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EVALUATING THE EFFECTIVENESS OF SUPPLIER QUALITY MANAGEMENT PRACTICES IN ENHANCING SUPPLY CHAIN PERFORMANCE OF PHARMACEUTICAL QUALITY MANAGEMENT SYSTEMS

A thesis submitted in partial fulfilment of the requirements for
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Submitted By

Anusha Thula

Dissertation Supervisor: Chiamaka Chiedozie

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DECLARATION

I, Anusha Thula, hereby certify that the dissertation titled " Evaluating the Effectiveness of Supplier Quality Management Practices in Enhancing Supply Chain Performance within Pharmaceutical Quality Management systems," submitted for the degree of MSc in Pharmaceutical Business and Technology, is the result of my own work. I have rigorously followed academic integrity standards, ensuring that all references to the work of others are properly acknowledged.

I affirm that this dissertation reflects my original insights, interpretations and conclusions derived from my personal academic efforts. Contributions from external sources have been appropriately cited, with full recognition given to the intellectual property of others.

I declare that the work presented in this dissertation is entirely my own. All sources and references utilized in this study have been accurately acknowledged, and any assistance received has been clearly stated. I confirm that this research has not been previously submitted for any degree or professional qualification. Additionally, I have adhered to the ethical guidelines set by my institution throughout the course of this research.

Signed: Anusha Thula

Date: 06/05/2025

Supervisor Signature:

Date: 06/05/2025

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LIST OF ABBREVIATIONS

SQM – Supplier Quality Management

SCR – Supply Chain Resilience

SCP – Supplier chain performance

SQMP - Supplier Quality Management Practices

PSQMP – Pharmaceutical Supplier Quality Management Practices

API - Supplier Quality Management Practices

GMP - Good Manufacturing Practice

GDP – Good Distribution Practices

EMA - European Medicines Agency

US FDA - U.S. Food and Drug Administration.

CDSCO - Central Drugs Standard Control Organization

China's NMPA - China's National Medical Products Administration

RBV – Resource Based View

VRIN – Valuable Rare Inimitable Non-substitutable

VRIO – Valuable Rare Inimitable Organization

KPI – Key Performance Indicators

ABSTRACT

This study investigates the implementation and effectiveness of Supplier Quality Management (SQM) practices in organizations, focusing on these practices influence on supply chain reliability, regulatory compliance, cost efficiency and technological integration. The core objective was to identify which factors significantly affect SQM effectiveness and how organizations respond to challenges and opportunities in supplier management.

In this research, a positivism philosophy with deductive approach is adopted to examine the impact of SQM on supply chain performance. A quantitative, cross-sectional research methodology was used, with data collected through structured questionnaires and non-probability purposive sampling was applied to target industry professionals. Data analysed by SPSS including descriptive statistics to determine variable relationships and the capabilities of selected variables. In the process all ethical procedures are duly abided and followed.

The findings of this study indicated a moderate level of SQM adoption across the sample, with variability in how frequently audits are conducted and how advanced technologies are integrated into quality systems. Notably, a significant positive correlation between SQM practices and regulatory compliance strengthens the industry standards and technology use is positively linked to cost efficiency, indicating the reduction in operational costs. Conversely, a significant negative correlation between the effectiveness of quality agreements and supply chain reliability, suggests a mismatch in expectations or execution. Regression results demonstrated that the model explained approximately 14.9% of the variance in SQM practices indicating a moderate relationship between the predictors and dependent variable. The ANOVA test supported the model's statistical significance ($F = 3.037$, $p = .009$), confirming that the selected independent variables collectively have a meaningful impact on SQM outcomes.

In conclusion, SQM practices significantly improves supply chain performance by the use of advanced technologies, enhancing regulatory compliance and operational efficiency but challenges remain in aligning with supplier non-compliance and reliability. Furthermore, future research should consider these insights for continuous improvement, strategic investment in digital tools and stronger supplier collaboration frameworks to support long-term quality objectives.

Keywords: Supplier Quality Management (SQM), Supply chain reliability, Regulatory compliance, Audits, continuous improvements, Quality agreements, collaboration frameworks, descriptive statistics.

Chapter 1: Introduction

1.1 Research Background

Product quality, safety and efficacy are absolute in the pharmaceutical industry, where it operates in a highly regulated environment. The varying quality standards for raw materials, active pharmaceutical ingredients (API) and packaging components demanded towards pharmaceutical supply chains make Supplier Quality Management (SQM) practices the key contributor in ensuring its pharmaceutical supply chains are unchanged in purity and potency. For a pharmaceutical quality management system (QMS) to be effective, Supplier Quality Management practices must be in place to avoid substandard products, regulatory non-compliance, recalls and reputational damage caused by poor supplier management (Teuchler, 2025).

With the increasing regulatory scrutiny, Supplier Quality Management practices are critical in pharmaceutical supply chains. There are strict guidelines drawn by regulatory agencies such as the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) & World Health Organization (WHO) regarding Good Manufacturing Practices (GMP) & supplier qualification processes. Major challenges in the pharmaceutical industry have been supply chain disruptions and quality failures. Vulnerabilities in the global pharmaceutical supply chain deepened during the COVID-19 pandemic, and it exacerbated the shortages of critical drugs and medical supplies. In addition to these shortages, supplier quality failures also played a role because manufacturing sites did not comply with regulatory standards, stopping the production. The example of valsartan, a widely used antihypertensive drug, is one of the risks of poor supplier quality management. In 2018, multiple batches of valsartan were recalled worldwide due to the presence of nitrosamine impurities, a known carcinogen. Investigations traced the contamination to raw materials supplied by a third-party manufacturer in China, demonstrating the far-reaching consequences of inadequate SQM (Patil, 2024).

Supplier selection and evaluation are important building blocks within supplier quality management practices in the pharmaceutical industry. According to a Deloitte (2021) study, 68% of pharmaceutical companies use multi-tier supplier assessment frameworks to evaluate quality, reliability, and regulatory compliance. Often, these criteria are manufacturing capabilities, financial stability, historical performance and GMP compliance. Despite this, many companies

find it difficult to maintain real-time visibility of supplier performance. For pharmaceutical quality management systems, risk management in supplier quality has received more attention. AI-driven quality management systems can analyse the historical performance of the supplier, spot anomalies, and give early warnings of possible deviations in quality. While these advancements were made, the challenges of data integration, cybersecurity risks, and technology adoption resistance persist, which hinders the purposes of digital SQM solutions.

Supplier quality management practices are necessary for sustaining high-quality pharmaceutical production. Total Quality Management (TQM) and Lean Six Sigma have been implemented to drive the supply chain supplier performance enhancement. Supplier development programs, including supplier training and initiatives, have also worked well in building suppliers' capacities. Regulatory compliance remains as a cornerstone of SQM in pharmaceutical supply chains. The International Council for Harmonisation (ICH) Q10 guideline on Pharmaceutical Quality Systems emphasizes the need for robust supplier qualification and monitoring. However, compliance challenges persist due to varying regulatory requirements across different markets. Non-compliance with regulatory requirements can result in severe financial and operational consequences. The FDA's Import Alert database recorded a 28% increase in import bans on pharmaceutical products between 2018 and 2022, primarily due to supplier quality violations (Najmi *et al.,* 2021).

Supplier Quality Management (SQM) is vital to the effectiveness of Pharmaceutical Quality Management Systems (PQMS) as it has a direct influence on product safety, regulatory compliance, and supply chain performance. SQM practices include supplier selection, qualification, performance monitoring, audit processes, and continuous improvement activities. These processes ensure that raw materials and components conform to high industry standards, minimizing risks of defective products, regulatory fines, and supply chain breakdowns. As per the views of Schellekens and Smith (2023), efficient SQM practices involve risk-based supplier assessment, conformity audits, Corrective and Preventive Actions (CAPA), and supplier development programs. These factors ensure quality consistency, improve collaboration with suppliers, and maximize supply chain efficiency. Assessing the efficacy of SQM in Pharmaceutical Quality Management Systems involves measuring its effect on operational efficiency, cost savings, and regulatory compliance. Organizations adopting sophisticated SQM systems tend to have

reduced recalls, better supplier reliability, and optimized production processes. This study seeks to evaluate how SQM practices support supply chain performance improvement, solve problems, and recommend best practices for ongoing quality improvement in the pharmaceutical sector.

1.2 Problem Statement

The pharmaceutical industry relies on complex and highly regulated supply chains to ensure product quality and safety. Despite that, supplier-related quality failures persist as both product recall, regulatory noncompliance and financial losses. Supplier-related deficiencies were responsible for 20 percent of drug recalls in the last decade, the U.S. Food and Drug Administration (FDA) reports. Poor supply chain management affects not only supply chain operations but also patient safety because defective or contaminated drugs get to market (Agyabeng-Mensah *et al.,* 2021). Good Manufacturing Practices (GMP) and rigorous supplier qualification programmes are well implemented by most pharmaceutical companies, but the plethora of monitoring, risk assessment, and regulatory compliance challenges have been a plague to many pharmaceutical firms. As the pharmaceutical supply chain has become more dependent upon global suppliers, there is a demand for studies concerning the ability of supplier quality management practices to enhance performance. This research focuses on the identification of some gaps in supplier management practices and suggestions to align with better supplier oversight, risk mitigation and supply chain efficiency.

1.3 Research Rationale

Supplier quality management, despite being one of the critical components of pharmaceutical quality management systems (QMS), has a significant influence on the performance of the pharmaceutical supply chain. As the global supply chain becomes more complex and gets regulated, it becomes important to understand how SQM practices can mitigate risks associated with supply chains. A report by Agyabeng-Mensah *et al.* (2021) on pharmaceutical supplier risk assessment indicates that 57% of pharmaceutical companies lack a comprehensive mechanism to assess their suppliers, which puts them at risk of compliance failure. The COVID-19 pandemic also reveals some weaknesses in pharmaceutical supply chains, therefore providing evidence of the importance of resilient and highly quality network suppliers. Previous research has been conducted on general supply chain management of pharmaceuticals, but no research has been

conducted on SQM effectiveness (Sim *et al.,* 2024) and this gap will be bridged by this research through evaluation of how SQM practices improve supply chain resiliency, regulatory compliance improves product quality and ultimately improve patient outcomes and operational sustainability in the pharmaceutical sector.

1.4 Research Aim and Objectives

Aim:

This study aims to evaluate the effectiveness of supplier quality management practices in enhancing supply chain performance within pharmaceutical quality management systems.

Objectives:

- To explore the effect of supplier quality management practices on the overall performance of pharmaceutical supply chains, focusing on key quality indicators such as cost efficiency, product integrity, lead times and supply chain reliability.
- To assess the main challenges and barriers in implementing effective supplier quality management practices by pharmaceutical companies.
- To investigate the role of technology and digitalisation in enhancing supplier quality management practices like real-time monitoring tools, AI-driven analytics and use of blockchain.
- To determine the influence of quality agreements between pharmaceutical companies and suppliers on regulatory compliance and product safety.
- To identify how pharmaceutical companies manage quality risks by integrating supplier quality management practises when dealing with multiple suppliers across various global standards.

1.5 Research Questions

1. What are the key supplier quality management practices implemented in the pharmaceutical industry?
2. How does supplier quality management impact supply chain performance in pharmaceutical quality management systems?
3. What challenges do pharmaceutical firms face in implementing and maintaining effective SQM practices?

4. How do regulatory compliance requirements influence supplier quality management and supply chain performance?

1.6 Research Significance

This research will provide useful insights into whether supplier quality management practices in the pharmaceutical industry can be effective, not only to the industries and academics, but which also be an integral part of industry best practices. Through an examination of how SQM affects supply chain performance, this study will allow pharmaceutical companies to strengthen the overhead on suppliers, cut quality-related stumbling blocks, and maintain regulatory compliance (Najmi *et al.,* 2021). Supplier quality management remains a top area that is emphasized by regulatory agencies such as the FDA, European Medicines Agency (EMA), World Health Organization (WHO), and others, as it's a way to ensure that drugs are safe and deliver results. It will provide practical recommendations that would enable pharmaceutical firms to forge ahead in SQM strategies that are in accord with the evolving state of play in the regulatory realms, thereby thinning down the odds of violation and consequent product recall (Agyabeng-Mensah *et al.,* 2021). Moreover, pharmaceutical companies are also embracing digital technologies like artificial intelligence (AI) and blockchain to enhance supplier quality monitoring. This study will examine how pharmaceutical firms can leverage emerging technologies to strengthen supplier quality management effectiveness in sense of building a more resilient, transparent supply chain.

Chapter 2: Literature Review

2.1 Introduction

This literature review focuses on evaluating the key information regarding the effectiveness of supplier quality management practices in increasing supply chain performance and addresses the key challenges that arrive in implementing supplier quality management practice within the pharmaceutical sector.

The effectiveness of supplier quality management (SQM) practices directly impacts the overall performance of the pharmaceutical supply chain, influencing product quality, regulatory adherence, operational efficiency, and risk mitigation Soares *et al*. (2017). Supplier quality management involves a systematic approach to selecting, evaluating and monitoring suppliers to ensure they meet predefined quality and regulatory requirements as stated by Parmata (2016). Pharmaceutical firms assess potential suppliers based on their compliance with industry standards, manufacturing capabilities and performance. By carefully selecting and qualifying suppliers, companies can reduce the likelihood of quality issues and ensure a more stable supply chain Dehshiri *et al.* (2022). Supplier qualification typically involves on-site audits, documentation reviews and quality risk assessments to verify that suppliers meet the necessary regulatory and quality requirements demonstrated by Lee *et al*. (2021). Continuous performance monitoring and regular supplier audits help identify potential risks, deviations from quality standards and areas for improvement to ensure ongoing compliance and quality assurance. The integration of advanced technologies such as artificial intelligence (AI), blockchain, and the Internet of Things (IoT) has further revolutionized supplier quality management in the pharmaceutical industry enhanced traceability across the supply chain (Malviya et al. (2025). Furthermore, strong supplier quality management practices contribute to supply chain resilience by reducing dependency on a limited number of suppliers and diversifying sourcing strategies.

Despite its benefits, implementing a robust supplier quality management system poses several challenges. The complexity of global supply chains makes it difficult to ensure consistent quality standards across multiple suppliers (khan *et al*., 2023) and regulatory variability across different countries complicates supplier compliance, as pharmaceutical firms must navigate diverse quality requirements and approval processes. However, the long-term benefits of supplier quality

management practices lead to improved product quality, regulatory compliance, and supply chain efficiency (Shahid *et al*., 2024). Understanding the relationship between supplier quality management and supply chain performance is essential for pharmaceutical companies seeking to improve operational effectiveness and maintain a competitive advantage in the market. As regulatory requirements continue to evolve and global supply chains become more interconnected, pharmaceutical firms must adopt proactive supplier quality management strategies.

This literature review will contribute to a deeper understanding of how supplier quality management practices influence supply chain performance for improving supplier management strategies within the pharmaceutical industry. By synthesizing findings from previous studies, the research will provide insights into best practices for supplier quality management, highlight common challenges faced by pharmaceutical firms and explore emerging trends in the field. Additionally, the study will identify areas where further research is needed to enhance supplier quality management strategies and optimize supply chain performance.

2.2 Role of Supplier Quality Management Practices in Pharmaceutical Industry

As per the knowledge of Patil (2024), the pharmaceutical industry applies Supplier Quality Management (SQM) as the method that establishes systematic measures to verify suppliers who provide raw materials and active pharmaceutical ingredients (APIs) and other material components to maintain the pharmaceutical industry. The fundamental role of SQM exists in preserving both product safety together with efficacy and regulatory compliance standards. However, Soares *et al*. (2017) has claimed that quality issues within supplier-managed pharmaceutical products, which creates substantial health risks that result in product recalls and regulatory actions together with severe reputational damage. Pharmaceutical organisations rely on thorough supplier quality management practices as a way to guarantee consistency and reduce supply chain-associated risks. The core elements of SQM begin with selecting suppliers followed by evaluations and maintaining ongoing assessment processes. As stated by Parmata (2016), pharmaceutical firms apply a formal supplier qualification system that requires complete assessments of manufacturing locations and quality management methods and regulatory compliance records of suppliers. Pharmaceutical firms monitor all suppliers through a combination of periodic audits together with performance reviews and quality inspection procedures. Sarangi and Ghosh (2024) have claimed that the

systematic approach serves to minimise possible quality issues, while guaranteeing an uninterrupted supply chain operation.

Supplier quality management depends on compliance with Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP). The pharmaceutical industry relies on GMP to create consistent products under quality standards and GDP serves to ensure correct distribution practices that protect product integrity. According to the views of Tayyab *et al*. (2022), considering these regulations ensures that contamination and mix-ups together with production errors remain prevented throughout the manufacturing and distribution operations. Quality risk management along with supplier audits stands as a fundamental element of supplier quality management practices. Lee *et al*. (2021) has also supported the above statement and claimed that pharmaceutical organisations carry out standard supplier inspection activities to detect quality problems that need correction prior to manufacturing delays. The firm uses Failure Mode and Effects Analysis (FMEA) and risk-based supplier categorisation to identify suppliers with high risks so they receive intensified oversight. Supply chain endurance and expensive product recalls prevention become possible through these operational practices. The pharmaceutical industry depends on SQM as its foundational quality management system which enables the selection of top-quality materials before production to meet regulatory requirements.

SQM is a crucial system in the pharmaceutical sector that guarantees raw materials, active pharmaceutical ingredients (APIs), and packaging materials adhere to very high quality and regulatory standards. The success of pharmaceutical products primarily relies on their suppliers' consistency and compliance, hence SQM is a very important component in the operations of the industry. Sawale (2022) claimed that a properly structured SQM framework has a number of prominent practices that include selecting and qualifying suppliers, monitoring their performance, and risk-based quality management. Supplier selection entails assessing prospective partners against manufacturing capabilities, compliance history, and conformity with international regulations like Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP). Supplier qualification, as emphasized by Dehshiri *et al.* (2022), entails thorough examination of manufacturing facilities, quality control procedures, and regulatory certifications to ensure that suppliers conform to industry standards.

In addition, pharmaceutical companies implemented continuous monitoring systems including regular audits, real-time monitoring of performance, and quality checks. According to Mishra *et al.* (2022), such practices ensure early identification of deviations in quality, avoiding expensive recalls and production hold-ups. Risk-based methods like Failure Mode and Effects Analysis (FMEA) also enable organizations to classify suppliers into risk categories, with heightened scrutiny for high-risk suppliers (Haputhanthrige, 2024). In addition, SQM makes supply chains resilient by providing guaranteed material quality and preventing risks from contamination, mis-mixing, and production defects. Next-generation digital technologies like blockchain-based traceability, predictive analytics for quality prediction, and automated inspection systems make supplier management more efficient. Ultimately, sound SQM practices do not only serve to ensure that pharmaceutical companies abide by regulatory regulations but also preserve product integrity and patient safety. By investing in stringent supplier management practices, pharmaceutical organizations can shore up their supply chains, eliminate operational risks, and retain faith in the worldwide healthcare market.

2.3 Impact of Supplier Quality Management on Supply Chain Performance

According to the knowledge of Khan *et al*. (2023), supplier Quality Management (SQM) functions as the key determinant for pharmaceutical supply chain efficiency alongside reliability and responsiveness. Resolution of operations depends on high-quality suppliers who send defect-free raw materials alongside active pharmaceutical ingredients (APIs) on time. Pharmaceutical companies face reduced disruptions and decreased production delays and stock shortages through strict quality standards adopted by their suppliers. As per the knowledge of Shahid *et al*. (2024), the management of supplier quality performance leads to better supply chain responsiveness due to the ability of allowing quick demand adjustments that support regulatory standards.

Supplier quality issues result in major operational problems that create manufacturing slowdowns and raise expenses associated with product withdrawal and harm the business brand reputation. Supplier quality creates substantial effects on the safety of products and regulatory adherence as well as patient health well-being. Agyabeng-Mensah *et al*. (2021) has claimed that the robust quality standards of the pharmaceutical compounds need to pass to ensure patient protection so any deterioration in supplier performance creates the risk of defective medication getting to

customers. The adherence to Good Manufacturing Practices (GMP) together with Good Distribution Practices (GDP) functions as an essential method to minimize such dangers. Gera *et al*. (2022) stated pharmaceutical firms that handle supplier quality effectively maintain proper compliance with regulatory bodies including FDA, EMA, and WHO to provide safe and effective products. It has been noticed that the 2008 heparin contamination scandal critically interrupted pharmaceutical supply chain performance, illustrating the dangers of inadequate Supplier Quality Management practices (Al-Hakim, 2021). Contaminated raw materials from an unregulated supplier resulted in product recalls, worldwide shortages, and enhanced regulatory attention (Christie, 2023). Supply chain inefficiencies arose as businesses struggled to locate alternate suppliers, resulting in delays and production shutdowns. Financial losses accumulated as a result of litigation, regulatory penalties, and tarnished reputations. In addition, increased quality control demands compelled businesses to adopt stricter supplier audits and monitoring, adding costs to operations. This crisis highlighted the importance of strong SQM to secure supply chain resiliency, product integrity, and patient safety. As stated by Zaid and Sleimi (2023), the use of contaminated materials from a Chinese supplier caused major adverse outcomes including deaths which forced regulatory authorities to implement stricter supplier control measures.

A well-implemented SQM system simultaneously optimizes inventory control as well as shortens delivery times while reducing costs. According to the understanding Patil (2024), high-quality scheduled deliveries from suppliers help pharmaceutical companies eliminate both inventory expenditures and quality assessment needs as well as product rework requirements. As evidence, the supplier quality program at Johnson & Johnson contains predictive analytics and risk-based supplier segmentation features as part of its comprehensive system. Soares *et al*. (2017) supported the above statement and claimed that the enhanced operational capabilities enable businesses to distribute their resources optimally while securing continuous supply of products for customers. Supplier quality management receives enhanced visibility through AI analytics because maintenance prediction occurs beforehand whereas blockchain documentation creates permanent supplier transaction details that increase both compliance and trust levels.

As demonstrated by Sarangi and Ghosh (2024), the Internet of Things (IoT) enables environmental condition monitoring through sensors which protect temperature-sensitive pharmaceuticals by keeping them within specified safety ranges. The implementation of blockchain technology by

Pfizer enables supply chain tracking through which pharmaceutical companies monitor their vaccine networks to reduce authentication issues and maintain quality standards during worldwide distribution (Akter, 2024). Supplier quality management establishes direct effects on supply chain performance by optimizing operations while maintaining regulatory standards and protecting patient medical welfare. According to the understanding of Tayyab *et al*. (2022), advanced technology implementation allows enhanced control of suppliers while simultaneously creating pharmaceutical supply chains that are both robust and visible and disadvantageously priced.

A strong Supplier Quality Management (SQM) system within the pharmaceutical sector goes beyond compliance to actively building supply chain resilience, efficiency, and strategic agility. By combining sophisticated supplier evaluation frameworks, companies can identify risks proactively, reduce disruptions, and optimize resource utilization. Supplier collaboration programs, including collaborative quality improvement initiatives and shared compliance audits, further promote operational consistency while minimizing the burden of individual monitoring. Jain *et al.* (2024) claimed that pharma firms are increasingly using real-time monitoring systems for suppliers based on machine learning algorithms that inspect patterns of defects, raise red flags on deviations, and forecast future failures before they become serious issues. Not only does this predictive ability reduce risk, but also enables companies to negotiate more favourable contracts with their suppliers using performance metrics that are data-driven. Additionally, diversification of suppliers through strategies like multi-sourcing key APIs and raw materials from various regions helps reduce geopolitical risk and improve supply chain responsiveness.

Yet another developing trend in SQM is the assessment of supplier sustainability, in which drug companies not only measure quality compliance but also ecological and ethical manufacturing practices. Ahmad *et al.* (2024) stated that integrating sustainability indicators in supplier appraisals assists companies in keeping up with corporate social responsibility goals while maintaining sustainable long-term supply chain viability. Moreover, strategic collaborations with regional suppliers in emerging economies can improve supply chain localization, minimizing reliance on far-away sources and transport-related risks. Andersson *et al.* (2024) also added that regulatory harmonization activities, including cross-border GMP convergence and mutual recognition agreements, further support supplier quality control by simplifying compliance procedures across worldwide markets. These activities minimize duplication of regulatory audits while ensuring

robust quality standards, enabling pharmaceutical companies to manage global supply chains more effectively. Overall, the inclusion of these advanced SQM practices guarantees that pharmaceutical companies not only comply with regulations but also attain a competitive edge through improved supplier relationships, operational resilience, and long-term cost savings in the face of an increasingly complex global supply chain environment.

2.4 Challenges in Implementing Supplier Quality Management in the Pharmaceutical Sector

As per the views of Lee *et al* (2021), the pharmaceutical industry encounters multiple hurdles during the implementation of Supplier Quality Management (SQM) due to the combination of high costs and non-standard procedures and supplier non-cooperation. The pharmaceutical industry advises substantial financial costs to companies when they execute supplier audits and conduct quality control while following strict regulatory needs. Khan *et al*. (2023) has also supported and claimed that small and mid-sized organisations find it difficult to handle the expenses required for implementing thorough quality assurance systems. The industry absence of standard supplier quality procedures causes businesses to experience unpredictable quality expectations. Supplier companies that serve multiple markets commonly reject unique compliance requirements which results in difficulties for maintaining consistent product quality standards. According to the knowledge of Agyabeng-Mensah *et al*. (2021), the complexity of controlling worldwide supplier networks becomes a major problem because regulatory standards between regions create additional challenges in quality management processes.

The pharmaceutical industry procures products from suppliers located throughout different nations while these entities answer to respective regulatory bodies which include the European Medicines Agency (EMA), and China’s National Medical Products Administration (NMPA). In addition to the EMA and NMPA, some of the most important regulators are the U.S. Food and Drug Administration (FDA), the World Health Organization (WHO), Japan's Pharmaceuticals and Medical Devices Agency (PMDA), and India's Central Drugs Standard Control Organization (CDSCO) (Yadav *et al.,* 2021). Each agency imposes separate quality and compliance standards, causing difficulties in the harmonization of supplier requirements from one region to another. Transcending such differing rules and regulations requires immense documentation, constant

audits, and strict supplier qualification procedures, enhancing the difficulty and expense of using effective Supplier Quality Management (SQM) for pharmaceutical supply chains.

Gera *et al*. (2022) has also found that the differences between compliance requirements and enforcement standards create obstacles for pharmaceutical companies to verify that their suppliers maintain uniform quality levels. Quality failures become more likely when cultural and language differences between suppliers operating internationally block effective communication and coordination success in their relationships. The ongoing challenge includes maintaining supplier compliance alongside tracking their performance levels constantly. The periodic auditing method that numerous pharmaceutical companies use enables inspections which demonstrate supplier quality levels at one point in time.

Further, this specific issue becomes worse due to the absence of real-time monitoring tools coupled with the absence of predictive analytics because quality issues typically arise after defective materials enter the production stage. As stated by Zaid and Sleimi (2023), some suppliers reduce costs through unapproved practices that damage pharmaceutical product quality. A number of well-known incidents demonstrate how inadequate supplier quality management practices lead to damaging results. According to the understanding of Shahid *et al*. (2024), widespread drug shortages combined with regulatory oversight and substantial financial losses mainly affected pharmaceutical companies throughout the world because of this failure. Lee *et al*. (2021) has also demonstrated that the industry requires pharmaceutical businesses to develop comprehensive supplier monitoring systems which combine digital technology with intensified compliance enforcement to maintain uninterrupted supplier quality.

The adoption of Supplier Quality Management (SQM) in the pharmaceutical industry is confronted with more challenges than regulatory intricacies, exorbitant costs, and supplier non-cooperation. Among the most important challenges is the vulnerability of the supply chain to geopolitical risks and trade restrictions. Political unrest, economic sanctions and trade tensions can jeopardize supplier relationships, slow down regulatory approvals, and cause sourcing challenges, which complicate companies' ability to uphold consistent quality standards. Sarkis *et al.* (2021) further added another challenge as the growing dependence on contract manufacturing organizations (CMOs), making quality control more difficult. Most pharmaceutical companies outsource

manufacturing to third parties, resulting in quality discrepancies stemming from differences in compliance with Good Manufacturing Practices (GMP) between countries. Without strict supervision, variations in quality can be unmonitored, making recalls and administrative fines more likely.

Additionally, cybersecurity threats and technological gaps impede efficient supplier quality management. Malviya *et al.* (2025) also supported the fact while claiming that although digital technologies such as blockchain and analytics powered by AI would improve transparency, numerous suppliers, particularly in the emerging markets, lack infrastructure to adopt such technologies. Data breaches and cybersecurity threats also risk confidential supplier audits and compliance reports. Finally, sustainability compliance is another challenge, with regulators and consumers calling for environmentally friendly pharmaceutical sourcing. Verifying that supplier meet sustainability and ethical sourcing requirements adds complexity to SQM implementation.

2.5 Regulatory Compliance and its Influence on Supplier Quality Management and Supply Chain Performance

Supplier Quality Management (SQM) in the pharmaceutical sector is heavily influenced by regulatory compliance guidelines that guarantee product safety, effectiveness, and supply chain integrity. The U.S. Food and Drug Administration (FDA) together with European Medicines Agency (EMA), World Health Organization (WHO) and ISO 9001 set strict quality standards to preserve product quality and patient safety and supply chain purity. The standards require supplier audits, risk evaluations, and corrective measures to ensure quality and minimize supply chain weaknesses. According to the views of Soares *et al*. (2017), the set of regulations directs pharmaceutical companies through their selection of suppliers as well as manufacturing techniques and quality control protocols and distribution requirements. Companies in the pharmaceutical industry need to follow Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP) standards to stay compliant while confirming that their suppliers maintain proper quality requirements.

The regulatory oversight framework verifies that pharmaceutical products fulfil all safety as well as efficacy standards and consistent quality performance. Tayyab *et al*. (2022) has also opened that the organisations need regulatory audits together with inspections to enforce requirements for

supplier quality standards. Official entities such as FDA and EMA inspect pharmaceutical businesses together with their supply networks to verify that organizations follow official regulatory standards. Audits consist of examining manufacturing operations and documenting assessment of quality control procedures in addition to process documentation. Non-compliance during the inspections generates warning letters, import bans and production stops that damage the pharmaceutical supply chain.

As stated by Khan *et al*. (2023), pharmaceutical companies need to conduct regular supplier audits to uphold their compliance while recognising potential risks which could grow into major problems. Audits are an indispensable part of Supplier Quality Management (SQM) in the pharmaceutical sector, validating that the suppliers comply with quality, regulatory, and contractual requirements. These audits offer objective assessments and added quality control, minimizing supply chain threats and improving the quality of pharmaceutical products as well as patient safety.

There are numerous types of audits conducted in SQM practices, all with a different purpose.

- Supplier audits are performed prior to doing business with a supplier to determine their capacity to comply with pharmaceutical quality and compliance requirements. Supplier audits review manufacturing capabilities, quality control systems, and regulatory compliance (Charoo *et al.,* 2023).
- Regulatory audits are conducted by regulatory agencies like the FDA, EMA, and WHO to verify compliance with Good Manufacturing Practices (GMP) and other applicable guidelines. Non-compliance can lead to penalties, recalls, or shutdown of production.
- Internal audits are conducted by pharmaceutical firms to evaluate their suppliers' continued adherence to internal quality requirements. Internal audits identify gaps, drive continuous improvement, and prepare for external regulatory audits. Whereas, Walvekar *et al.* (2024) claimed that For-Cause audits are conducted due to quality issues, supplier non-conformance, or product defects to assist in the investigation of specific issues and corrective action.
- Third-Party audits are independent testing conducted by outside auditors to confirm compliance by suppliers with industry standards and good practices.

The failure to meet regulatory demands produces multiple severe outcomes which include halted supply chains and product recalls as well as financial penalties. As demonstrated by Patil (2024), widespread drug shortage together with worldwide regulatory investigation and pharmaceutical industry financial losses became the consequences of this production failure incident. Pharmaceutical firms must develop ahead-of-time compliance strategies for supplier quality practices to meet regulatory requirements. According to the views of Parmata (2016), pharmaceutical companies required a combined system of real-time monitoring capabilities with blockchain traceability features to supplement automated quality control mechanisms for detecting and blocking compliance violations. Pharmaceutical companies can overcome the regulatory challenges through regular training of suppliers alongside the transparent documentation while using predictive analytics. Constant supplier training and transparent documentation supports more effective compliance process. Stronger regulatory compliance management boosts the reliability of suppliers, avoids supply interruptions and ultimately improves pharma supply chain performance and overall patient safety in addition to averting expensive supply disruptions and regulatory penalties.

2.6 Literature Gap

Research on Supply Chain Quality Management has gained significance but studies need additional focus on understanding direct effects of supplier quality management (SQM) practices on pharmaceutical supply chain performance (Khan *et al*., 2023). Current studies only emphasize Good Manufacturing Practices (GMP) and regulatory compliance but do not reflect on how emerging technologies such as AI and blockchain improve monitoring suppliers. There is also limited study on cost-benefit analysis and real-time monitoring through these technologies and barriers to technology adoption in small and medium-sized pharmaceutical companies in establishing SQM over large-scale organizations. Supplier quality practices vary significantly across regions due to cultural, regulatory and economic differences; limited research exists on how cultural factors influence supplier compliance and transparency particularly in global supply chains. Although supplier monitoring and compliance are well-studied, there is limited research on long-term supplier relationships and collaborative risk management strategic partnerships in enhancing compliance and quality performance. Present studies mainly explore supply chain key performance indicators yet they analyse insufficient empirical data focused on the pharmaceutical

industry specific regulatory aspects and operational requirements. The existing literature about supply chain quality management focuses mainly on theoretical examinations without sufficient industry-based case research (Agyabeng-Mensah *et al*., 2021). A standardised evaluation framework for assessing SQM effectiveness remains absent when dealing with different regulatory conditions because pharmaceutical supply chains operate across international borders. Study regarding how Artificial Intelligence as well as blockchain and predictive analytics improves pharmaceutical-supplier compliance and quality assurance during digital supply chain transformations is still needed to investigate (Lee *et al*., 2021).

2.7 Conceptual Framework

The conceptual framework integrates supplier quality management theories with supply chain performance measurement models, providing a structured approach in understanding how supplier quality management influences pharmaceutical supply chains. By incorporating regulatory, technological, and operational challenges, it offers a comprehensive analysis on how firms can improve supplier collaboration, compliance, and supply chain visibility to enhance overall performance. This framework ensures that pharmaceutical companies can develop strategic approaches to supplier management, ultimately enhancing compliance, reducing risks, and improving operational efficiency.

2.7.1 Theoretical basis of the conceptual framework

Resource-based View Theory

Firms develop competitive advantages because of their exclusive resources which incorporate supplier relationships together with quality management capabilities and regulatory compliance expertise according to the Resource-Based View (RBV) Theory. Supplier quality management (SQM) in pharmaceuticals uses the Resource-Based View Theory by transforming high-quality suppliers along with their stringent compliance frameworks and sophisticated quality assurance processes into strategic assets that boost supply chain performance (Huang *et al*., 2023). The research objective of this study complies with RBV principles based on its examination of supplier quality management practices as valuable rare inimitable non-substitutable (VRIN) resources that strengthen pharmaceutical supply chains. Studying crucial SQM practices enables organizations

to discover unique business abilities which boost drug safety levels and lower recall events and increase operational efficiency (Khanra *et al*., 2022).

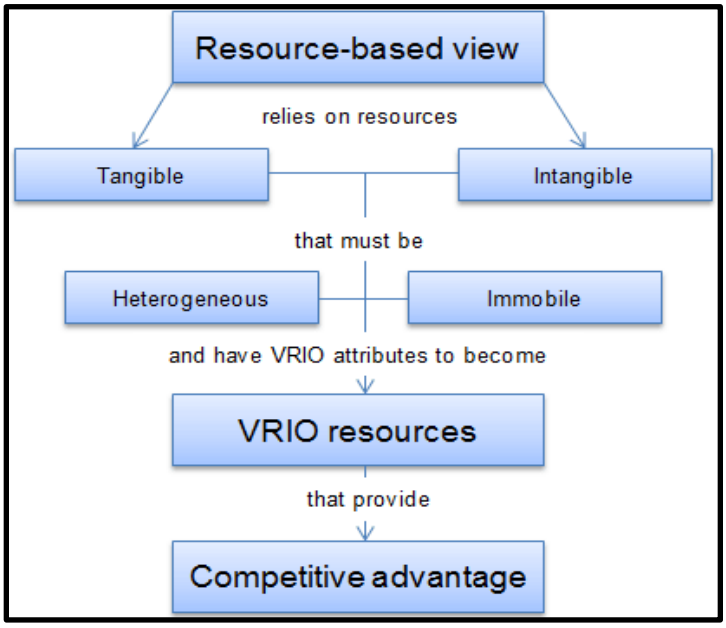


Figure 1 : Resource-based View Theory

(Source: Huang *et al*., 2023)

The above presented image displays the RBV model, where competitive advantage is seen as originating from a company's internal resources. It classifies resources as tangible or intangible and marks their features—heterogeneous and immobile—prior to analysing them using VRIO attributes to verify their input towards competitive advantage.

- Tangible Resources– These are physical and quantifiable assets like machines, plants, raw materials, and capital. In SQM, tangible resources are supplier plants, inspection equipment, and quality control systems.
- Intangible Resources– These are non-physical assets like patents, reputation, knowledge, and organizational culture. In supply chain performance, intangible resources are supplier relationships, skill in managing risk, and proprietary quality assurance techniques.
- Heterogeneous– Resources are not the same between firms, that is, no two companies share the same resources. In SQM, there are different quality control mechanisms among some suppliers, resulting in varying supply chain efficiencies (Agrawal *et al.,* 2024).

- Immobile– Resources are hard to move from one firm to another. For example, an organization's rich supplier relationships and quality management expert knowledge cannot be easily imitated by competitors.

The resources of VRIO attributes are as follows:

- Valuable (create efficiency or cost benefits)
- Rare (not widely available)
- Inimitable (difficult to copy)
- Organized (properly managed to extract value)

For SCP and SQM, VRIO resources are crucial. A company with strong supplier evaluation systems (VRIO-compliant) guarantees quality consistency, cutting down on defects and recalls, thus improving supply chain efficiency. Companies using VRIO attributes in managing suppliers attain long-term cost efficiency, reduce operational risks, and ensure regulatory compliance, hence a sustainable competitive advantage in the market. The evaluation of SQM's performance impact on supply chains uses RBV to showcase how quality-focused supplier relationships create more efficient production with cost savings and maintain continuous supply. The examination of SQM implementation barriers evaluates the issues companies encounter when they seek to acquire then sustain strategic resources. Firm capability in regulatory compliance serves as a vital component of RBV which deduces market accessibility and minimizes risk duration. According to the knowledge of Khanra *et al*. (2022), using RBV the study demonstrates how supplier quality functions as a vital strategic resource that advances pharmaceutical supply chains and produces better competitive outcomes.

Supply Chain Resilience Theory

A resilient supply chain should possess capabilities to both see and respond to disruptions before successfully recovering operations at high efficiency levels according to the Supply Chain Resilience Theory. Supplier quality management (SQM) emerges as a critical component in pharmaceutical operations because it enables enhancement of supply chain resilience together with product availability consistency along with regulatory compliance and patient safety assurance (Ivanov, 2021). The research objective matches supply chain resilience goals because it examines how SQM practices strengthen pharmaceutical supply chains through improved adaptability and

robustness. The evaluation of SQM practices reveals potential risk assessment strategies and continuing monitoring processes and contingency plans that decrease disruptions. Supplier Quality Management solutions produce tangible benefits to supply chain operational performance by strengthening relationships between resilient suppliers which enhance delivery times and stock management and regulatory compliance ability (Zhao *et al*., 2023).

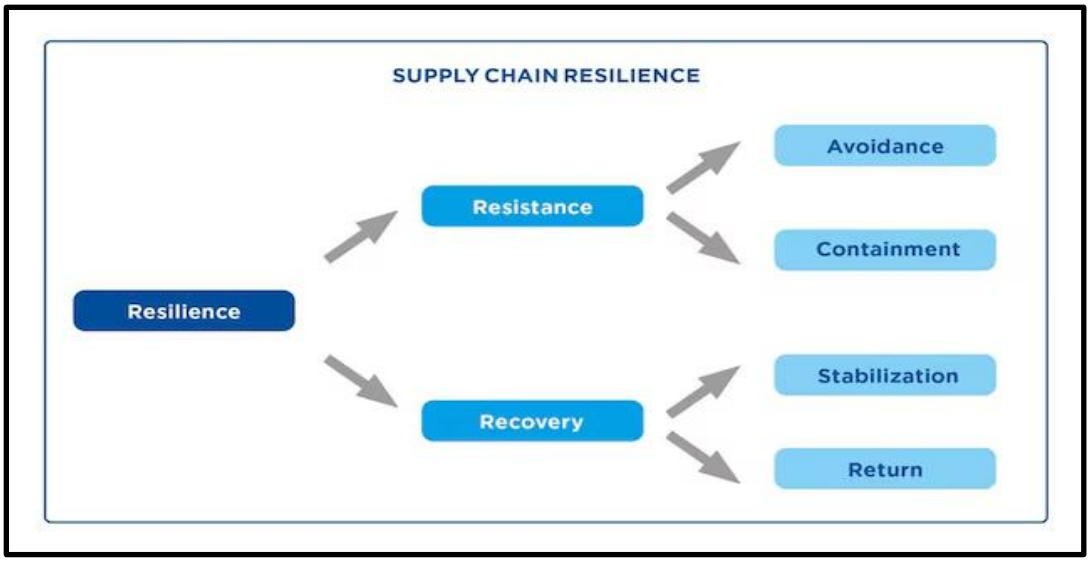


Figure 2 : Framework of Supply Chain Resilience Theory

(Source: Mecalux, 2021)

The analysis of SQM implementation challenges identifies hurdles which include supplier disregarding quality standards as well as geopolitical dangers and disruptions that reduce supply chain stability. Supply chain continuity receives benefits from Good Manufacturing Practices (GMP) and quality audits as studied under resilience theory (Adewusi *et al*., 2024). This research applies Supply Chain Resilience Theory to prove how effective supplier quality management ensures pharmaceutical supply chains survive risks as they continue delivering efficiency and regulatory compliance.

2.7.2 key concepts of conceptual framework

The framework consists of three primary components:

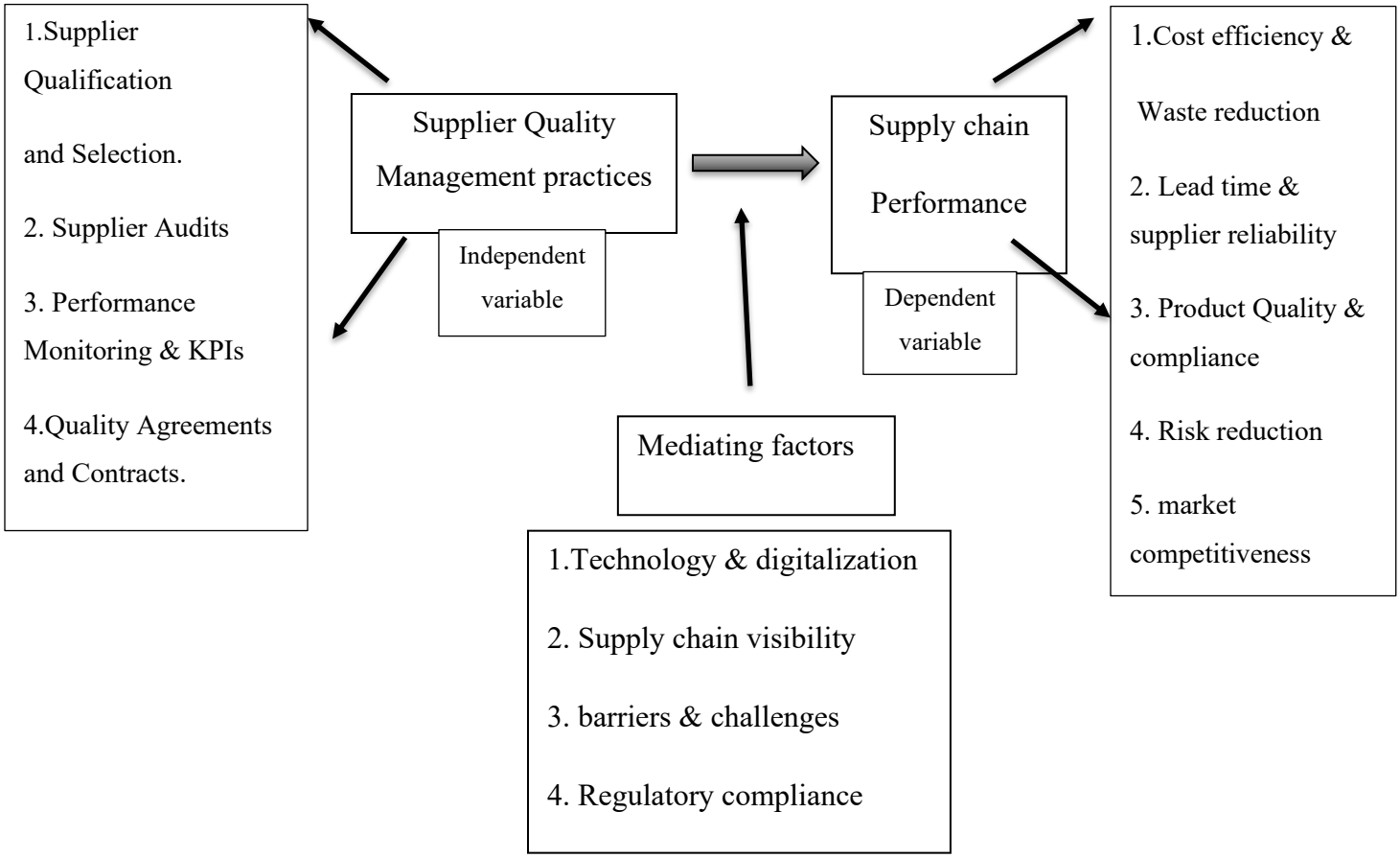
Independent variables (SQM practices), Mediating factors (regulatory compliance, technology, and challenges) and dependent variables (supply chain performance measured through key performance indicators).

Independent variables: Key SQM practices such a supplier qualification and audits, performance monitoring, quality agreements and risk-based supplier management directly influence the ability of pharmaceutical firms to ensure product quality and safety of supply chains by improving supplier reliability and efficiency through performance monitoring, reducing compliance risks and product recalls by enforcing quality agreements (richard, 2025).

Dependent variables: Supply Chain Performance (SCP) in measuring the effectiveness of supplier quality management is evaluated by using Key Performance Indicators (KPIs) that assess various aspects of supplier quality and supply chain efficiency to improve regulatory compliance by reducing legal risks and enhancing market reputation with better supplier performance leads, cost savings, operational efficiency and increased customer satisfaction which enhances pharmaceutical firms' credibility.

Mediating factors: The relationship between SQM practices and supply chain performance is influenced by several mediating factors such as regulatory compliance, technology integration with challenges and barriers including high costs, resistance to change and lack of supply chain visibility in implementing SQM practices for achieving optimal supply chain efficiency. Regulatory compliance mediates the effectiveness of SQM by ensuring that supplier quality standards align with legal and safety requirements. Emerging technologies such as Blockchain, Artificial Intelligence and Internet of Things (IOT) play a crucial role in enhancing supplier monitoring, risk management, and compliance tracking by improving transparency and traceability in supplier transactions there by predicts potential quality risks and enhances decision-making in supplier selection and enables real-time monitoring of supplier facilities and environmental conditions (galina, 2024). Companies that adopt digital solutions gain a competitive advantage in ensuring supplier compliance and risk mitigation.

Figure 3 : key components of conceptual framework



Chapter 3: Research Methodology

3.1 Introduction

Research methodologies are a set of defined procedures or techniques used to identify, select, process, and analyse information on a topic of research, presenting readers opportunity to understand and assess the credibility of study done based in the process. This chapter outlines the methodological framework to collect relevant data and analyse them in an accurate manner for evaluating the effectiveness of supplier quality management practices in enhancing supply chain performance of pharmaceutical quality management systems. The research will also explore the key challenges faced by pharmaceutical companies in integrating supplier quality management practices due to regulatory complexity, cost constraints, supplier resistance and auditing burdens. By leveraging a structured and theoretically informed methodology, this research aims to provide robust insights in enhancing the supply chain performance (SCP) and creates empirical validity in evaluating supplier quality management optimization methods specifically for pharmaceutical supply chain.

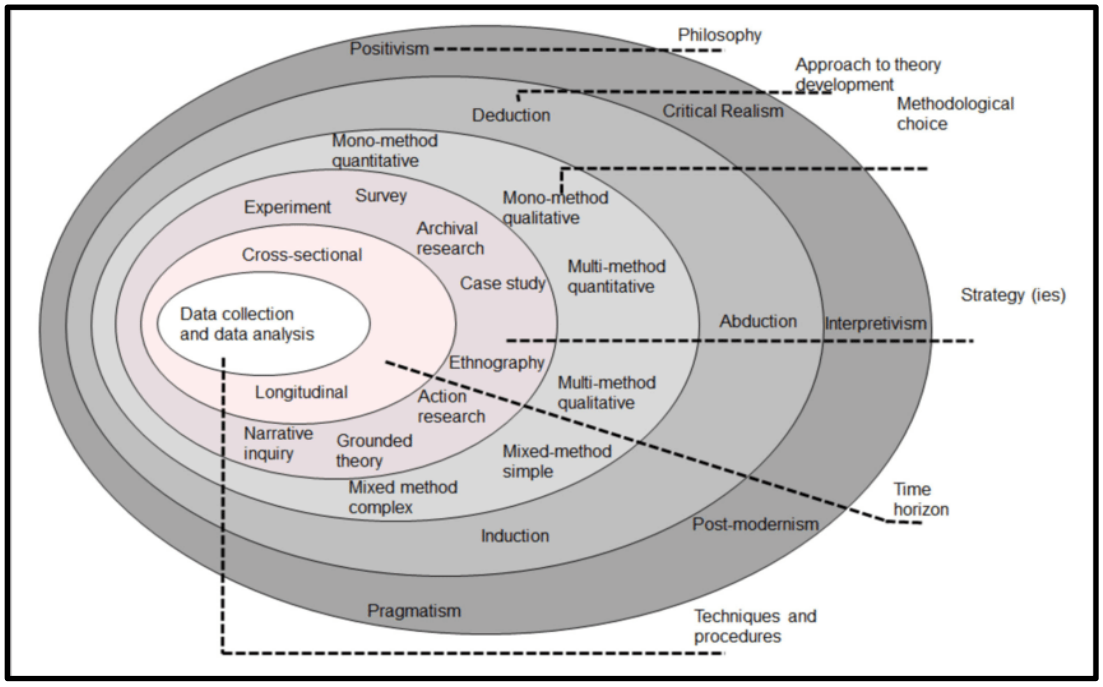


Figure 4 : Research Onion

(Source: Pandey and Pandey, 2021)

Research onion proposed by Saunders assists to select methodology for this study on supplier quality management in pharmaceutical supply chains. The research adopts positivism at its outer layer to establish objective and measurable conduct. Researchers use a deductive method to create valuable knowledge on research questions and objectives through existing theories before analysing the data (Verma *et al*., 2024). The descriptive research design was chosen as the optimal approach to develop a methodical description of supplier quality management practice effects. However, application of quantitative approach matches the study's objective by incorporating both graphics; and statistical data analysis methods (Kumari *et al*., 2023).

Therefore, it assists to acquire direct information from industry professionals, while gaining relevant primary data using structured surveys and questionnaires. At the core of the research onion statistical techniques perform analysis to determine the relationships between supplier quality practices and supply chain performance. Thus, the method mentioned in the above Onion framework guarantees scientific evaluation of pharmaceutical supplier quality management by performing empirical research.

3.2 Research Philosophy

The application of research philosophy provides a fundamental knowledge and understanding on the research process, which guides the researchers to interpret the outcome of this research. Also, research philosophy is mainly used to ensure research legitimacy, and gives scientifically sound research findings. As per the views of Dubey and Kothari (2022), application of a suitable research philosophy provides a detailed guideline that makes the research process smoother, manageable, and effective. In this study, Positivism Philosophy is used to examine the connection between supplier quality management (SQM) practices and supply chain performance within pharmaceutical quality management systems. Positivism adheres to the principle that findings should be replicable which means that other researchers should be able to conduct similar studies and obtain similar results. This enhances the reliability and credibility of the research. According to (Park *et al.*, 2020) positivism emphasizes the importance of objective measurement and quantification, allowing for precise data collection and analysis. The research topic involves evaluating the effectiveness of supplier quality management practices, which lends itself to objective measurement allows for a rigorous assessment of whether specific practices lead to improvements in supply chain performance metrics.

According to Nayak and Singh (2021), the tested variable consists of SQM practices that include supplier audits along with certification requirements and risk assessment along with AI analytics and blockchain monitoring technologies. Thus, the study evaluates supply chain performance by assessing its cost efficiency together with product integrity and lead times and supply chain reliability. The regulatory compliance standards operate as a controlling element that shapes how SQM practices affect performance through mandatory quality and safety limitations. Moreover, Islam *et al*. (2022) has claimed that, positivism philosophy assists to apply primary data collection with statistical methods to prove hypotheses and show cause-effect relationships. Thus, positivism philosophy helps to evaluate detailed knowledge regarding how to increase supply chain performance within the pharmaceutical quality management approach.

3.3 Research Approach

As per the views of Singh (2022), the concept of research approach is essential for ensuring the success of research by applying suitable data collection, analysis method, while ensuring validity, and credibility. However, by choosing an appropriate research approach, it is possible to develop a specific plan for the investigation, while considering the research objectives, and questions. In this study, the researcher has used the deductive research approach, to establish theories together with supplier quality management (SQM) studies and supply chain performance literatures form the basis for creating research hypotheses. As inspired by Gupta and Gupta (2022), quality management, supply chain efficiency and regulatory compliance theoretical structures serve as starting points for the research before data collection and analysis.

The independent variable in this study comprises five elements of SQM practices that include supplier selection and qualification, supplier audits, risk assessments as well as digital monitoring and quality agreements. Cost efficiency together with product integrity, lead times and reliability make up the dependent variables for supply chain performance measurement. Therefore, Aityan (2022) has claimed that business compliance requirements act as a controlling factor that determines how supply chain results respond to SQM implementation strategies. The research design uses structured methodology to move between general theories and specific observational data through quantitative information collection and statistical research methods. According to Mishra and Alok (2022), the research implements the deductive approach to maintain objective results and allow testable hypothesis development and causal relationship detection. Therefore, by

using this method researchers ensure they evaluate SQM's pharmaceutical supply chain contribution through systematic evidence-based assessment.

3.4 Research Design

The integration of suitable research design is considered as the blue-print of study, which assists the researcher to keep the research on a proper track. Therefore, in this study, the researcher has decided to use descriptive design that enables the opportunities to analyse the impacts of SQM or supplier quality management practices on supply chain performance within the quality management system. However, Newman and Gough (2020) have claimed that the descriptive approach proves suitable, due to the ability for analysing the existing SQM practices together with their implementation obstacles as well as their influence on supply chain performance improvement.

According to the knowledge of Ma *et al*. (2020), the assessment of supply chain performance consists of two elements: cost efficiency alongside product integrity and lead times and reliability. The level of regulatory compliance functions as a controlling factor to manage the impact of SQM practices on performance through proper adherence to industrial requirements and safety legislation. Moreover, Cooksey *et al*. (2019) has claimed that the descriptive research design enables analysts to gather quantitative survey data through standardized questionnaires which produce objective results about current practices and industry trends. Further, the research enables the detection of shared obstacles along with excellent methods employed by pharmaceutical organizations throughout the industry. The study presents a detailed factual summary of SQM's supply chain optimization function through its descriptive design which ensures reliable results.

3.5 Research Strategy

This study adopts a quantitative, cross-sectional research strategy with theory-based hypotheses about how specific supplier quality management practices affect supply chain performance. The cross-sectional design will capture current supplier quality management practices and performance levels useful for assessing perceptions, attitudes, and knowledge related to pharmaceutical practices. As inspired by Mishra and Alok (2022), supplier quality management (SQM) practices combine supplier audits with quality control mechanisms, digital monitoring and risk assessment tools which make up the independent variable. Supply chain performance is measured using four

variables that include cost efficiency and product integrity alongside lead times and supply reliability. Newman and Gough (2020) has suggested that the impact of Supply Quality Management (SQM) practices on whole supply chain efficiency receives regulatory compliance as a governing element. Organisations use quantitative methods to build structured data collection systems that rely on surveys and structured questionnaires as well as statistical metrics for data acquisition.

Moreover, Dźwigoł and Dźwigoł-Barosz (2018) has claimed that through this method researchers can perform numerical data analysis and test hypotheses while establishing relationships between supply quality management practices and supply chain results. Zangirolami-Raimundo *et al*. (2018) has also opined that the results attain greater validity through statistical tools including regression analysis, descriptive statistics and correlation analysis. Further, utilising quantitative methods enables the study to establish objectivity while allowing generalisation and replication, which produces empirical data about SQM optimization for pharmaceutical supply chains.

3.6 Data Collection Method

According to the knowledge of Bhattacharyya and Jha (2018), the most important part within the research process is considered as a data collection method that allows the researcher to gain necessary knowledge and data based on the research topic. In this study, primary data collection method is used for a structured survey method. Niraula (2019) has claimed that the chosen data collection methods allow the researcher to explore first-hand evidence about how supplier quality management (SQM) practices boost supply chain performance in pharmaceutical quality management systems. Structured questions with closed-ended questions are used to compose the survey design to obtain quantitative data from respondents. Moreover, Baran (2022) has assisted that suppliers audits and quality monitoring joins digital tracking systems and risk management strategies make up the primary independent variable in the study.

Supply chain performance measured using cost efficiency together with product integrity and lead times and supply reliability. The study will evaluate how regulatory compliance functions as a moderating element which determines SQM practice effectiveness in supply chain enhancement. Mohajan (2018) has also claimed that the data collection method provides both reliability and consistency and statistical validity through its systematic approach.

3.7 Sampling Strategy

The study employs non-probability purposive sampling to select participants, ensuring that individuals included in the research possess relevant expertise and experience aligned with the research focus. Purposive sampling involves intentionally selecting the accessible participants based on knowledge and experiences pertinent to the study's objectives there by improving the validity of findings.

As the research does not aim to generalise findings statistically to a wider population, the sample size is not determined by using traditional probability-based formulas, instead a target population size of approximately 200 has been set with sample size of 132 participants and direct responsibility or must be employed in Quality Assurance/Control, procurement compliance and supply chain management related to pharmaceutical quality management systems whose insights contributes in understanding the effectiveness of supplier quality management (SQM) practices (Harrison, 2019). Participants will be recruited from small, medium and big pharmaceutical companies to get a diverse representation. This multi-modal method optimizes response rates with ethical research approaches.

The criteria used in selecting these study participants were based on:

- Industry Experts (E.g., Regulatory compliance specialists, QA/QC associates/managers, Manufacturing Technicians, Procurement officers, Finance team, Supply chain professionals)

The quality managers ensure GMP compliance and supplier audits while the procurement officers ensure supplier selection, quality agreements and contract management. On the other hand, the supply chain professionals and risk management team ensure supplier performance, risk mitigation, and regulatory compliance. A structured questionnaire was prepared using Microsoft Forms consisting of 15 closed-ended infographic-based questions that improve participant engagement and data clarity through its visual appeal and easy interpretation. The survey assessments guarantee the study captures credible, industry-specific information on the challenges, obstacles and technological developments impacting supplier chain performance.

3.8 Data Analysis Strategy

As stated by Bairagi and Munot (2019), the evaluation of supplier quality management (SQM) practices on pharmaceutical supply chain performance employed statistically along with graphical analysis techniques during this investigation. Statistical analysis performed with IBM SPSS software, an individual statistical package containing tools and methods most effective for survey data, such as descriptive and inferential statistics and regression examination. This is because it changes the user's mode of operation in data processing by offering a platform that deals with data manipulation, visualisation and analysis. Thus, the study analysed the link between SQM practices and essential supply chain metrics by using regression analysis to evaluate cost efficiency together with product integrity and lead times and reliability. The survey results underwent descriptive analysis for identifying main patterns together with correlation analysis which evaluated the strength of SQM factor relationships. Mishra and Alok (2022) has claimed that a combination of Microsoft Forms serves to design surveys and collect responses and then export the data to create visualizations in Excel. Different visual charts including bar graphs and histograms were used to present survey response distributions to explain variable relationships and new patterns emerging from the data. Singh (2022) has also opined that the visual data analysis together with statistical results gave a better view into the challenges while showing how regulations affect SQM practices and technological developments. This study undertook an extensive data-based evaluation of supplier quality management through statistical methods with graphical depiction to understand pharmaceutical supply chain operations better.

3.9 Ethical Consideration

The research involves collecting and analysing supply chain data which may involve sensitive information about manufacturing processes, supplier performance and compliance levels. Ensuring proper data protection and confidentiality is crucial to protect companies from competitive risks and reputational damage. The research process adhered to ethical guidelines at every stage, ensuring the protection of participants. Explicit consent measures will be obtained from each participant before any data is collected. The participants were not required to give any personal identifying information such as emails or names which could expose them to risk on the questionnaire which helps to attain the anonymity of results.

However, to ensure the study ethics, Data Security and Confidentiality procedures to monitor data and ensure security were reviewed and maintained strictly under the project guidelines. All concerns around research data management and storage followed GDPR Guidelines with everything being my sole responsibility till submission. Access to results is limited to the authors personal password protected device (laptop) and google drive under the data protection services provided with Microsoft forms. All data recorded will later be handed over to the Griffith College as part of a thesis submission.

Furthermore, there was a normative aspect regarding the storage of data for the right amount of time. Data shall be kept for a duration of two years after submission or longer if deemed useful for validation of the study results in the future without necessarily identifying the participants with control on its disposal at the authority and discretion by Griffiths college after handover. Finally, the study respected the strictly set laws and regulations on data protection, including the GDPR for the European region, among others. This way the study ensures relevant ethical clearances or permission from the concerned institutional review boards or ethical committees prior to starting the research.

Chapter 4: Findings and Discussion

4.1 Introduction

"The effectiveness of supplier quality management practices in enhancing supply chain performance within pharmaceutical quality management systems" is the main objective of this research. Statistical data analysis and its respective discussion section are covered within the findings and discussion chapter. The statistical data analysis section consists of various statistical methods that have been used to evaluate the collected information, extracted from the survey in terms of responses. In this chapter, "descriptive statistics, correlation and regression" has been performed in terms of analysing the data, collected as responses from the survey. Against the study aim, findings are discussed in the discussion section while addressing the research questions.

4.2 Graphical Analysis

What is your current job role?

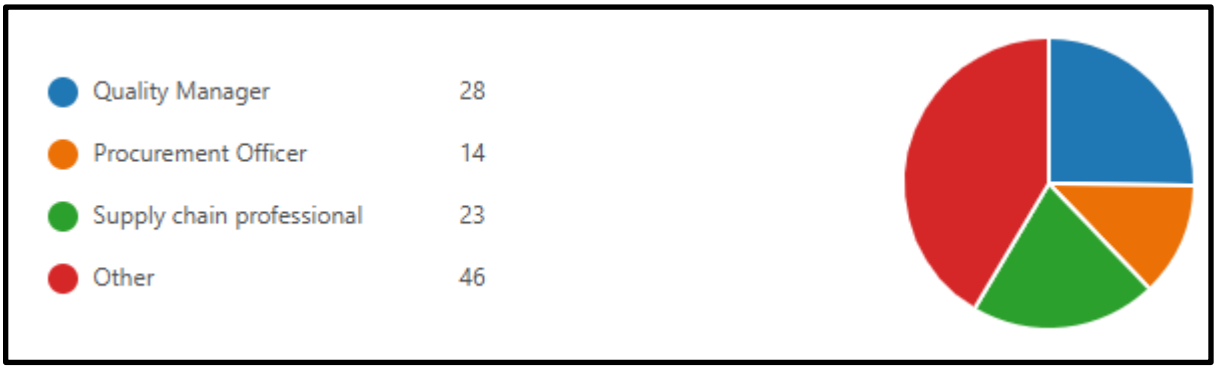


Figure 5 : Current job role

The target sample size for this study was initially set as 136 responses. However, due to time constraints, the study ultimately collected 111 responses, among them

28 participants were quality managers

14 participants were procurement officers

23 participants were supply chain professionals

46 participants came from other job roles

How frequently does your company conduct supplier audits?

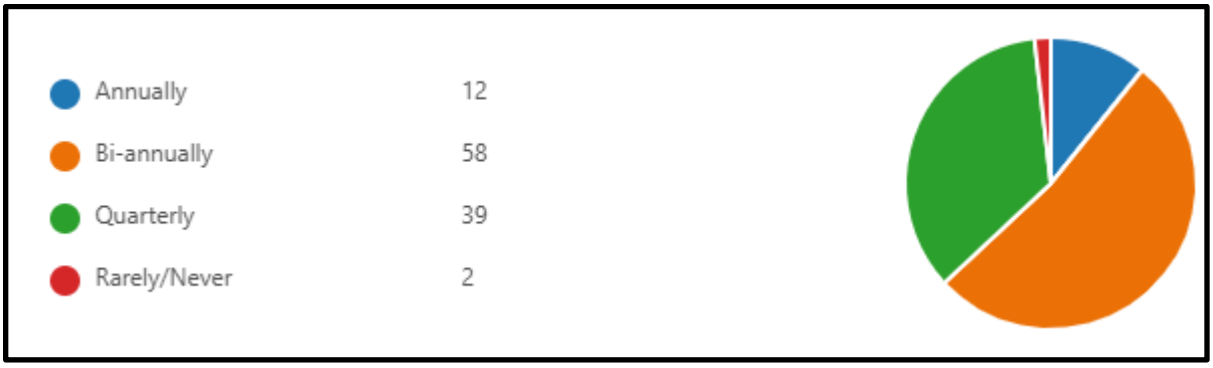


Figure 6 : Frequency of supplier audits

Audit activities conducted by 58 companies take place twice yearly whereas 39 companies perform them four times each year. The annual audit frequency is maintained by 12 companies while 2 businesses audit suppliers either infrequently or not at all.

What supplier quality management practices are implemented in your company?

Figure 7 : What SQM practices are implemented

The survey shows that around 46 participants claimed that supplier audits combined with performance evaluations stand as the top adopted quality management practice. The least adopted quality management systems include digital tracking systems, quality agreements, and risk-based management. On the other hand, 24 participants claimed supplier qualification and selection follows as the second most common practice.

How effective are your company's supplier quality management practices in ensuring regulatory compliance?

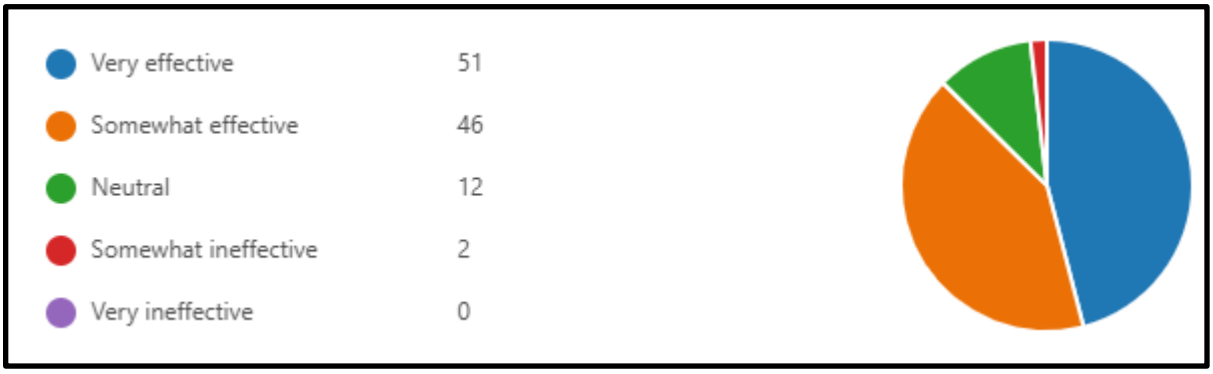


Figure 8 : How effective are your company's SQMP in ensuring regulatory compliance

From the above graphical representation, it has found that 46 participants address the company's supply chain as somewhat effective, where 51 participants consider it very effective. On the other hand, 12 participants have provided neutral opinions.

To what extent does your company use technology (AI, blockchain, real-time monitoring) to enhance supplier quality management?

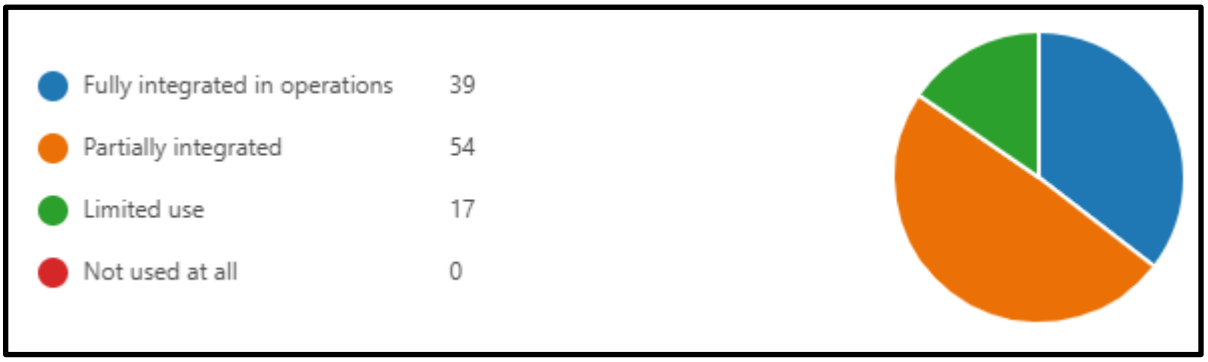


Figure 9 : To what extent does your company use technology (AI, blockchain, real-time monitoring)

According to 54 survey participants, most organisations embrace partial technology integration of AI and blockchain for supplier quality management yet 39 organisations fully implement these technologies. The survey shows that seventeen organizations utilize these technologies to a small extent but all companies reject the notion that they do not utilize them at all.

How would you rate the impact of supplier quality management on cost efficiency in your company?

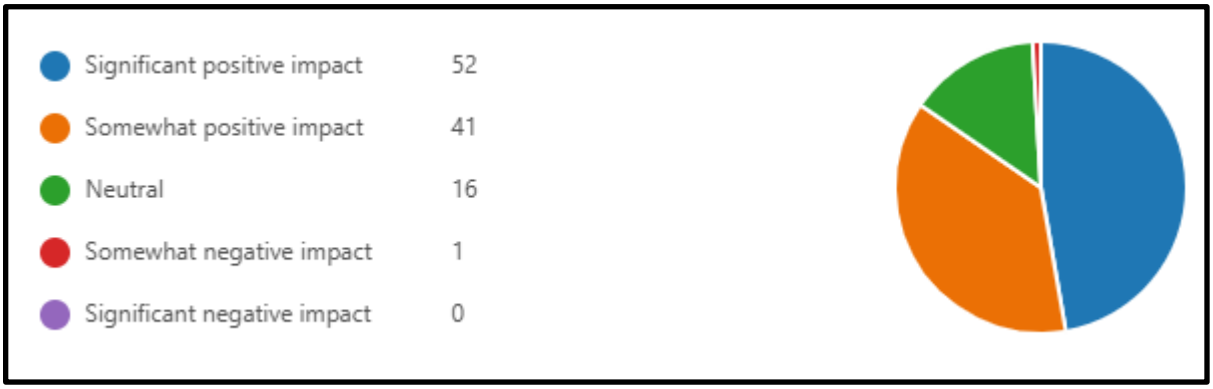


Figure 10 : impact of supplier quality management on cost efficiency

As per 52 participants, the survey demonstrates that supplier quality management practices directly influence cost efficiency at a high level, where 41 individuals acknowledge its moderate positive effects. Among the surveyed group 16 participants have shown neutrality toward the impact and only 1 person views it as slightly negative while the rest hold mixed or positive opinions.

To what extent do supplier quality management practices affect supply chain reliability in your organization?

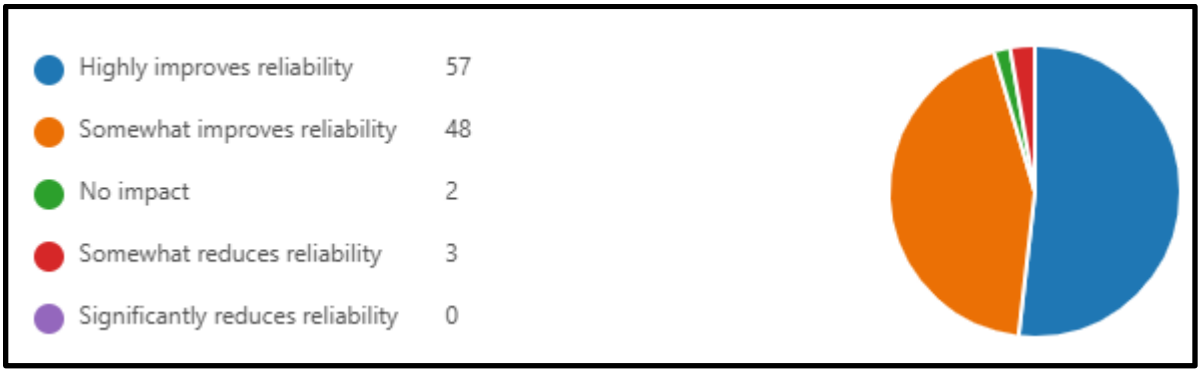


Figure 11 : To what extent do SQMP affect supply chain reliability

Participants indicated that supplier quality management practices create a high degree of supply chain reliability, due to the reason that 57 people endorsed this view while 48 people indicated it has a moderate impact. The survey found that 2 participants did not notice any impact of supplier

quality management, but 3 others participants noticed a slight decrease in reliability while no participant noticed a significant decrease.

How does your company handle supplier non-compliance issues?

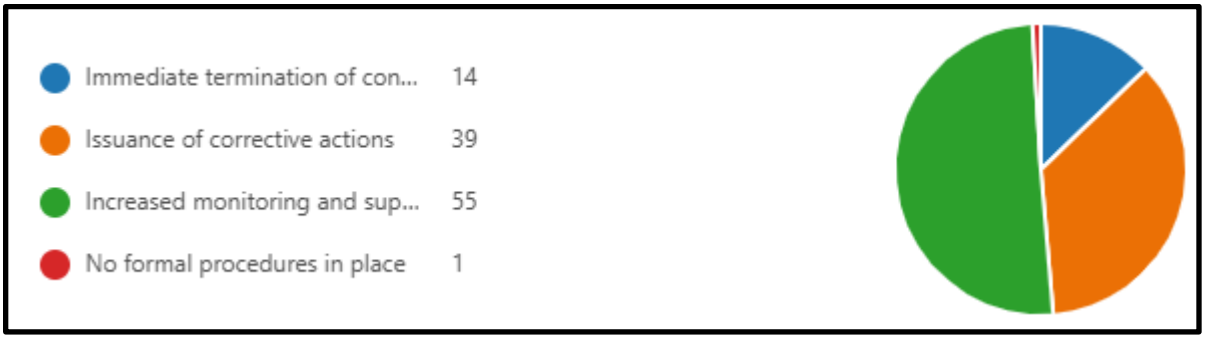


Figure 12 : supplier non-compliance issues

The above figure claimed that around 55 participants claimed that their company increased monitoring, and support systems to handle supplier non-compliances issues. On the other hand, 39 participants indicated the approaches of issuance of corrective actions, and 14 participants mentioned the initiatives of immediate termination of contact for handling non-compliance issues.

How effective are quality agreements in maintaining supplier accountability?

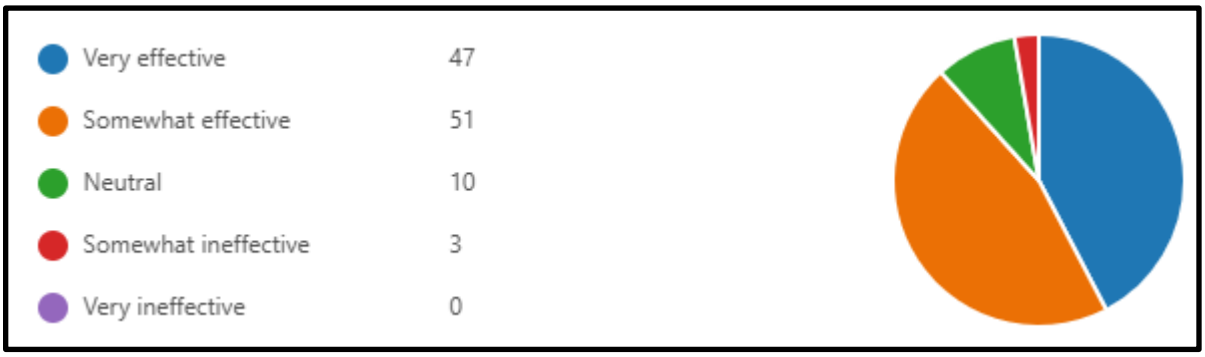


Figure 13 : How effective are quality agreements in maintaining supplier accountability

Most survey participants evaluated quality agreements positively regarding supplier accountability, due to the reason that 51 people rated them somewhat effective and 47 people rated them very effective.

What are the biggest challenges in implementing supplier quality management practices in your company?

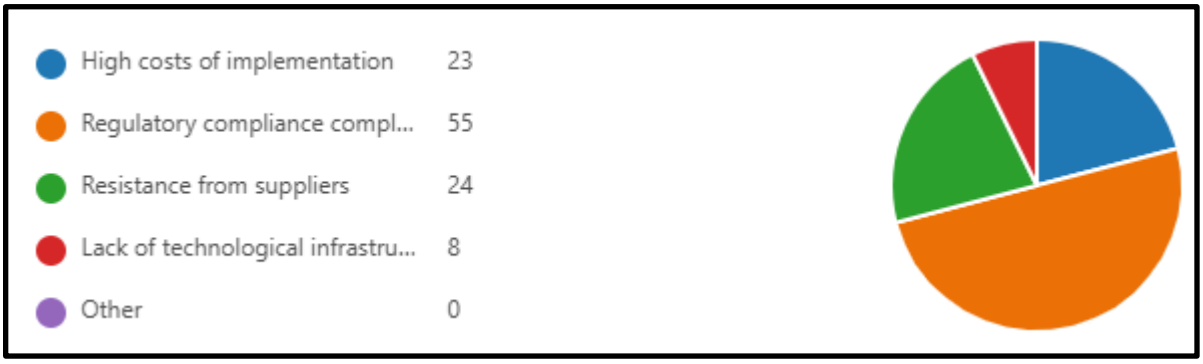


Figure 14 : biggest challenges in implementing SQM practices

A total of 55 respondents defined regulatory compliance complexities as the primary challenge while supplier resistance emerged second with 24 responses and implementation costs placed third with 23 responses.

In your opinion, what improvements would enhance supplier quality management effectiveness?

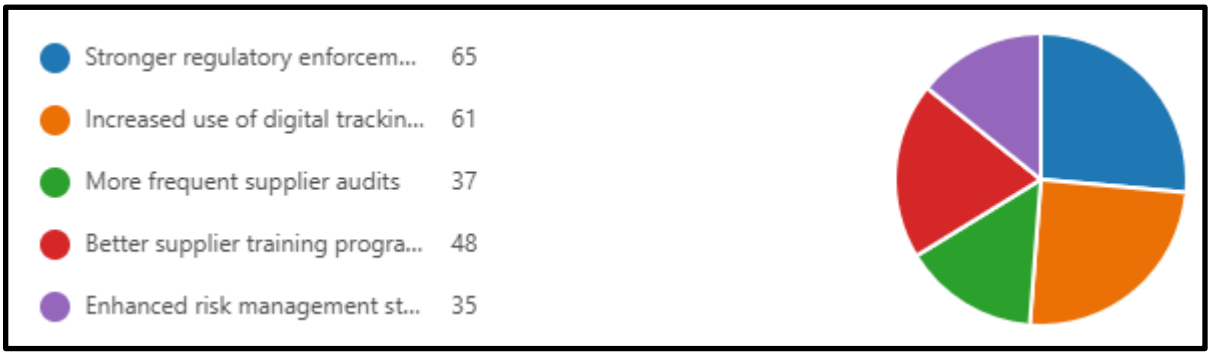


Figure 15 : what improvements would enhance SQM effectiveness

The above survey figure indicates that 65 participants believed in stronger regulatory enforcement, and 61 participants believed in increased use of digital tracking tools. On the other hand, other 48 participants claimed that better supplier training, and 37 participants claimed that approaches of more frequent supplier audits, help to increase supplier quality management.

Would you be interested in adopting AI-driven analytics or blockchain solutions to enhance supplier quality management in the future?

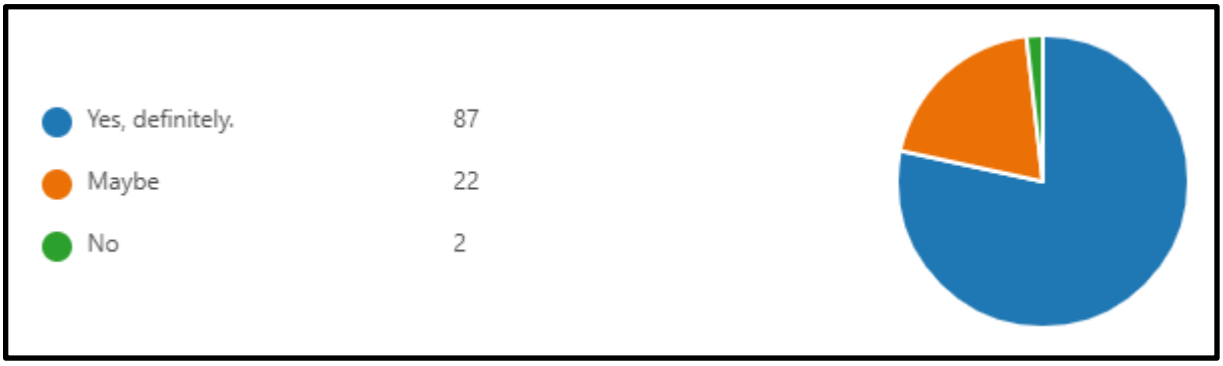


Figure 16 : interested in adopting AI-driven analytics or blockchain solutions to enhance SQM in the future

Around 87 participants showed their strong interest to adopt AI-driven analytics or blockchain solutions for supplier quality management but 22 were undecided and only 2 participants did not show interest.

4.3 Quantitative Analysis: SPSS

4.3.1 Descriptive Statistics Analysis

Descriptive statistics provides a fundamental view into how respondents perceive and engage with supplier quality management practices. To summarize data and provide insights into the mean, standard variation and variance and range of responses to understand the overall pattern of the data which is essential for identifying trends and preparing for further statistical analysis such as correlation, regression and ANOVA.

Descriptive Statistics								
	N	Range	Minimum	Maximum	Mean		Std. Deviation	Variance
	Statistic	Statistic	Statistic	Statistic	Statistic	Std. Error	Statistic	Statistic
frequency of supplier audits	111	3	1	4	2.28	.064	.677	.458
Implementation of SQM practices	111	4	1	5	3.43	.127	1.339	1.793
Effectiveness in ensuring regulatory compliance	111	3	1	4	2.83	.108	1.135	1.289
Use of technology (AI, blockchain, real-time monitoring)	111	3	1	4	3.12	.088	.932	.868
Impact on cost efficiency	111	4	1	5	3.59	.110	1.156	1.336
Impact on supply chain reliability	111	4	1	5	2.95	.099	1.048	1.098
Handling of supplier non-compliance issues?	111	4	1	5	3.21	.070	.740	.548
Effectiveness of quality agreements	111	3	1	4	2.78	.104	1.099	1.207

challenges in implementing SQM practices	111	4	1	5	3.70	.100	1.058	1.120
Suggestions for improvements	111	45	1	46	23.97	1.263	13.303	176.972
Interest in future adoption of AI-driven analytics/ blockchain	111	2	1	3	2.59	.076	.803	.645
Valid N (listwise)	111							

Table 4. 1 Descriptive Statistics

Analysis:

Frequency of Supplier Audits (Mean = 2.28; SD = 0.677)

The relatively low mean indicates that supplier audits are conducted occasionally but not regularly. With a standard deviation of 0.677, there's moderate variation among companies, suggesting differing audit practices.

Implementation of Supplier Quality Management Practices (Mean = 3.43; SD = 1.339)

With a high mean and large standard deviation, the data reveals that while many companies implement several SQM practices, with significant variability in how companies implement these practices.

Effectiveness in Ensuring Regulatory Compliance (Mean = 2.83; SD = 1.135)

Respondents perceive their SQM practices as only moderately effective in achieving regulatory compliance. The high variability also suggests that effectiveness differs based on company size, industry, or the robustness of their systems.

Use of Technology (AI, Blockchain, Real-Time Monitoring) (Mean = 3.12; SD = 0.932)

This result shows a moderately high level of technological adoption. The standard deviation reflects varying levels of technology integration among firms.

Impact on Cost Efficiency (Mean = 3.59; SD = 1.156)

A relatively high mean suggests that most companies recognize a strong impact of supplier quality management on cost efficiency which reflects on the cost-saving potential of reduced defects,

fewer compliance issues, and better supplier relationships. The high standard deviation is possibly due to differences in implementation.

Impact on Supply Chain Reliability (Mean = 2.95; SD = 1.048)

While SQM practices are seen as somewhat effective in enhancing supply chain reliability, the relatively neutral mean and high variability imply that other factors (like logistics, inventory control, or supplier location) also play critical roles.

Handling of Supplier Non-Compliance (Mean = 3.21; SD = 0.740)

This suggests a moderate consistency in effectively managing non-compliance and most companies have some procedures in place, but perhaps not formalized or enforced to the same degree.

Effectiveness of Quality Agreements (Mean = 2.78; SD = 1.099)

This score indicates mixed views about the effectiveness of quality agreements in ensuring supplier accountability. This could reflect some inconsistency within written agreements, lack of enforcement or low supplier commitment across organizations.

Challenges in Implementation (Mean = 3.70; SD = 1.058)

A high mean indicates that most respondents face significant challenges in implementing supplier quality management practices. The standard deviation supports the presence of variation, possibly depending on organizational size or industry.

Interest in Future Adoption of AI/Blockchain (Mean = 2.59; SD = 0.803)

The relatively high score suggests outlook toward adopting advanced technology. Organizations are increasingly aware of the benefits of predictive analytics, traceability and automation in improving supplier quality outcomes.

4.3.2 Correlation Analysis

The correlation analysis aimed to explore the relationships between various dimensions of supplier quality management (SQM) practices and organizational performance factors such as regulatory compliance, cost efficiency, and supply chain reliability.

Correlations

		Supplier audits frequency	SQM practices	Regulatory compliance	Technology (AI, blockchain, real-time monitoring) use	Cost efficiency
Supplier audits frequency	Pearson Correlation	1	-.135	.027	-.096	-.153
	Sig. (2-tailed)		.159	.776	.318	.109
	N	111	111	111	111	111
SQM practices	Pearson Correlation	-.135	1	.199*	.178	-.007
	Sig. (2-tailed)	.159		.037	.062	.946
	N	111	111	111	111	111
Regulatory compliance	Pearson Correlation	.027	.199*	1	-.325**	-.082
	Sig. (2-tailed)	.776	.037		.001	.391
	N	111	111	111	111	111
Technology (AI, blockchain, real-time monitoring) use	Pearson Correlation	-.096	.178	-.325**	1	.206*
	Sig. (2-tailed)	.318	.062	.001		.030

	N	111	111	111	111	111
Cost efficiency	Pearson Correlation	-.153	-.007	-.082	.206*	1
	Sig. (2-tailed)	.109	.946	.391	.030	
	N	111	111	111	111	111
*. Correlation is significant at the 0.05 level (2-tailed).						
**. Correlation is significant at the 0.01 level (2-tailed).						

Table 4. 2 Correlations first five questions

Analysis:

- Supplier Quality Management Practices & Regulatory Compliance
  A positive correlation ($r = 0.199$, $p < 0.05$) was found between the implementation of supplier quality management practices and their effectiveness in ensuring regulatory compliance. This suggests that firms that actively implement quality management protocols are more likely to comply with industry regulations.
- Use of Technology & Cost Efficiency
  Significant positive correlation ($r = 0.206$, $p < 0.05$) between the use of emerging technologies (e.g., AI, blockchain) and improvements in cost efficiency. Technology adoption can optimize operational costs in quality management.
- Regulatory Compliance & Technology Use
  Negative correlations ($r = -0.325$, $p = 0.001$) with integration of new technologies might introduce complexity and temporarily disrupt established regulatory processes.
- The frequency of supplier audits did not significantly correlate with cost efficiency or technology use, suggesting that audit practices alone may not be a strong determinant of performance outcomes.

		Supply chain reliability	Non-compliance handling	Quality agreements	SQM challenges	Interest in Technology adaption
Supply chain reliability	Pearson Correlation	1	-.082	-.490**	.004	-.303**
	Sig. (2-tailed)		.394	.000	.965	.001
	N	111	111	111	111	111
Non-compliance handling	Pearson Correlation	-.082	1	-.112	.195*	-.053
	Sig. (2-tailed)	.394		.241	.040	.580
	N	111	111	111	111	111
Quality agreements	Pearson Correlation	-.490**	-.112	1	-.048	.134
	Sig. (2-tailed)	.000	.241		.617	.159
	N	111	111	111	111	111
SQM challenges	Pearson Correlation	.004	.195*	-.048	1	-.029
	Sig. (2-tailed)	.965	.040	.617		.766
	N	111	111	111	111	111

Interest in Technology adoption	Pearson Correlation	-.303**	-.053	.134	-.029	1
	Sig. (2-tailed)	.001	.580	.159	.766	
	N	111	111	111	111	111

Table 4. 3 Correlations second five questions

Analysis:

A positive correlation was found between how organizations handle supplier non-compliance and the challenges they face in SQM implementation ($r = 0.195$, $p < 0.05$). This suggests that companies with non-compliance issues tends to face more challenges in implementing supplier quality management (SQM) practices, suggesting a possible link between regulatory enforcement and operational complexity.

Similarly, negative relationship between supply chain reliability and interest in adopting advanced technologies ($r = -0.303$, $p < 0.01$) quality agreements ($r = -0.490$, $p < 0.01$) implies that companies satisfied with current SQM outcomes may lack motivation to explore innovative digital solutions and decreased operational resilience due to more formalized contractual agreements with suppliers.

4.3.3 Regression Analysis

Model Summary									
Model	**R**	**R Square**	**Adjusted R Square**	**Std. Error of the Estimate**	**Change Statistics**				
					R Square Change	**F Change**	**df1**	**df2**	**Sig. F Change**
1	.386[a]	.149	.100	1.270	.149	3.037	6	104	.009

Dependent Variable: What supplier quality management practices are implemented in your company? Predictors: (Constant) Would you be interested in adopting AI-driven analytics or blockchain solutions to enhance supplier quality management in the future? What are the biggest challenges in implementing supplier quality management practices in your company? How effective are your company's supplier quality management practices in ensuring regulatory compliance? How does your company handle supplier non-compliance issues? To what extent does your company use technology (AI, blockchain, real-time monitoring) to enhance supplier quality management? To what extent do supplier quality management practices affect supply chain reliability in your organization?

Table 4. 4 Regression analysis

Analysis:

As per the " Regression model Summary (Table 4.3) it has been emphasized that a multiple linear regression analysis yielded R value of 0.386, indicating a moderate positive correlation between the selected independent variables such as the extent of technology use (e.g., AI, blockchain), regulatory compliance practices, non-compliance handling, perceived challenges and adopt to digital solutions—and the dependent variable measuring the effectiveness or outcomes of supplier quality management. R-squared value was 0.149, meaning that approximately 14.9% of the variance in SQM effectiveness can be explained by the set of predictors and the model is statistically significant, with a p-value of 0.009 suggesting these predictors contribute to SQM effectiveness. The standard error of estimate which provides a measure of accuracy of predictors is 1.270 and is acceptable as lower values suggest better fit (Michael Carmichael, 2013).

4.3.4 ANOVA

ANOVA[a]						
Model		**Sum of Squares**	**df**	**Mean Square**	**F**	**Sig.**
1	Regression	29.409	6	4.901	3.037	.009[b]
	Residual	167.835	104	1.614		
	Total	197.243	110			

Table 4. 5 ANOVA

To evaluate the effect and overall significance of multiple independent variables on the implementation of supplier quality management practices an ANOVA (Analysis of Variance) is performed.

Null hypothesis (H_0): There is no statistically significant relationship between the independent variables/predictors and the implementation of supplier quality management practices.

From the ANOVA output the $F > 1$ ($F = 3.037$) indicates some variance between the groups and p-value is 0.009 and the regression model is statistically significant at the 0.05 level. This indicates that the null hypothesis is rejected and combination of predictors including regulatory compliance effectiveness, technology adoption (AI, blockchain, real-time monitoring), handling of non-compliance, supply chain reliability and adopt to future AI/blockchain integration meaningfully contributes to explaining variations in the implementation of supplier quality management practices. This finding supports the integration of these six independent variables in further regression analysis have the strongest influence on supplier quality management practices and also justifies which individual variable has the strongest predictive power, as identified in coefficients table.

4.3.5 Coefficient model

Coefficients									
Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	Correlations		
		B	Std. Error	Beta			Zero-order	Partial	Part
1	(Constant)	1.534	1.139		1.347	.181			
	SQM practices in ensuring regulatory compliance	.338	.118	.286	2.851	.005	.199	.269	.258
	Use of technology (AI, blockchain, real-time monitoring)	.385	.143	.268	2.698	.008	.178	.256	.244
	Supply chain reliability	.114	.132	.089	.858	.393	.059	.084	.078
	Supplier non-compliance issues	-.310	.170	-.171	-1.822	.071	-.192	-.176	-.165
	Challenges in implementing SQM practices	.005	.118	.004	.046	.963	-.043	.005	.004
	Interest in adopting AI-driven analytics for future use	.148	.159	.089	.926	.357	.075	.090	.084

a. Dependent Variable: What supplier quality management practices are implemented in your company?

Table 4. 6 Coefficients

Analysis:

The regression model examined six independent variables to determine their influence on the dependent variable. Coefficient table in regression analysis helps to understand the individual contribution and significance of each independent variable (predictor) to the dependent variable.

Two predictors were found to be statistically significant at the 0.01 level:

1. Effectiveness of Regulatory Compliance Practices with significance level (p-value) of 0.005 indicating a positive effect on the dependent variable. Companies that report higher effectiveness in ensuring regulatory compliance are significantly more likely to implement robust supplier quality management practices.
2. Use of Advanced Technology (AI, Blockchain, Real-Time Monitoring) a p-value of 0.008. So increased adoption of technology is positively associated with the implementation of supplier quality management practices, reinforcing the role of digital transformation in supply chain performance.

The other predictors such as the impact of supplier quality management on supply chain reliability, handling of supplier non-compliance, perceived challenges and interest in future technologies were not statistically significant ($p > 0.05$). This suggests that while they may conceptually relate to quality management, they do not independently predict the level of SQM implementation within the model.

Based on the responses gathered in this thesis research on supplier quality management practices, several critical insights emerged through detailed statistical analyses including descriptive statistics, correlation, ANOVA, and regression. The data obtained from 111 respondents enabled a comprehensive understanding of how different factors interact in the context of supplier quality performance, compliance, technological adoption, and overall supply chain effectiveness.

4.4 Discussion:

The research aimed to explore how organizations implement supplier quality management practices (SQMP), handle supplier non-compliance, adopt to technological solutions and their perception of challenges and improvements in the supply chain. Quality agreements, audits, and compliance initiatives are important, but they need to be part of a broader strategy that includes relationship management, continuous improvement, and digital transformation. The moderate

correlation and regression values suggest that supplier quality is not driven by any single factor, but rather by interrelated elements that must be aligned for optimal results.

Role of SQM practices in supplier evaluation

The literature strongly emphasizes the strategic role of SQM practices in evaluating and selecting suppliers. As patil (2024) highlights evaluating supplier's compliance with GMPs standards, operational performance and capacity for innovation is critical to operational success. While quality agreements are foundational but their impact may vary based on implementation or mutual understanding between parties. The negative correlation between supply chain reliability and quality agreements ($r = -0.490$, $p < 0.01$), explain why strong contractual frameworks don't always translate directly to higher supply chain reliability unless supported by continuous monitoring mechanisms and there might be underlying inefficiencies or gaps in implementation. This could mean that while agreements are in place, they may not be sufficient or effective on their own to drive actual performance improvements.

For variable "how frequently does your company conduct supplier audits?" the descriptive statistics provided a foundational understanding of the frequency and extent to which these practices are being used. Most participants indicated that their organizations conducted supplier audits with 2.28 mean suggested that while supplier audits were not conducted excessively without regular patterns, they were not ignored either. This balance may indicate that audits are carried out based on certain triggers or risk levels rather than on a rigid schedule. Additionally, the average rating of implemented SQMP indicated a moderately high level of commitment towards managing supplier quality, suggesting that a fair number of companies had structured mechanisms to ensure supplier performance and compliance.

Regulatory compliance as key driver of SQM practices

In the findings, respondents consistently rated compliance-related variables as key elements influencing supplier performance. The variable "How effective are your company's supplier quality management practices in ensuring regulatory compliance?" showed a mean value 2.82, suggesting that organizations prioritize compliance as part of their SQM strategy. This directly reflects Khan et al. (2023) and Soares et al. (2017) who argue that regulatory audits and supplier assessments are integral tools for maintaining quality and mitigating risks.

Furthermore, from coefficients table it is identified regulatory compliance as a significant predictor of effective SQM practices with significance level (p-value) of 0.005, validating the assertions made by Tayyab et al. (2022) and Charoo et al. (2023) that regulatory oversight enforces accountability and improves operational consistency. Companies that report higher effectiveness in ensuring regulatory compliance are significantly more likely to implement robust supplier quality management practices and frameworks. This is aligned with the literature's emphasis on GMP and GDP as baseline quality indicators across the supply chain.

The positive correlation found between regulatory compliance and SQM practices ($r = 0.199$, $p < 0.05$) confirms Walvekar et al. (2024), who states that various types of audits such as regulatory, internal, and third-party are critical in ensuring adherence to regulatory compliance risks.

Technology usage and integration in SQM:

The findings from the study reveal that technology adaptation plays a pivotal role in enhancing Supplier Quality Management (SQM) within the pharmaceutical supply chain. Sarangi and Ghosh (2024) emphasized the role of IoT which enhances quality assurance throughout the supply chain. Similarly, Akter (2024) noted that Pfizer's implementation of blockchain illustrates how digital tracking strengthens both authentication and regulatory compliance. The statistical analysis demonstrated a significant and positive relationship between technology adaptation as reflected in the regression coefficient ($p < 0.01$). This suggests that firms that actively integrate digital technologies into their supplier management processes tend to experience better quality control, higher compliance, and improved operational performance. A similar negative correlation was found between the use of AI or blockchain technology and the reliability of the supply chain ($r = -0.303$, $p < 0.01$) indicates advanced technologies are often associated with efficiency and accuracy. That is, organizations struggling with supplier issues may be more inclined to adopt AI or blockchain to rectify those problems, rather than already having a reliable system and then adding technology on top and this could explain the negative correlation.

Furthermore, Tayyab et al. (2022) argued that the integration of AI and blockchain significantly improves supplier visibility and control, which aligns with study's finding that technology adaptive firms show higher SQM performance. In addition, Malviya et al. (2025) note that digital technology integration leads to operational efficiency and costs benefits where strong positive

correlation noted between the use of emerging technologies (e.g., AI, blockchain) and improvements in cost efficiency ($r = 0.206$, $p < 0.05$) indicates companies that leverage digital technologies can reduce rework costs and optimize supplier performance monitoring.

In conclusion, the statistical analyses conducted provide understanding of how supplier quality management practices are implemented and perceived. The data reveals both strengths and gaps in current approaches, offering valuable insights for practitioners and academics. Organizations must continue to invest in not only the structural components of SQMP such as audits and agreements but also in other elements like supplier relationships, training, and change management. Additionally, the effective integration of technologies like AI and blockchain holds promise but must be done with a clear strategy and readiness assessment. By interpreting the data holistically, this research contributes to the growing body of knowledge on supply chain management and underscores the importance of a comprehensive, data-informed approach to supplier quality assurance.

Chapter 5: Conclusion and Recommendations

5.1 Conclusion

The research examined how effective Supplier Quality Management (SQM) practices plays a vital role in enhancing supply chain performance in pharmaceutical quality management systems. Implementation of robust supplier quality management practices such as supplier audits, risk assessments, digital AI, and blockchain tools increases performance indicators of supply chain efficiency, product safety, and delivery reliability. The research discovered that SQM implementation occurs frequently in companies yet regulatory obstacles together with supplier non-compliance issues and high implementation expenses continue to exist (Agyabeng-Mensah *et al.*, 2021). The implementation of digital technologies leads the organisations to achieve operational efficiency while maintaining higher regulatory compliance. The study also concluded that formal contracts effectively increase supplier accountability while reducing operational risk.

It also helped assess the impact of formal contracts on safety compliance and product quality. Through this research supplier development and selection practices demonstrated their capability to make supply chains more reliable (Soares *et al*., 2017). The research proved the theoretical models by validating Resource-Based View and Supply Chain Resilience frameworks that demonstrate that SQM operates as a strategic business resource for competitive advantage. This study provides essential knowledge that highlights the need for pharmaceutical companies to improve their SQM frameworks by implementing technological advancements to maintain sustainable, resilient, and compliant supply chain operations (Zaid and Sleimi, 2023).

Objective 1: To explore the effect of supplier quality management practices on the overall performance of pharmaceutical supply chains

The research demonstrated the extent to which supplier quality management (SQM) practices influence the overall performance of the pharmaceutical supply chain. The analysis revealed strong positive relationships between variables such as supplier audits, supplier compliance management and regulatory alignment, indicated that organizations with robust SQM frameworks tends to experience more stable and predictable supply chain operations (Lee *et al*., 2021). Statistical data confirms that SQM practices were statistically significant predictors of improved supply chain

outcomes, highlighting their influence on performance variability and a direct relationship between supply chain reliability and the use of SQM practices confirms that variation in supply chain performance can be significantly explained by the degree of SQM practice implementation.

Objective 2: To assess the main challenges and barriers in implementing effective supplier quality management practices by pharmaceutical companies.

The second objective revealed that while SQM is essential, its implementation is obstructed by a complex interplay of internal limitations, supplier-side constraints and regulatory fragmentation. However, literature review focussed on barriers such as high implementation costs, technological disparities among global suppliers, geopolitical risks and inconsistent enforcement of Good Manufacturing Practices and Good Distribution Practices (Khan *et al*., 2023). Smaller pharmaceutical firms, in particular, were found to lack the resources needed for regular supplier audits, real-time quality tracking, or advanced analytics adoption, leading to reactive rather than preventive quality management. The research highlighted a positive correlation between how organizations manage supplier non-compliance and the challenges they face in SQM implementation. This implies that firms experiencing greater challenges such as lack of standard procedures, supplier resistance, or high regulatory burdens are often those that also struggle with frequent cases of supplier non-compliance. These findings revealed the need for harmonized global regulations, improved supplier partnerships, and scalable digital solutions to streamline and enforce SQM practices.

Objective 3: To investigate the role of technology and digitalisation in enhancing supplier quality management practices

The literature review further elaborated on how digitalization enables real-time performance monitoring, predictive risk analysis and automated quality audits, helping firms detect deviations early and reduce recall risks. Researchers such as Malviya et al. (2025) and Mishra et al. (2022) emphasized that technology is not merely supportive but transformative converting quality management into proactive and predictive quality assurance systems. Based on the statistical analysis, the use of technology in SQM practices and improved cost efficiency, suggesting that firms leveraging digital tools not only enhance the processes but also reduce the costs associated with manual inspections, delayed quality reporting and non-compliance penalties. Furthermore,

digitalization helps standardize supplier assessments, overcome geographical barriers and synchronize data across various stakeholders, aligning with Good Manufacturing Practices (GMP). The study also identified a negative correlation between supply chain reliability and the adoption of digital technologies, indicates that despite the potential benefits of technologies the digital divide remains a barrier. Thus, while digital tools offer substantial enhancements to SQM, their successful deployment depends on organization readiness, training and supplier collaboration.

Objective 4: To determine the influence of quality agreements between pharmaceutical companies and suppliers

This objective focused on assessing how formal supplier agreements contribute to maintaining quality assurance and meeting the stringent regulatory standards of the pharmaceutical industry. The literature and data analysis reveal that regulatory compliance is strengthened when quality agreements are complemented by active SQM practices—such as routine audits, real-time monitoring, and risk-based evaluations According to Sarangi and Ghosh (2024), quality agreements serve as a critical tool for audit responsibilities, documentation standards and change control procedures. Patil (2024) and Dehshiri et al. (2022) also emphasized that robust agreements significantly reduce ambiguity in regulatory audits, helping organizations demonstrate supplier oversight and adherence to protocols.

Based on the statistical findings, the study observed a negative correlation between the existence of supplier agreements and supply chain reliability. While this may initially appear contradictory, it suggests having agreements in place does not automatically guarantee a reliable supply chain unless those agreements are effectively enforced and supported by continuous collaboration and communication. Pharmaceutical companies must ensure that agreements are not just legal formalities, but dynamic management tools that are regularly reviewed, updated, and enforced to maintain product integrity and meet evolving regulatory standards.

5.2 Recommendations

Based on the comprehensive analysis of the research findings, a series of key recommendations can be drawn to guide organizations toward strengthening their supplier quality management (SQM) practices. These recommendations are aimed at addressing the challenges identified

through the data while aligning with the objectives of enhancing supply chain reliability, regulatory compliance, and operational efficiency.

The data indicated a strong correlation between the effectiveness of SQM practices and the reliability of the supply chain. This underscores the need for companies to adopt a more structured and strategic approach to quality management across their supplier base. Therefore, one broad recommendation is for organizations to develop a standardized SQM framework that encompasses regular audits, performance evaluations and continuous improvement mechanisms.

A further recommendation is the integration of advanced technologies, such as artificial intelligence (AI), blockchain, and real-time monitoring tools, into supplier quality management process. The study showed a moderate but significant interest among respondents in using such technologies to enhance SQM outcomes. This points to a need for organizational investment in digital transformation, particularly in systems that provide transparency, traceability and predictive insights into supplier performance.

Another area of focus should be the refinement of quality agreements and enforcement mechanisms. The results suggested mixed effectiveness of existing quality agreements in maintaining supplier accountability. Organizations are encouraged to revisit the structure and content of their quality agreements to ensure clarity, enforceability and alignment with both regulatory standards and business goals. Agreements should also include provisions for penalties, performance-based incentives and escalation procedures to address non-compliance swiftly.

The analysis further revealed that challenges such as lack of technological infrastructure, insufficient supplier training and regulatory complexity continue to impede SQM implementation. To address these issues, companies should work towards building internal capacity and fostering a culture of quality across the supply chain. This includes implementing risk-based supplier assessment models combined with enhanced audit frequencies, offering training programs for suppliers, engaging in joint quality improvement initiatives, and simplifying compliance procedures where possible (Ivanov, 2021).

5.3 Limitations and Future Scope

One of the primary limitations of this study lies in its sample size. Although a sufficient number of responses were collected to conduct meaningful statistical analyses (including correlation, regression, and ANOVA), the study was limited to a particular group of respondents. This may limit the generalizability of the findings to broader industrial contexts. Future research should consider a larger and more diverse sample to enhance external validity and to better understand cross-sectoral differences in SQM implementation.

Additionally, this study focused on a defined set of variables related to SQM such as supplier audits, regulatory compliance, technological integration, and the impact on cost efficiency and supply chain reliability. However, other potentially influential factors such as organizational culture, leadership commitment, supplier development strategies or geopolitical risks were not explored. Future researchers could expand the scope to include these variables and examine their interactive or moderating effects on SQM outcomes.

While respondents expressed interest or noted their company's use of such technologies, the study did not assess the actual extent of implementation, technical maturity or return on investment. Future research could explore how specific digital tools are integrated into SQM frameworks, what barriers exist to their adoption, and how their usage correlates with tangible improvements in quality performance and compliance metrics.

Another limitation is related to time-bound data. The survey captured responses at a single point in time, offering a cross-sectional view of SQM practices. However, quality management is dynamic, and its effectiveness evolves as systems mature and as suppliers develop. Longitudinal studies tracking changes over time would provide a more comprehensive understanding of how organizations adapt their SQM strategies in response to external pressures, regulatory changes, or internal performance outcomes.

Furthermore, while the regression model in the study showed a statistically significant relationship between certain predictor variables and the implementation of SQM practices, the R-square value indicated that only a portion of the variance was explained by the model. This suggests that there are other influential factors not accounted for in the current research. Future studies should aim to

build more robust predictive models using additional variables and possibly exploring advanced analytical techniques to understand the causal relationships within SQM frameworks.

In conclusion, although the study provides valuable insights into the correlation and influence of key factors on supplier quality management, the limitations around sample size, data type, variable scope and methodological constraints suggest the need for future research to build upon and refine these findings.

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APPENDICES

Appendix A: Ethics Application & Declaration Form

Innopharma education

Ethics Application & Declaration Form

DISSERTATION TITLE: **Evaluating the Effectiveness of Supplier Quality Management Practices in Enhancing Supply Chain Performance of Pharmaceutical Quality Management Systems.**

RESEARCHER'S NAME: **Anusha Thula**

PROGRAMME OF STUDY: **Master of Science in Pharmaceutical Business and technology.**

SUPERVISOR'S NAME: **Chiamaka Chiedozie**

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:

T Anusha

DATE: 12/03/2025

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

For Supervisor:

Ethics Committee Approval Required: Yes ☐ No ☑

SUPERVISOR SIGNATURE:

DATE: 18/3/2025

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

Pharmaceutical Quality Management Systems (QMS) are designed to ensure that products consistently meet quality standards within pharmaceutical operations. However, supplier performance has a significant impact on these systems making Supplier Quality Management (SQM) practices integral part of quality systems. Despite the critical role of supplier quality management in the pharmaceutical industry, there is need for more research to evaluate how supplier quality management practices enhance supply chain performance (SCP) and the research topic intends to focus on understanding the relationship and effectiveness of supplier quality management practices and their influence on supply chain performance within pharmaceutical quality management Systems. For maintaining product integrity together with the reduction of supply chain disruptions and regulatory compliance such as Good Manufacturing Practices (GMP) and guidelines from FDA, EMA, and ICH requires effective Supplier Quality Management (SQM) practices in pharmaceutical operations.

Objectives of the research:

- To explore the effect of supplier quality management practices on the overall performance of pharmaceutical supply chains, focusing on key quality indicators such as cost efficiency, product integrity, lead times and supply chain reliability.
- To assess the main challenges and barriers in implementing effective supplier quality management practices by pharmaceutical companies.
- To investigate the role of technology and digitalisation in enhancing supplier quality management practices like real-time monitoring tools, AI-driven analytics and use of blockchain.
- To determine the influence of quality agreements between pharmaceutical companies and suppliers on regulatory compliance and product safety.
- To identify how pharmaceutical companies manage quality risks by integrating supplier quality management practises when dealing with multiple suppliers across various global standards.

1.2 Research methodology:

A quantitative cross-sectional research design along with structured online surveys will enable the collection of primary data from pharmaceutical supply chain professionals. The use of structured surveys, supplier performance databases and statistical analysis aligns with the positivist philosophy, allowing for the identification of patterns, correlations in supplier quality management practices and ensures accuracy, consistency and validity for achieving real-time data findings. By focusing on quantitative methods, research will examine lead times, compliance scores and overall supply chain efficiency. Participants will include quality managers, procurement officers and supply chain professionals.

The research instrument for data collection for this study consists of a questionnaire containing closed-ended questions to evaluate the impact of supplier quality audits, compliance monitoring and digital quality management systems on supply chain performance. Random sample selection methods will be used to achieve diverse participation from pharmaceutical companies of various sizes. Testing of the questionnaire involves a pilot stage to confirm both clarity and reliability measures prior to its distribution process. The strategy for reaching target participants will include email distribution, google forms and LinkedIn usage together with communications through the industry networks.

A graphical analysis of the collected data will determine the connection between supply chain efficiency and Supplier quality management practices. The chosen method enables the research to obtain dependable results which enhance comprehension of preferred methods for pharmaceutical supplier quality management.

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

The research is aimed at supplier quality management professionals in the pharmaceutical sector, includes quality managers, procurement officers and supply chain professionals, regulatory affairs specialist, finance and risk management team with direct responsibility or must be employed in a pharmaceutical company involved in the manufacturing, validation

and distribution or supply of pharmaceutical products and possess significant insight into pharmaceutical supply chain management. The quality managers ensure GMP compliance and supplier audits while the procurement officers ensure supplier selection, quality agreements, and contract management. On the other hand, the supply chain professionals and risk management team ensure supplier performance, risk mitigation, and regulatory compliance.
These respondents are selected because they have hands-on experience in applying and overseeing supplier quality management (SQM) practices, thus being the best sources to assess the efficacy of SQM in improving supply chain performance. Their experience guarantees the study captures credible, industry-specific information on the challenges, obstacles, and technological developments impacting supplier quality.

4.2 How do you plan to gain access to/contact/approach your participant(s).
Participants will be recruited through random sampling to get a diverse representation from small, medium, and big pharmaceutical companies. The process will begin by out through LinkedIn, pharmaceutical industry networks, and professional associations. The survey invitations will be distributed by through email outreach to target companies. The pre-structured online survey will be sent through Google Forms or an equivalent platform. This multi-modal method optimizes response rates with ethical research approaches.

SECTION 5: INFORMATION, CONSENT AND CONFIDENTIALITY

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

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

SECTION 6: STORAGE OF DATA

6.1. How will you store the research data and for how long? How will you manage data protection issues?
Data collected from the research will be stored electronically in a secure password protected laptop and encrypted cloud storage server (Google Drive, OneDrive) that has access limitations for the researcher and supervisor only. Data will be stored up to 2 years from dissertation submission, and then deleted permanently.
For GDPR and data protection law compliance, the following measures will be taken. Participant responses will be anonymized and no personally identifiable information will be captured. Participants will be asked to read and sign a consent form prior to taking part. The data will not be disclosed to third parties, and survey answers will be kept in a password-protected area. The participants can ask for the data deletion at any time prior to the final analysis stage. All these steps ensure that participant privacy is guarded without losing data integrity and abiding by ethical research guidelines.

SECTION 7: NON-DISCLOSURE AGREEMENT & STUDENT CONSENT

7.1 **Non-Disclosure Agreement (NDA)**

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

No

7.2 **Student consent**

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

Yes

SECTION 8: RECORDING AND RETENTION OF DISSERTATION VIVA

8.1 **Viva Recording**

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

SECTION 9: DOCUMENT CHECKLIST

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

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

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

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

For Student:

STUDENT SIGNATURE:

DATE: 12/03/2025

Appendix B: Survey questionnaire

Research survey

Dear Respondent,

I am Anusha Thula, a post graduate student, carrying out a research study to evaluate the effectiveness of supplier quality management practices in enhancing supply chain performance of pharmaceutical quality management systems as part of completing my Master's degree in pharmaceutical business and technology through Griffith College/Innopharma, Dublin, Ireland and involves a comprehensive survey that aims to explore the effect of supplier quality management practices on the overall performance of pharmaceutical supply chains.

Your participation is valuable and will contribute significantly to the success of the study. The survey should take approximately 10 minutes, and all responses will be anonymous, confidential and handled in compliance with the current General Data protection Regulations (GDPR).

If you have any queries regarding the survey, please do not hesitate to contact me at anusha.thula@student.griffith.ie

Have you understood the purpose of the study?

- Yes
- No

Do you give consent to participate in this survey?

- Yes
- No

1. What is your current job role?

- Quality Manager
- Procurement Officer
- Supply Chain Professional
- Other

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

- Less than 2 years
- 2–5 years
- 6–10 years
- More than 10 years

3. What is the size of your company?

- Small (Less than 50 employees)
- Medium (50–500 employees)

- Large (More than 500 employees)

4. In which region does your company primarily operate?

- North America
- Europe
- Asia-Pacific
- Other

5. How frequently does your company conduct supplier audits?

- Annually
- Bi-annually
- Quarterly
- Rarely/Never

6. What supplier quality management practices are implemented in your company?

- Supplier qualification and selection criteria
- Supplier audits and performance evaluations
- Digital tracking systems (e.g., blockchain, AI analytics)
- Quality agreements with suppliers
- Risk-based supplier management

7. How effective are your company's supplier quality management practices in ensuring regulatory compliance?

- Very effective
- Somewhat effective
- Neutral
- Somewhat ineffective
- Very ineffective

8. To what extent does your company use technology (AI, blockchain, real-time monitoring) to enhance supplier quality management?

- Fully integrated in operations
- Partially integrated
- Limited use
- Not used at all

9. How would you rate the impact of supplier quality management on cost efficiency in your company?

- Significant positive impact
- Somewhat positive impact
- Neutral
- Somewhat negative impact
- Significant negative impact

10. To what extent do supplier quality management practices affect supply chain reliability in your organization?

- Highly improves reliability
- Somewhat improves reliability
- No impact
- Somewhat reduces reliability
- Significantly reduces reliability

11. How does your company handle supplier non-compliance issues?

- Immediate termination of contract
- Issuance of corrective actions
- Increased monitoring and supplier training
- No formal procedures in place

12. How effective are quality agreements in maintaining supplier accountability?

- Very effective
- Somewhat effective
- Neutral
- Somewhat ineffective
- Very ineffective

13. What are the biggest challenges in implementing supplier quality management practices in your company?

- High costs of implementation
- Regulatory compliance complexities
- Resistance from suppliers
- Lack of technological infrastructure
- Other (please specify)

14. In your opinion, what improvements would enhance supplier quality management effectiveness? (Select all that apply)

- Stronger regulatory enforcement
- Increased use of digital tracking tools
- More frequent supplier audits
- Better supplier training programs
- Enhanced risk management strategies

15. Would you be interested in adopting AI-driven analytics or blockchain solutions to enhance supplier quality management in the future?

- Yes, definitely
- Maybe
- No