like ICH Q9 and EU GMP.

4.3.2 Maturity of QRM Practices within Organizations

4.3.2.1 Variations in QRM Maturity Levels Across Sites

The results indicate that QRM practices are highly diverse in terms of maturity at surveyed sites. As an example, the ANOVA output revealed a significant difference in the maturity rating of QRMs ($F = 4.780$, $p = .004$) and hence not all of the sites are at the same stage of risk management incorporation. The maturity scores were higher and lower in sites that claimed to

use QRM consistently in CAPA investigations and sites that tended to be fragmented or reactive respectively.

At mature sites, QRM is integrated into the daily practices and the leadership commitment and training enable the reliable results of the CAPA. On the other hand, those sites that have lower levels of maturity perceive QRM more as a procedural demand, which restricts its potential in terms of fighting against repeat of issues. Such an imbalance in maturity demonstrates the role of organizational culture, management assistance, and resource allocation in the QRM adoption.

4.3.2.2 Influence of QRM Maturity on Overall Quality Culture

The maturity of QRM practices has a drastic impact on the greater quality culture in pharmaceutical organizations. The correlation analysis indicated that there was a significant positive correlation ($r = .444$, $p < .01$) between QRM maturity and belief in CAPA effectiveness, which indicated that the stronger the QRM practices, the louder the belief of the problem is resolved. Locations that have developed well-established QRM models are likely to have developed a proactive culture, in which employees do not see quality as something which the company is required to do but as a collective task.

Conversely, the QRM immature sites tend to have a reactive culture where problems are solved once they come up, thus causing recurrent CAPA problems. This unresponsive system undermines accountability and reduces the learning and process improvement opportunities. Incorporating QRM into the everyday operations of the organization enhances cross-functional cooperation, more transparency in decision making, and the culture of continuous improvement.

4.3.3 Relationship Between QRM and CAPA Outcomes

4.3.3.1 Link Between QRM Tools and CAPA Effectiveness

The results of the current study show that there is a close association between the usage of QRM tools and the perceived effectiveness of the CAPA processes. The ANOVA analysis showed the presence of statistically significant differences in responses ($F = 9.157$, $p = .000$), which also means that the higher the respondents rated QRM tool implementation, the higher was the level of CAPA effectiveness reported. Based on this evidence, it can be concluded that systematic risk-based methods add clarity and prioritization to the CAPA investigation and help guarantee that the corrective measures are not only instituted but also sustainable.

As an example, risk analysis methods like Failure Mode and Effects Analysis (FMEA), or risk ranking approaches can be used to determine organizational sources of repeating deviations. This is consistent with the survey results in which 52 respondents responded that CAPA problems were experienced only "occasionally," though there was a significant reduction of repetition in organizations with high levels of QRM integration. These tools enable the making of data-driven decisions and reduce subjective decisions and enhance accountability.

4.3.3.2 Connection Between QRM Maturity and CAPA Recurrence

It was found that there was a strong correlation between the level of maturity of QRM activities and the number of CAPA occurring. The correlation coefficient value corresponded to a moderate, but significant relationship ($r = .241$, $p = .011$), and it was reasonable to conclude that as the level of QRM maturity increases, CAPA recurrence is more likely to decrease. This underscores the fact that the presence of well-implanted QRM frameworks in organizations gives them the better edge of pinpointing effective causes of deviations and avoiding reoccurrence.

The survey results revealed that 74 respondents belonged to the group who answered that the problems with CAPA were occasional and 28 replied that they happened rarely. Notably, sites with a higher maturity score (those assigning the higher scores to their QRM practices) were more likely to fall in the lower end of the scale (and thus, in line with the idea that strong QRM maturity leads to more consistent CAPA results, the higher the score, the more likely the site to report low levels of CAPA outcome). On the contrary, companies that did not have more advanced QRM practices showed a greater rate of recurrence, highlighting risk assessment and management shortcomings.

4.3.4 Determinants of CAPA Recurrence

4.3.4.1 Role of Regulatory Alignment with EU GMP and ICH Q9

Regression analysis revealed that compliance with EU GMP and ICH Q9 is a significant determinant in the reduction of CAPA recurrence ($\beta = .291$, $p = .002$). Websites that followed these guidelines had fewer recurrent problems, which shows the importance of regulatory congruence in terms of enhancing quality systems. This adherence will make the CAPA investigations to be in accordance with the internationally accepted standards in risk management and control of processes. Organizations that are in line with these guidelines enjoy well-organized methodologies that will improve on consistency, accountability, and prevention. It means that the compliance with the regulations is not only something that should

be observed and enforced but also a key factor in terms of CAPA sustainability and long-term quality enhancement.

4.3.4.2 Contribution of QRM Maturity to Reducing CAPA Issues

Results indicate that QRM maturity has a major impact on CAPA recurrence (β = .220, p = .018). The sites at higher maturity levels of the implementation of QRM tools reported lower occurrences of the frequently or very frequently reported CAPA problems, proving that the risk-based thinking enables more effective preventive actions. The systematic risks identification, prioritisation of action and outcomes verification that mature QRM practices allow eliminates the risk of recurrence. Companies promote consistency in the implementation of CAPA by incorporating QRM into the culture of the organization. It is important to underline that QRM maturity development is not merely an operational enhancement but a strategic requirement to sustain compliance and long-term product and patient safety.

4.3.4.3 Limited Influence of Formal Policies and Routine Applications

Regression results indicated that having a formal QRM policy (β = –.062, p = .504) and the routine application of QRM during CAPA investigations (β = –.016, p = .866) had limited or no significant impact on CAPA recurrence. This indicates that maturity and depth are not possible through policies and frequent use. Organizations can adopt QRM in a formal manner and fail to train, provide resources, or cultural determination to make it successful. This result supports the idea that a facile obedience is not a substitute of real maturity, and the actual effects are defined by the depth of QRM practices adoption and maintenance in the everyday practice.

4.3.5 Alignment and Support for Existing Literature

This study in particular builds immensely on the consensus in the current literature that the maturity of Quality Risk Management (QRM) practices is one of the key drivers of the effectiveness of CAPA. The identified positive correlation between QRM maturity and lower recurrence of CAPA issues directly proves the previous claims by Ramnarine & O Donnell (2018) and Jones et al. (2020), who have emphasized that more advanced risk management maturity provides a basis on which sustainable quality results can be achieved. On the same note, the regression analysis also affirmed that QRM maturity and regulatory alignment with EU GMP and ICH Q9 were both important predictors of better outcomes, as expected at EMA (2022) and HPRA (2023) in terms of risk-based CAPA frameworks to enhance robustness and regulatory preparedness.

Moreover, these findings resonate with Waldron (2017) and Greene et al. (2018), who observed that CAPA recurrence is frequently caused by a superficial investigation and thus why maturity is more important than procedural adherence. The lack of a significant influence of formal policies or routine applications of QRM reflects the reservations of McDermott et al. (2022) and Mulholland (2024) who noted that, in many sites in Ireland, QRM is implemented so as to pass audits but not cultural depth. On the whole, the research confirms literature which emphasizes that QRM maturity, regulatory alignment and actual cultural integration, rather than formality, are the major contributors of quality improvement.

4.3.6 Contradiction with Existing Literature

Although the results show general consistent findings with the previous studies, there are some areas that indicate subtle contradictions. The greatest tension is associated with the reported adoption of QRM tools. Descriptive analysis showed that there was a relatively common application of structured approaches like Failure Mode and Effects Analysis (FMEA) and Risk Ranking and Filtering. On its face, this may not be in line with other critiques in the literature (Waldron, 2017; McDermott et al., 2022) that such tools are, in many cases, underutilised or inconsistently applied in Irish pharmaceutical contexts. Nevertheless, this difference can be justified by the gap between the frequency of usage (what is measured by surveys) and quality or profundity of implementation (what is stressed in the literature). There is the possibility that although the tools are widely used, they are usually used in a shallow manner or to a compliance level hence limiting their effectiveness.

The other contradiction is that the formal QRM policies are not significant and the routine application of QRM within CAPA. As implied in literature like Teasdale & Elder (2018), codified frameworks were deemed to reinforce practice but in the present study, these types of variables did not seem to decrease CAPA recurrence. This tension emphasises that formalisation per se cannot work unless there is cultural acceptance and analytical rigor. These results indicate that, although the focus on tools and frameworks in the literature makes sense, it is not very effective unless maturity, integration, and organisational mindset are present.

4.4 Summary

Analysis and findings have revealed that QRM maturity and compliance with EU GMP as well as ICH Q9 is the greatest determinant of CAPA effectiveness. The mature QRM practices lower the chances of recurrence as organizations incorporate risk-based thinking in the organizational

culture and regulatory compliance enhances consistency and compliances. On the other hand, formal policies and routine applications do not have much effect as they are not comprehensive or incorporated. Altogether, the analysis points out that authentic maturity, cultural adoption, and compliance with global standards are essential to sustainable CAPA improvement.

Chapter 5 – CONCLUSIONS AND RECOMMENDATIONS

5.1 Introduction

This chapter gives the conclusions and recommendations made based on the study, summarizing the results and the analytical findings that have been discussed in the previous chapters. The objective is to summarize the evidence in such a manner that it presents clear results that respond to the research objectives, and qualifies its practical and academic implications. The chapter starts with the highlights of the main conclusions and then makes recommendations addressing the main areas of CAPA improvement and QRM maturity in the pharmaceutical industry.

5.2 Summary of key findings

The results of the given study emphasize the importance of Quality Risk Management (QRM) practices in determining the effectiveness of Corrective and Preventive Actions (CAPA). On the whole, the findings indicate the existence of the obvious statistical correlations among QRM maturity, regulatory compliance, and CAPA issue recurrence.

To begin with, the ANOVA revealed that there were significant differences on the perceptions of the respondent groups in relation to the question of whether QRM tools enhance effectiveness of the CAPA with $F = 9.157$, $p < 0.001$. This implies that although there are groups of respondents who find the effects of QRM very important, there are still others who feel less convinced that it is important, which is an indication of the different maturity levels of implementation at the different sites. Likewise, when rating the QRM maturity in itself, there was a considerable difference ($F = 4.780$, $p = 0.004$), which demonstrates the differences in the level of QRM implementation in various organizations.

Secondly, a solid and significant connection between the maturity of QRM and the efficiency of CAPA was attested through correlation analysis ($r = 0.444$, $p < 0.01$). The sites that showed greater maturity had higher chances of reporting better CAPA results. Also, a lower and yet statistically significant relationship was found between QRM maturity and lower CAPA recurrence ($r = 0.241$, $p < 0.05$), which indicated that maturity contributes a certain amount of role in maintaining the long-term success.

Thirdly, regression analysis also provided deeper details. The model accounted for 14.6 percent of the CAPA recurrence variance ($R 2 = 0.146$, $p = 0.003$). QRM maturity ($\beta = 0.220$, $p =$

0.018) was significant among predictors and the strongest effect was exhibited by alignment with EU GMP/ICH Q9 ($\beta = 0.291$, $p = 0.002$). Formal QRM policies ($p = 0.504$) and routine applications ($p = 0.866$) did not have much standalone effect, in contrast.

In a nutshell, the findings establish the fact that QRM maturity as well as regulatory alignment are key determinants of CAPA success. Nevertheless, the existence of policies, devoid of risk-based approaches practically embedded, is not enough to ensure the long-term changes.

5.2 Research questions and their answers

1. To what extent does the integration of ICH Q9-based QRM reduce recurring CAPAs in Irish pharmaceutical manufacturing?

The research results give a clear indication that QRM maturity and regulatory conformity to the ICH Q9 is an essential factor towards minimizing CAPA recurrences. Regression model proved that alignment with EU GMP/ICH Q9 was the most powerful predictor of reduced CAPA recurrence that had a significant contribution ($p = 0.002$, 0.291). Also, the maturity levels of QRM were linked to the reduced frequencies of recurring problems with a strong correlation between the maturity and CAPA recurrence ($r = 0.241$, $p < 0.05$). Such findings mean that the more an organization integrates the ICH Q9 principles into its organisation, the better it controls deviations, but also maintains the enhancement of its CAPA systems. Although integration does not completely prevent recurrence, it offers a very strong framework that supports root cause analysis, prioritization, and prevention strategies.

2. What are the practical barriers to implementing effective QRM systems that prevent CAPA recurrence in Ireland's GMP-compliant pharma sector?

The results indicate that formal policies of QRM exist in most organizations but they are not necessarily utilized successfully. The regression analysis found that the existence of an official QRM policy that conforms to ICH Q9 was not a significant predictor of a decrease in CAPA recurrence by itself ($p = 0.504$). In the same manner, independent use of QRM at the time of CAPA investigations had a low impact ($p = 0.866$). Such findings point to some obstacles like excessive reliance on documentation without integrating risk principles in practice, incoherent training, and inconsistent involvement of employees at operational levels. The other obstacle is the non-homogeneous maturity of QRM across locations, where ANOVA results indicate the significant variation in the perceptions of maturity ($F = 4.780$, $p = 0.004$).

3. How do Quality Assurance professionals in Irish pharmaceutical companies assess the effectiveness of QRM in managing recurring deviations?

Quality Assurance professionals usually think of QRM as a key contributor to CAPA efficacy, though they perceive it differently on a basis of organizational maturity. The correlation analysis proved that there is a strong connection between the QRM maturity and the perceived CAPA effectiveness ($r = 0.444$, $p < 0.01$). Nevertheless, ANOVA outcomes also demonstrated the variance in the assessment of QRM value among the groups of respondents ($F = 9.157$, $p < 0.001$). This implies that most of the professionals have realized the advantages of QRM, but some professionals might not be convinced because of mixed results in different sites. In more mature settings, professionals report more confidence in the potential of QRM to eliminate recurring deviations, whereas skepticism prevails where settings are less mature.

5.3 Recommendations

5.3.1 Industry Recommendations

In the case of the pharmaceutical industry in Ireland, there is a need to enhance the practical incorporation of QRM in order to minimize the recurring CAPA problems. Firms cannot afford to have formal policies but ensure that the principles of QRM are manifested every day in the activities of the company. These include specific training of personnel across the board, increased management support of a risk-based culture, and increased application of standardized QRM tools during CAPA investigation. In addition, alignment with EU GMP and ICH Q9 regulations should be considered a priority since it has been determined as the most significant factor affecting CAPA recurrence. There is also a possibility that investment in digital QRM systems can contribute to better traceability and consistency. All these measures can bring a proactive culture where risks are detected early and the effectiveness of CAPA is greatly improved.

5.3.2 Academic Recommendations

Academically, this study will help in the knowledge of the role of QRM maturity in the effectiveness of CAPA but more knowledge should be sought. In the future, researchers should not focus on Irish pharmaceutical companies only, but rather compare the practices internationally, which makes it possible to benchmark the QRM maturity level across regulatory environments. The cultural and behavioral aspects that lead to practical adoption of

QRM should also be explored by the researchers as it was found that policies are not enough to ensure effectiveness. Such a combination of mixed-methods, which involve surveying and in-depth case studies, may yield deeper information on the operationalization of QRM at the shop-floor. Also, longitudinal studies that would trace the recurrence of CAPA over time would provide evidence of the long-term effect of QRM practices. Such guidelines would reinforce academic theory and practical implementation in pharmaceutical management of quality.

5.4 Limitations And Contributions

This research gives useful information on the correlation between QRM maturity, regulatory alignment, and CAPA recurrence; nevertheless, it is necessary to distinguish a few limitations. To begin with, the study relied on self-reporting surveys that can be susceptible to bias during the recording or variation in the understanding of the QRM practices. Only the Irish pharmaceutical sector was researched, which also decreases the applicability of the results to other regulatory/cultural environments. Also, though correlations and the regression results were determined in the analysis, the cause and result cannot be put on solid ground.

Nevertheless, the research has several contributions. In practical terms, it shows how important QRM maturity and regulatory alignment are in minimising the reoccurring CAPAs and provides industry with a clear path of improvement. Academically, it can add to the rare literature linking QRM frameworks and CAPA efficacy, specifically in the framework of EU GMP and ICH Q9 compliance. All in all, it can serve as a good basis to further, more extensive research.

5.6 Suggestions for Future Research

Future studies on the topic must improve on the current study by using wider and more comprehensive data gathering procedures that should include, among others, longitudinal case-studies or first hand auditing of QRM practices to minimize the use of self-reported data. An extension to other sectors with the Irish pharmaceutical industry would help to present comparative data in varying regulatory environments and to identify whether the relationship between QRM maturity and CAPA recurrence is generalizable or specific. Also, it would be good to look at how organizational culture, leadership commitment and resource allocation contributes to QRM maturity sustainability. A second useful step would be to use advanced statistical modeling or structural equation modeling to investigate causal pathways in a stronger way. Lastly, including regulatory perspectives along with industry practitioners would enhance

the analysis and give a comprehensive picture of the manner in which QRM frameworks affect long term CAPA effectiveness and continuous improvement within the pharmaceutical industry.

REFERENCES

Arunagiri, T., Kannaiah, K.P. and Vasanthan, M., 2024. Enhancing Pharmaceutical Product Quality With a Comprehensive Corrective and Preventive Actions (CAPA) Framework. *Cureus*, 16(9), p.e69762.

Butler, S., Haddad, G., Kelleher, D., O'Donnell, K. and Tobin, D., 2020. Understanding the Concept of Formality in Quality Risk Management. *Level 3*, 15(2), Article 15. Available at: https://arrow.tudublin.ie/level3/vol15/iss2/15 [Accessed 21 June 2025].

Calnan, N., O'Donnell, K. and Greene, A., 2013. Enabling ICH Q10 Implementation—Part 1. Striving for Excellence by Embracing ICH Q8 and ICH Q9. *PDA Journal of Pharmaceutical Science and Technology*, 67, pp.581–600.

Charoo, N. and Ali, A.A., 2013. Quality risk management in pharmaceutical development. *Drug Development and Industrial Pharmacy*, 39(6), pp.947–960.

Chordiya, M.A., Gangurde, H. and Sancheti, V., 2019. Quality by Design: A Roadmap for Quality Pharmaceutical Products. *Journal of Reports in Pharmaceutical Sciences*, 8, pp.289–294.

George, C., 2025. Conceptual Framework and Illustrative Figures. [Own work]. Included in dissertation submitted to Griffith College Dublin.

EMA, 2022. *EU Guidelines for GMP Chapter 1: Pharmaceutical Quality System*. Available at: https://www.ema.europa.eu/en [Accessed 20 June 2025].

Greene, A., Barry, C. and Brennan, M., 2018. Impact of QRM on Pharmaceutical Process Efficiency. *Journal of Validation Technology*, 24(2), pp.42–51.

Guilfoyle, D., Friedman, R.L., Hughes, P., Hussong, D., Rosenberg, A. and Brorson, K., 2013. Microbial Risk in Pharmaceutical Manufacturing and ICH Q9. *PDA Journal of Pharmaceutical Science and Technology*, 67(1), pp.79–80.

Gupta, N.V., Reddy, V.V., Raghunandan, H.V. and Kashyap, U.N., 2014. Quality Risk Management in Pharmaceutical Industry: A Review. *International Journal of PharmTech Research*, 6(3), pp.908–914.

ICH, 2008. *ICH Q10: Pharmaceutical Quality System*. Geneva: International Council for Harmonisation. Available at: https://www.ich.org/page/quality-guidelines [Accessed 21 June 2025].

Kartoglu, U. and O'Donnell, K., 2024. QRM and the Importance of ICH Q9(R1). *Pharmaceutical Technology*, July 2024.

Lexchin, J., Bero, L., Djulbegovic, B. and Clark, O., 2003. Pharmaceutical Industry Sponsorship and Research Outcome and Quality: Systematic Review. *BMJ*, 326, pp.1167–1170.

McDermott, O., Whelan, P., O'Callaghan, J. and Byrne, M., 2022. Barriers and Enablers for Continuous Improvement Methodologies in Irish Pharma. *Processes*, 10(1), p.73.

Mulholland, V., 2024. *Effective Risk-Based Decision Making in Quality Risk Management*. PhD thesis. Technological University Dublin. Available at: https://arrow.tudublin.ie/schschpsdis/5 [Accessed 21 June 2025].

Niazi, S.K., 2021. *Quality Risk Management*. In: *Sterile Manufacturing*. 1st ed. Boca Raton: CRC Press.

O'Donnell, K., Greene, A., Zwitkovits, M. and Calnan, N., 2012. Quality Risk Management: Putting GMP Controls First. *PDA Journal of Pharmaceutical Science and Technology*, 66(3), pp.243–261.

Oktaviani, L., Ginting, M. and Sunardi, O., 2020. Voluntary Behaviour, Knowledge Sharing and Quality Management System Implementation in Pharmaceutical Industry: A Preliminary Study. *International Journal of Knowledge Management Studies*, 11(2), pp.129–145.

PDA, 2012. *QRM Maturity Model and Technical Reports on Operational QRM*. Bethesda, MD: Parenteral Drug Association.

Pharmaceutical Technology, 2024. ICH Q9 Revision: Implementation and Future Directions. *Pharmaceutical Technology*, 48(7), pp.3–12. Available at: https://www.pharmtech.com [Accessed 21 June 2025].

Poli, M., Petroni, D., Berton, A., Campani, E., Felicini, C., Pardini, S., Menichetti, L. and Salvadori, P.A., 2014. The Role of Quality Management System in the Monitoring and Continuous Improvement of GMP-Regulated Short-Lived Radiopharmaceutical Manufacture. *Accreditation and Quality Assurance*, 19(4), pp.343–354. https://doi.org/10.1007/s00769-014-1070-7

Ramnarine, E. and O'Donnell, K., 2018. Demonstrating Pharmaceutical Quality System Effectiveness and Driving Continual Improvement: Evidence-Based Risk Reduction. *PDA Journal of Pharmaceutical Science and Technology*, 72(4), pp.338–345.

Rompicherla, N.C., Paul, E., Ganesh, A. and Narayanan, A., 2020. The Significance of Quality Metrics in a Pharmaceutical Quality Management System – A Case Based Study. *Indian Journal of Pharmaceutical Education and Research*, 54(3), pp.798–808.

Saunders, M., Lewis, P. and Thornhill, A. (2012) *Research methods for business students*. 6th ed. London: Pearson Education. Cited in: Tengli, M.B., 2020. *Research Onion: A Systematic Approach to Designing Research Methodology*. AESA Blog, [online] (132), pp.1–20. Available at: https://www.aesanetwork.org/blog-132-research-onion-a-systematic-approach-to-designing-research-methodology/ [Accessed 4 Aug. 2025].

Teasdale, A. and Elder, D., 2018. *ICH Quality Guidelines: An Implementation Guide*. 1st ed. Hoboken, NJ: John Wiley & Sons.

Waldron, K., 2017. *Managing Risk to the Patient: Recoding Quality Risk Management for the Pharmaceutical and Biopharmaceutical Industries*. Doctoral thesis. Dublin Institute of Technology. Available at: https://arrow.tudublin.ie/sciendoc/190 [Accessed 20 June 2025].

Waldron, K., Ramnarine, E. and Hartman, J., 2017. 2015/2016 Quality Risk Management Benchmarking Survey. *PDA Journal of Pharmaceutical Science and Technology*, 71(5), pp.330–345. https://doi.org/10.5731/pdajpst.2017.007526

Ethics Application & Declaration Form

DISSERTATION TITLE: Evaluating the Role of ICH Q9-Based Quality Risk Management in Reducing CAPA Recurrence Rates: A Study of GMP-Regulated Pharmaceutical Companies in Ireland

RESEARCHER'S NAME: CLADISSOPHIYA GEORGE

PROGRAMME OF STUDY: MSC in Pharmaceutical business and technology

SUPERVISOR'S NAME: Victor David Vendrell

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: G. Cladissophiya

DATE: 27/06/2025

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

For Supervisor:

Ethics Committee Approval Required: Yes [X] No [ ]

SUPERVISOR SIGNATURE:

DATE: 06/07/2025

For Ethics Committee (if required):

Ethics Committee Approval Given: Yes ☐ No ☐

ETHICS COMMITTEE MEMBER SIGNATURE:

DATE:

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

SECTION 1: DESCRIPTION OF RESEARCH STUDY

1.1 Purpose and objectives of research

Purpose: The purpose of this research is to evaluate the maturity of Quality Risk Management (QRM) practices, specifically those aligned with the ICH Q9 guideline, and their effectiveness in reducing the recurrence of Corrective and Preventive Actions (CAPAs) within GMP-regulated pharmaceutical manufacturing companies in Ireland. Although ICH Q9 provides a structured, science-based framework for proactive risk management, existing literature indicates gaps in its real-world application, particularly in the integration of QRM into CAPA systems. Many companies continue to experience repeated deviations due to inadequate root cause analysis, inconsistent use of risk tools, and insufficient training. This study aims to quantify the relationship between QRM maturity and CAPA recurrence while identifying barriers to effective QRM implementation in the Irish context. The findings will support improvements in quality system performance and regulatory compliance across the pharmaceutical industry.

Objectives:

1. Assess the current practices of integrating ICH Q9-based QRM principles into CAPA systems in GMP-regulated pharmaceutical companies in Ireland.
2. Evaluate whether a mature QRM implementation correlates with reduced CAPA recurrence.
3. Identify the challenges and gaps in applying QRM tools during CAPA lifecycles.
4. Propose a practical framework for enhancing CAPA outcomes through improved QRM integration.
5. Provide recommendations to support continuous improvement in pharmaceutical quality systems.

1.2 Research methodology:

This study adopts a positivist philosophical approach, aligning with a quantitative research strategy using an online survey via Google Forms to collect structured data. Participants will be recruited through purposive and snowball sampling across professional networks (linkedin), industry forums, and direct email invitations. Target participants include QA/QC professionals, such as Quality Managers, Compliance Officers, QC Analysts, and Operational Excellence Leads working in GMP-regulated pharmaceutical manufacturing companies in Ireland with a minimum of two years of experience.

The survey will focus on assessing the maturity level of QRM implementation (as per ICH Q9), the frequency of CAPA recurrence, the types of risk management tools employed, and perceived barriers to effective QRM integration. Participants not based in Ireland, or who do not work in GMP-regulated settings, will be excluded.

A minimum sample size of 60 participants is targeted, considered sufficient for this exploratory study to yield meaningful insights into QRM practices and CAPA system performance. The survey questionnaire consists of approximately 13 closed-ended and Likert-scale questions, and is designed to evaluate QRM tool usage, CAPA recurrence frequency, training levels, and operational challenges. (Refer to Appendix 10.2 for the full questionnaire.)

The data will be analysed using descriptive statistics (frequency, percentage distribution) and cross-tabulation to explore relationships, particularly between QRM maturity and CAPA recurrence. Visual outputs including charts and tables will be used to illustrate key findings, and open text responses will be thematically categorized to identify common challenges or improvement suggestions.

SECTION 2: POSSIBLE ETHICAL ISSUES

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

SUBJECT MATTER

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

RESEARCH PROCEDURES

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

PARTICIPANTS

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

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

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.**

This study targets professionals working in GMP-regulated pharmaceutical manufacturing companies in Ireland, specifically those involved in quality-related functions. The participant profile includes:

- **Quality Assurance (QA) Managers** – who oversee CAPA systems and ensure compliance with regulatory frameworks like ICH Q9.
- **Quality Control (QC) Analysts** – who perform product and process quality checks and often contribute to deviation reporting and investigations.
- **Compliance Officers** – responsible for ensuring that internal quality systems align with EMA, FDA, and GMP expectations.
- **Operational Excellence Leads or Continuous Improvement Specialists** – who work on improving CAPA effectiveness through systems like QRM.

These professionals have direct experience with root cause investigations, QRM tool usage (e.g., FMEA, HACCP), and CAPA management, making them well-suited to evaluate how QRM maturity affects CAPA recurrence. Their practical insights will inform the study's exploration of real-world challenges and opportunities for enhancing pharmaceutical quality systems.

Participants will have at least two years of experience in a relevant role, ensuring that their responses are grounded in substantial professional knowledge. No names, company affiliations, or identifying data will be collected.

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

I plan to contact participants through professional platforms such as LinkedIn, email, and WhatsApp groups related to the pharmaceutical industry. I will reach out to QA/QC professionals, compliance officers, and other relevant personnel through my existing professional network and request them to participate in the survey.

I will also use snowball sampling by asking initial participants to share the survey with colleagues who meet the criteria. Each participant will receive a brief explanation of the study, along with a link to the online questionnaire (Google Form).

All participation will be voluntary, anonymous, and GDPR-compliant. No personal or company-identifiable data will be collected.

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, including survey responses and analysis files, will be stored securely on a password-protected electronic device (laptop). A backup copy will also be maintained on a secure cloud storage platform (OneDrive) to prevent data loss.

The data will be retained for up to two years following the awarding of the qualification. This retention period aligns with data protection regulations and allows for any required verification or secondary analysis. After this period, all research data will be securely and permanently deleted.

To ensure proper data protection:

1. Anonymization: No personally identifiable information (such as names or contact details) will be collected. If any such information is provided, it will be removed and replaced with unique identifiers to maintain participant anonymity.
2. Password Protection: All research-related files will be protected by strong, unique passwords. Only the researcher will have access to these files.
3. Access to Data: The anonymized raw data will be submitted securely to Griffith College's Moodle platform as part of the final dissertation submission process.
4. Data Encryption: Both physical and cloud-based storage will be encrypted to protect against unauthorized access or breaches.

This data management approach ensures full compliance with GDPR and national data protection legislation, while also safeguarding the confidentiality and integrity of participant information throughout the research process.

SECTION 7: NON-DISCLOSURE AGREEMENT & STUDENT CONSENT

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

No

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

Yes

SECTION 8: RECORDING AND RETENTION OF DISSERTATION VIVA

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

SECTION 9: DOCUMENT CHECKLIST

NOTE: Applicants must attach the following documents in electronic format to the appendix.

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

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

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

For Student:
STUDENT SIGNATURE: G. Cladiss Priya

DATE: 27/06/2025

SECTION 10: APPENDIX

This study aims to evaluate the impact of Quality Risk Management (QRM) maturity, particularly under ICH Q9 guidelines, on the recurrence of Corrective and Preventive Actions (CAPAs) in GMP-regulated pharmaceutical companies in Ireland. The findings will support the development of better CAPA systems and improve overall pharmaceutical quality compliance and efficiency.

As a participant, your role involves completing a short anonymous survey (approx. 8–10 minutes) based on your professional experience with QRM and CAPA systems. Your insights are valuable in identifying practical challenges, tool usage, and improvement opportunities.

Section 1: Consent and Demographics

1. Do you consent to participate in this research study?
   ☐ Yes, I consent to participate
   ☐ No, I do not consent to participate
2. What is your current role?
   ☐ QA Manager
   ☐ QC Analyst
   ☐ Compliance Officer
   ☐ Operational Excellence Lead
   ☐ Other (please specify): _____
3. Years of experience in pharmaceutical industry (GMP environment):
   ☐ Less than 1 year
   ☐ 1–3 years
   ☐ 4–6 years
   ☐ More than 6 years
4. Does your site follow EU GMP and ICH Q9?
   ☐ Yes
   ☐ No
   ☐ Not sure

Section 2: QRM Implementation

5. Does your company have a formal QRM policy aligned with ICH Q9?
   ☐ Yes
   ☐ No
   ☐ Not sure
6. How would you rate the maturity of QRM practices at your site?
   ☐ Very Low
   ☐ Low
   ☐ Moderate
   ☐ High
   ☐ Very High
7. Which QRM tools are commonly used in your organization? *(Select all that apply)*
   ☐ FMEA
   ☐ HACCP
   ☐ Risk Ranking & Filtering
   ☐ Fault Tree Analysis
   ☐ Other: _____
8. Is QRM routinely applied during CAPA investigations?
   ☐ Always
   ☐ Often
   ☐ Sometimes
   ☐ Rarely
   ☐ Never

Section 3: CAPA Practices and Outcomes

9. How often do CAPA issues recur at your site?
   ☐ Very Frequently
   ☐ Frequently
   ☐ Occasionally
   ☐ Rarely
   ☐ Never
10. What is the most common reason for CAPA recurrence in your experience?
   ☐ Inadequate root cause analysis
   ☐ Poor follow-up
   ☐ Lack of risk prioritization
   ☐ Incomplete actions
   ☐ Other: _____
11. Do you believe QRM tools improve CAPA effectiveness?
   ☐ Strongly Disagree
   ☐ Disagree
   ☐ Neutral
   ☐ Agree
   ☐ Strongly Agree
12. What challenges do you face when applying QRM in CAPA investigations? *(Select all that apply)*
   ☐ Lack of training
   ☐ Limited resources
   ☐ No SOP support
   ☐ Management resistance
   ☐ Not applicable
   ☐ Other: _____
13. Please share any suggestions or barriers your team faces in using QRM to manage CAPAs:(open ended)
   ……..

10.2 Sample size calculation

Cochranes Formula

$$N = \frac{z^2 \times P(1-P)}{e^2}$$

N = Sample Size

Z = Confidence Level

P = Population Proportion

E = Margin of Error

As of 2025, Ireland's pharmaceutical sector employs approximately 30,000–35,000 professionals across areas such as Quality Assurance (QA), Quality Control (QC), Manufacturing, Compliance, and Regulatory Affairs**.** Given the specialized nature of Quality Risk Management (QRM) and Corrective and Preventive Action (CAPA) systems, it is estimated that only 10%–15% of this workforce is directly involved in activities related to risk-based decision-making, root cause analysis, and regulatory compliance**.** This translates to a potential population of 3,000–5,000 professionals who are qualified to provide meaningful insights into the maturity and effectiveness of QRM practices under ICH Q9 guidelines. This estimate has been used to guide sample size justification and participant selection criteria for the current research study.

Z = Confidence Level= 95%

P = Population Proportion= 10%

E = Margin of Error= 7%

$$N = \frac{(1.96)^2 \times 0.10(1-0.10)}{(0.07)^2}$$

$=70.56$

N= 70 participants

GRIFFITH COLLEGE

Participant Information Letter

"Evaluating the Role of ICH Q9-Based Quality Risk Management in Reducing CAPA Recurrence Rates: A Study of GMP-Regulated Pharmaceutical Companies in Ireland"

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

WHO I AM AND WHAT THIS STUDY IS ABOUT

My name is Cladissophiya George, and I am currently pursuing an MSc in Pharmaceutical Business and Technology at Griffith College in collaboration with Innopharma Education. This study forms a key component of my final dissertation project for the successful completion of this Master's programme.

We are conducting this research to evaluate the role of Quality Risk Management (QRM), specifically as outlined in the ICH Q9 guideline, in reducing the recurrence of Corrective and Preventive Actions (CAPAs) in GMP-regulated pharmaceutical manufacturing companies in Ireland. The aim of the study is to assess the maturity of QRM practices and explore how these practices are integrated into CAPA systems.

The study uses an anonymous online survey to collect insights from quality professionals working in the pharmaceutical sector. Your participation will contribute to a better understanding of current QRM implementation and support continuous improvement efforts in pharmaceutical quality systems.

This research is entirely academic in nature and is not affiliated with or influenced by any particular company or regulatory agency. The study has been reviewed in line with the ethical requirements of Griffith College.

WHAT WOULD TAKING PART INVOLVE?

If you agree to take part in this research, you will be asked to complete an anonymous online survey. The survey will take approximately **8 to 10 minutes** of your time and consists of multiple-choice and Likert-scale questions, along with one optional open-ended question. It is designed to gather your professional insights into how Quality Risk

Management (QRM) is implemented at your organization and how it may influence the recurrence of Corrective and Preventive Actions (CAPAs).

Your participation is **entirely voluntary**, and no identifiable personal or company-related information will be collected. You will not be asked to disclose confidential or sensitive data. There are no known risks or direct benefits to taking part in the study, but your input could help improve understanding of QRM practices in the pharmaceutical sector and contribute to academic knowledge.

You can choose to stop the survey at any point without providing a reason, and you are free to decline participation altogether. The study does not involve any interviews or audio/video recordings.

By completing the survey, you are giving your consent to take part in the research. All responses will be handled confidentially and stored securely in compliance with GDPR and Griffith College's ethical research standards.

WHY HAVE YOU BEEN INVITED TO TAKE PART?

You have been invited to take part in this research study because you are a professional working in a GMP-regulated pharmaceutical manufacturing company in Ireland, and your role is likely to involve quality-related activities, such as Quality Assurance (QA), Quality Control (QC), Compliance, or Operational Excellence.

The study specifically seeks the perspectives of individuals with at least two years of experience in such roles, as your insights into Quality Risk Management (QRM) practices and Corrective and Preventive Action (CAPA) systems are highly valuable to the research objectives.

You may have been identified through professional networks such as LinkedIn, industry forums, email invitations, or referrals from colleagues (snowball sampling). Your experience and knowledge will help us understand how QRM is applied in real-world settings and how it may influence the recurrence of CAPAs.

Your participation will support academic research aimed at improving quality practices across the pharmaceutical industry.

DO YOU HAVE TO TAKE PART?

Please note:

- Participation in this study is entirely **voluntary**.
- Choosing **not to take part** will have **no adverse consequences** of any kind.
- You may choose to **skip any question** or **withdraw from the survey at any time** without giving a reason.
- If you decide to withdraw after submitting the survey and would like your data removed, please contact me as soon as possible—ideally **within one week of completion**.

For withdrawal or any questions about your participation, please contact:
Cladissophiya George
Email: cladissophiya.george@student.griffith.ie
Supervisor: **Victor David Vendrell**
Email: victor.vendrell@griffith.ie

WHAT ARE THE POSSIBLE RISKS AND BENEFITS OF TAKING PART?

Risks:
There are no significant risks. The survey is anonymous and does not collect personal or company-specific data. A minor risk of discomfort may arise when reflecting on professional practices, but all questions are optional, and you may withdraw at any time. Data will be securely stored and handled according to GDPR and Griffith College ethical standards.

Benefits:
While there is no direct personal gain, your input will support academic research aimed at improving Quality Risk Management (QRM) and CAPA systems in the Irish pharmaceutical industry. The findings may help guide future improvements in quality practices and compliance.

WILL TAKING PART BE CONFIDENTIAL?

Yes, your participation is fully confidential and anonymous. No personal or company details will be collected. Data will be securely stored and used only for academic purposes, following GDPR and Griffith College guidelines.

Confidentiality will only be breached if there is a serious risk of harm, abuse, or criminal activity. As this is an anonymous online survey, no signed consent forms or recordings will be collected.

HOW WILL INFORMATION YOU PROVIDE BE STORED AND PROTECTED?

All survey data will be stored securely on a password-protected laptop and backed up on encrypted cloud storage (OneDrive), accessible only to the researcher. As this is an anonymous online survey, no personal identifiers or signed consent forms will be collected.

The anonymised data will be used solely for academic purposes and submitted as part of the final dissertation. It will be retained for two years after the degree has been awarded, in line with Griffith College's data retention policy. After this period, all data will be securely deleted.

Under Freedom of Information legislation, you have the right to access the information you provided at any time.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

The results of this study will be used solely to complete my Master's dissertation as part of the MSc in Pharmaceutical Business and Technology at Griffith College. The final dissertation will be submitted for academic assessment and may be made accessible in the Griffith College library or internal online repositories.

There are no current plans to publish the results in academic journals, present at conferences, or use them for teaching purposes. However, if such opportunities arise in the future, all data will remain anonymous, and no identifying details will be included.

WHO SHOULD YOU CONTACT FOR FURTHER INFORMATION?

For any questions or further information regarding this study, please contact any of the following researchers:

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Victor David Vendrell
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[THANK YOU]