YANGON UNIVERSITY OF ECONOMICS

DEPARTMENT OF MANAGEMENT STUDIES

MBA PROGRAMME

EFFECT OF QUALITY MANAGEMENT PRACTICES ON FIRM PERFORMANCE AT PHARMACEUTICAL FACTORY (INSEIN)

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EMBA II – 63

EMBA 20th BATCH (ONLINE)

JUNE, 2025

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ACADEMIC YEAR (2023-2025)

Supervised By:

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This thesis is submitted to the Board of Examiner in partial fulfillment of the requirements for the degree of Master of Business Administration (MBA).

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ACCEPTANCE

This is to certify that the thesis entitled "**Effect of Quality Management Practices on Firm Performance at Pharmaceutical Factory (Insein)**" has been accepted by the Examination Board for awarding Master of Business Administration (MBA) degree.

Board of Examiners

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ABSTRACT

This study aims to analyze the effect of quality management practices on firm performance and to analyze the mediating effect of the organizational capability on the relationship between quality management practices and firm performance at pharmaceutical Factory (Insein). Both primary and secondary data are utilized. There are total 102 managers. Questionnaire survey method is used to collect data. The sample size is determined using the Raosoft sample size calculator. Primary data is collected from 81 out of 102 managers who have the best knowledge about the operation and quality management practices in Pharmaceutical Factory (Insein) using simple random sampling method. Descriptive statistics and regression analysis are used to analyze the data. Among the variables, continuous improvement and customer focus have positive and significant effect on firm performance while top management commitment does not have significant effect on firm performance. Moreover, the study finds that organizational capability has a mediating effect on the relationship between quality management practices and firm performance. Pharmaceutical Factory (Insein) should consider reconsidering the emphasis on top management commitment with its strategic frameworks. Pharmaceutical Factory (Insein) should focus on continuous improvement and customer focus to yield more significant returns and improve firm performance.

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LIST OF ABBREVIATIONS

CPPs	Critical Process Parameters
CQAs	Critical Quality Attributes
CAPA	Corrective and Preventive Actions
GMP	Good Manufacturing Practices
ISO	International Standardization for Organization
KPI	Key Performance Indicator
OOS	Out of Specification
OOT	Out of Trend
PDCA	Plan-Do-Check-Act
PDSA	Plan-D0- Study-Act
QbD	Quality by Design
QMPs	Quality Management Practices
QMS	Quality Management System

CHAPTER 1
INTRODUCTION

Nowadays, quality management practices have been widely adopted in most organizations to enhance organizational performance. All manufacturing companies strive to adopt and implement proven quality management practices that have been effective in other organizations (Fassoula, 2006). Quality management practices is a critical role in the pharmaceutical industry. It ensures that all pharmaceutical products for human consumption are safe, efficient, and qualified. The pharmaceutical industry is highly regulated, and quality management is crucial in meeting regulatory requirements. Poor quality management practices can negatively impact patient safety, result in costly product recalls, and tarnish the reputation of a pharmaceutical factory. To increase performance, organizations have implemented a variety of quality management systems, including ISO, just-in-time concepts, and quality management practices. The most widely recognized quality concepts are ISO and quality management practices. The underlying philosophy of quality management practices is that quality assurance serves as the foundation of quality management systems (Wanyoike, 2016).

Quality management practices are defined as a set of principles, tools, and methodologies used to monitor, control, and improve quality at every stage of production (Wanyoike, 2016). Quality management practices are best practices of management, such as continuous improvement, customer focus and top management commitment to achieve a continual quality improvement (Mulyungi, 2018). Quality management system (QMS) based on quality management practices serves as a fundamental framework for other quality management methods, ultimately improving performance (Taylor, 1997). According to Lin and Jang (2008), total quality management serves as the foundation for various quality management practices. Quality management practices include continuous improvement, customer focus and top management commitment (Wanyoike, 2016).

Continuous improvement is defined as a process that aims to optimize information, physical flows and products in order to control production costs and quality (Coutarel et al., 2010). It involves a systematic approach to identifying, analyzing, and implementing improvements through methodologies such as plan-do-check-act (PDCA), six sigma, Kaizen, and quality management practices**.** The goal is to ensure consistent quality,

customer satisfaction, regulatory compliance, and competitive advantage while fostering a culture of innovation and excellence within the organization (Fassoula, 2006).

Customer focus is defined as a business strategy that prioritizes understanding and meeting customer needs, expectations, and satisfaction, aiming to build strong relationships and drive loyalty (Mulyungi, 2018). Customer focus is a business philosophy that places the customer at the center of all business development and management decisions. Elvira and Shpetim (2016) stated that customer satisfaction can be impacted by various issues, including service features, consumer emotions, customer perception, workplace colleagues, friends, and family. Hapsari et al. (2017) stated that customer satisfaction is influenced in most instances by the customer service a given organization offers as well as the price it charges for such service.

Top management commitment refers to the active and continuous involvement, support, and leadership of an organization's senior executives in implementing and sustaining quality management systems (Kanji, 1990). It ensures that quality is a strategic priority, integrated into the company's culture, policies, and objectives. The key aspects of top management commitment in quality management practices are setting a clear quality vision and policy, resource allocation, leadership and engagement, customer focus, compliance and continuous improvement, performance monitoring and review. Top management commitment is crucial for driving operational efficiency, regulatory compliance, and continuous improvement, which ultimately enhances competitive advantage and overall organizational performance (Kanji, 1990).

Organizational capability is defined as the ability of an organization to perform a coordinated set of tasks, utilizing organizational resources, for the purpose of achieving a particular end result (Helfat & Peteraf, 2003). Organizational capability is fundamental to firms` ability to solve effectively the organizational problems. It includes a process-orientation that streamlines workflows and operations for greater efficiency and consistency, along with a strong quality culture that promotes continuous improvement, customer satisfaction, and excellence. By integrating both elements, organizational capability strengthens performance, ensures regulatory compliance, and enables businesses to adapt to evolving market demands (Dosi et al., 2000). Organizational capability includes process orientation and quality culture (Wanyoike, 2016).

Process orientation is defined as the organizational effort required making business processes the platform for organizational structure and strategic planning (Suter, 2009). Process orientation means focusing on business processes rather than emphasizing

functional structure or hierarchy (Dosi et al., 2000). Quality culture refers to an organizational culture where all stakeholders, both internal and external, actively participate in enhancing quality through critical reflection (Bendermacher & Egbrink, 2016).

Firm performance refers to the overall success of any firm, which is influenced by the performance of individuals within the firm and the systems in place to support them (Lai et al., 2008). Firm performance is composed of two dimensions: financial and market performance. Financial performance referred to revenue growth and profitability, while market performance was about improving a firm's position against its competitors (Mithas et al., 2011). Freeman (2004) defined firm performance as the total value created by the firm through its activities, which is the sum of the utility created for each of a firm's legitimate stakeholders.

Firm performance measures are used to prove that quality management practices help in stepping up efficiency in the firm, leading to high performance (Wanyoike, 2016). For the purpose of this study, firm performance measures are defined in terms of productivity, effectiveness and employee satisfaction (Wanyoike, 2016). Numerous firms have found that focusing on and implementing product and quality management practices as a strategic tool to improve company performance is essential to firm performance and competitive success (Lai et al., 2008).

There are eleven local pharmaceuticals factory including state-owned and private owned in Myanmar. Among them, Pharmaceutical Factory (Insein) is the foremost and largest pharmaceutical factory. It was founded in 1954 and producing wide range of pharmaceutical products. Pharmaceutical Factory (Insein) is the state-owned and under the supervision of Myanmar Pharmaceutical Industrial Enterprise, Ministry of Industry. Pharmaceutical Factory (Insein) produces only 15% of the domestic medicine needs. Pharmaceutical Factory (Insein) received ISO 9001, ISO 45001 and ISO 17025. It plays a key role in providing essential medicines for the country, making its performance vital for the nation. This study investigates the mediating effect of organizational capability on the relationship between quality management practices and firm performance.

1.1 Rationale of the Study

The pharmaceutical industry is essential for public health because it ensures that people have access to safe and effective medicines. As the demand for medicines grows, it

is crucial to have strong manufacturing processes to maintain consistent quality. In Myanmar, the pharmaceutical sector plays a particularly important role in improving health outcomes and supporting economic development. The Pharmaceutical Factory (Insein) plays a key role in providing essential medicines for the country, making its performance vital for the nation.

Firm performance in the pharmaceutical industry involves not only efficiency and productivity but also the ability to meet stringent regulatory standards and adapt to dynamic healthcare needs. High-performing firms consistently deliver safe, reliable, and innovative products. For government-owned institutions like the Pharmaceutical Factory (Insein), achieving high firm performance ensures that public resources are used effectively and that national healthcare goals are met. Poor firm performance can result in operational inefficiencies, increased costs, substandard product quality, and a decline in public trust.

The process orientation and quality culture are critical to enhancing firm performance. Process orientation is crucial for high firm performance because it ensures that organizational activities are systematically designed, managed, and aligned to improve efficiency, reduce variability, and maintain consistency across departments. This structured approach supports adherence to regulatory standards such as Good Manufacturing Practices (GMP) and optimizes resource utilization. Quality culture is essential for high firm performance because it fosters a shared commitment to excellence, continuous improvement, and customer satisfaction across all levels of the organization. Moreover, a strong quality culture enhances employee engagement, encourages proactive problem-solving, and supports compliance with regulatory and industry standards.

Quality management practices are critical for improving firm performance. When process orientation and quality culture are embedded in daily operations, quality management practices become more than a compliance activity—it becomes a strategic tool for success of firm performance. In particular, continuous improvement, customer focus, and top management commitment are vital components of quality management that drive firm performance. In the pharmaceutical industry, continuous improvement is vital for managing rising costs, increasing productivity and flexibility, adopting new technologies and maintaining high standards of quality and value. Continuous improvement fosters innovation and operational excellence; customer focus ensures the development of products that meet patient needs and build trust; and top management commitment ensures that quality is a central pillar of organizational strategy and resource allocation.

This study aims to understand how these quality management practices, supported by process orientation and a quality culture, affect the firm performance of the Pharmaceutical Factory (Insein). The findings can offer practical insights to improve the firm's performance, product quality, and competitiveness. Moreover, the study contributes to broader knowledge on how organizational capability and quality management practices can enhance firm performance in pharmaceutical manufacturing—insights that can benefit similar public and private institutions in Myanmar.

1.2 Objectives of the Study

The objectives of the study are as follows:

(1) To analyze the effect of quality management practices on firm performance at Pharmaceutical Factory (Insein), and

(2) To analyze the mediating effect of the organizational capability on the relationship between quality management practices and firm performance at Pharmaceutical Factory (Insein).

1.3 Scope and Method of the Study

This study focuses on quality management practices and firm performance at Pharmaceutical Factory (Insein). Both primary data and secondary data are used in this study. The population is 102 managers in 2025. The sample size is set at 81, as calculated by the Raosoft sample size calculator. The simple random sampling method is used to ensure each respondent has an equal chance of selection and to minimize sampling bias. The primary data is collected using questionnaire survey method from managers who have the best knowledge about the operation and quality management in Pharmaceutical Factory (Insein). Relevant secondary data is gathered from relevant texts, journals, other local MBA research papers from the library and other resources. Descriptive statistics and regression analysis are applied for data analysis.

1.4 Organization of the Study

This study is divided into five chapters. Chapter one involves an introduction, including the rationale of the study, objectives of the study, scope and method of the study and organization of the study. Chapter two covers the theoretical background of quality management practices, organizational capability, firm performance, previous study, and conceptual framework of the study. Chapter three describes the profile, organizational

structure, quality management practices, organizational capability of pharmaceutical Factory (Insein), respondents' profile and reliability analysis. Chapter four contains analysis on the effect of the quality management practices on firm performance at Pharmaceutical Factory (Insein). Chapter five includes the conclusions drawn from the findings and discussions, along with suggestions, recommendations, and needs for further research.

CHAPTER 2

THEORETICAL BACKGROUND

This chapter includes the highlights of the theoretical background of the study, which is the concept of quality management practices, organizational capability, and firm performance, previous study and the conceptual framework of the study.

2.1 Quality Management Practices

Quality management is a management philosophy that seeks to achieve and sustain high quality output by enhancing efficiency and effectiveness of processes (Salimian et al., 2021). Quality management helps organizations meet and exceed customer expectations while staying ahead of competitors (Agyei et al., 2021). It is based on principles, practices, and techniques, where principles guide actions, and practices are routine activities within the organization (Ukab, 2021).

Quality management practices are defined as the actions and procedures implemented to ensure the provision of high-quality products or services (Barros et al., 2014). Quality management practices refer to the activities undertaken routinely by a firm and are vital for successful quality performance and customer satisfaction (Sharma & Joshi, 2020). Quality management practices are routine activities that help improve product and service quality (Wambui & Bett, 2019). They also reduce costs, increase efficiency, boost productivity, and enhance financial performance. Quality management practices are the visible aspect of quality management through which managers strive to achieve organizational improvements (Sousa & Voss, 2002). Quality management principles are too general for empirical research, while quality management practices are too specific to obtain reliable results. Senior management can use quality management principles as a framework to guide their organizations toward improved performance. These principles can be applied in various ways, depending on the organization's nature and the unique challenges it encounters.

Quality management practices greatly influence both internal process and product quality, as well as operational performance. The relationship between quality management principles and practices and organizational performance indicates a positive link between the implementation of quality management practices and improvements in organizational

performance (Sampaio et al., 2009). Manufacturing organizations perform better when they use quality management practices (Terziovski & Samson, 1999). Quality management practices are managerial actions related to quality management activities (Flynn et al., 1995).Quality management practices enhance product quality and reduce scrap and rework, leading to lower production costs and shorter production times (Orwig & Brennan, 2000)). Additionally, quality management practices empower participants to reach the full potential and achieve objectives through cooperation and mutual learning, thereby contributing positively to performance (Stefan & Yvonne, 2012). Quality management practices include continuous improvement, customer focus and top management commitment (Wanyoike, 2016).

2.1.1 Continuous Improvement

Continuous improvement is defined as a set of practices that are used to improve processes of business for long-standing performance and cost improvements (Jimoh et al., 2016). Continuous improvement involves the ongoing enhancement of products, services, or processes through either small, incremental changes or significant, breakthrough advancements. To encourage participation across the organization, it is essential to provide employees with the necessary training (Needle, 2023). Continuous improvement is described as an ongoing company-wide process focused on small, continuous innovations (Bessant et al., 1994). Continuous improvement is seen as efforts aimed at increasing success and reducing failures (Juergensen, 2000). Some consider continuous improvement as a part of quality management practices, while others view it as a separate approach to achieving market excellence and fostering creativity (Oakland, 1999). Maintaining total quality requires continuous improvement to improve at all levels of an organization (Kossoff, 1993).

In quality management practices, continuous improvement is crucial for enhancing work processes and consistently delivering high-quality products or services. Continuous improvement also focuses on developing employees' skills, which benefits both the organization and the employees. According to Bangert (2019), the PDSA Cycle (plan-do-study-act) is a structured method for continuous improvement, providing valuable insights and learning. This cycle can be repeated to solve new problems or address ongoing issues. To remain competitive, healthcare providers—from primary care physicians to large medical centers—and suppliers, including laboratories and pharmaceutical companies,

must incorporate rapid continuous improvement and quality management practices into their strategic planning processes (Swinehart & Green, 1995).

2.1.2 Customer Focus

Customer focus means meeting the needs and expectations of current and potential customers by developing a comprehensive understanding of customer needs and then delivering perceived value to customers (Sharabi, 2015). Customer-focused strategy includes delivering value to customers, fostering customer loyalty, and ultimately enhancing business profitability. For an effective customer-focused quality management process, it is essential to identify customers' needs, preferences, and challenges. This information can be gathered through creating buyer persons, collecting customer reviews and feedback, and conducting customer interviews (Needle, 2023). It is crucial for everyone in the organization to have a clear understanding of the organization's customers, suppliers, and competitors. Organizations should be open to making adjustments based on customer feedback and should actively respond to customer needs.

Customer focus is described as putting customers' interests first while still considering other stakeholders like owners, managers, and employees to ensure long-term business success (Deshpande et al., 1993). Customers can be both internal (employees) and external (consumers). To serve external customers well, businesses should also take good care of their employees (Conduit & Mavondo, 2001). Customer focus is not just about direct interactions with customers. It applies to many areas of business, including product design, handling complaints, and building long-term relationships. Considering these points, customer focus is defined as an organization's commitment to understanding and meeting the needs, wants, and expectations of both current and future customers in a proactive way to ensure long-term success (Needle, 2023). A customer-focused culture encourages employees to take actions that align with this mindset. Customer focus cannot be achieved by just improving small service details (Nwankwo, 1995). Instead, it must be deeply embedded in the organization's culture (Kennedy et al., 2002).

Customer focus is described as a company culture that creates the right behaviors to deliver high value to customers, leading to long-term business success (Narver & Slater, 1990). A company must ensure that all employees share the belief that the business exists to meet customer needs. This mindset can be present in every department and work culture within the organization. Employees can understand how to respond to different situations in a consistent, customer-focused way. When this culture is strong, the organization as a

whole is likely to perform better (Mallak et al., 2003). A company can provide consistently excellent customer service only if it has a deeply ingrained customer-focused culture. Since customer focus is linked to better service quality, higher customer and employee satisfaction, and greater profitability, businesses have strong reasons to develop and maintain this culture (Agarwal et al., 2003).

2.1.3 Top Management Commitment

Top management commitment refers to direct participation by the highest-level executives in a specific and critically important, aspect or program of an organization (Mallak et al., 2003). It includes setting up and serving on a quality committee, formulating and establishing quality policies and objectives, providing resources and training, overseeing implementation at all levels of the organization, and evaluating and revising relevant policies in light of results achieved.

Top management commitment is crucial for driving quality management practices because it helps set the right priorities and ensures commitment to quality management principles throughout the organization (Lawler, 1992). Many quality issues are seen as management challenges that need to be addressed through the management structure (Talib & Rahman, 2010). When top management is committed, it helps organizations achieve their quality goals more effectively. Their involvement is essential for strategic planning, setting values and goals, meeting customer expectations, and implementing quality management practices across the organization, which leads to better performance (Lawler, 1992). According to Javed (2015), senior leaders are responsible for creating systems that impact how products and services are designed and delivered. Therefore, quality improvement should start with leadership's commitment to quality. Top management should also participate in improvement efforts to align strategies and goals with market demands and customer needs, leading to better organizational performance and profitability (Oparinde, 2019).

Top management commitment should be shown through actions, not just words or policy statements (Talib & Rahman, 2010). Leaders must use their influence to motivate others and identify key success factors while reviewing management structures (Yusuf et al., 2007). Strong leaders inspire their teams through high moral standards, motivation, intellectual stimulation, and personal attention (Javed, 2015).

2.2 Organizational Capability

Organizational capability is defined as a firm`s capacity to deploy its resources, tangible or intangible, to perform a task or activity to improve performance (Teece et al., 1997). Organizational capability is considered to be the most intangible resources of a company, playing a crucial role in achieving high performance (Tomer, 1987). From a strategic management point of view, how a company organizes its efforts can be a strength that gives it a competitive edge and helps it perform better (Barney, 2001). These organizational capabilities provide the environment in which employees contribute to the organization's growth, service, or other organizations' goals. Ultimately, these goals are reflected in some form of performance measurement (Poksinska et al., 2002).

Organizational capability refers to an organization's ability to effectively integrate, manage, and optimize its resources—people, processes, and technologies—to achieve strategic objectives and sustain competitive advantage (Zu, 2009). It encompasses process orientation**,** which focuses on aligning workflows and operations for efficiency and consistency, and quality culture, which instills a commitment to continuous improvement, customer satisfaction, and excellence (Collis, 1994). The process orientation and quality culture enable businesses to enhance performance, ensure regulatory compliance, and adapt to dynamic market demands (Winter, 2003).

2.2.1 Process Orientation

Process orientation refers to focusing on business processes ranging from customer to customer instead of placing emphasis on functional structures (Reijers, 2006). It enhances on improving an organization's efficiency through high-level coordination of an organization's activities in a rationalized system of end-to-end processes (Benner & Tushman, 2002). Process orientation is a management approach that focuses on aligning workflows, activities, and systems to optimize efficiency, consistency, and customer satisfaction. It emphasizes end-to-end process management rather than isolated functional improvements, ensuring that all departments work cohesively toward organizational goals (Zu, 2009).

Frei et al. (1999) provided empirical evidence supporting the positive impact of process orientation on business performance. Adopting a process-oriented approach can directly enhance customer satisfaction. Customer satisfaction contributes to increased market value and financial returns, thereby reinforcing the connection between process orientation and tangible business success (Ittner & Larcker, 1997). Process orientation

improves business performance, reduces interdepartmental conflicts, and enhances team spirit (McCormack, 2001). Similarly, Gustafsson and Nilsson (2003) confirmed a direct link between process orientation and customer satisfaction. In the modern business environment, process orientation appears to be an attractive and effective organizational approach. Process orientation has a direct and positive influence on business outcomes. Additionally, by increasing process transparency, it fosters a culture of continuous improvement and facilitates reengineering efforts. While process orientation may seem essential and advantageous, it is important to recognize that many professionals still operate within traditional bureaucratic structures characterized by task fragmentation, specialization, and rigid hierarchies (Buchanan, 1998).

2.2.2 Quality Culture

Quality culture is a system of shared values, beliefs and norms that focuses on delighting customers and continuously improving the quality of products and services (Khatri et al., 2009). In an organization with a quality culture, quality is deeply embedded in virtually every aspect of organizational life, including hiring and promotion, employee orientation and ongoing training, compensation, management style, decision making, organizational structure, work processes and office layout. In a quality culture, quality is a way of life; quality principles are mirrored in organizational practices and behaviors.

Quality culture refers to the collective values, beliefs, and behaviors within an organization that prioritize quality in all processes, products, and services (Zu, 2009). A strong quality culture fosters continuous improvement, proactive problem-solving, employee involvement, and customer focus, ensuring that quality remains a fundamental and integrated aspect of the organization's operations and decision-making.

Building a quality culture involves intentionally choosing values, methods, and tools to continuously improve an organization’s processes and better serve its customers (Nilsson-Witell et al., 2005). Quality culture refers to the shared patterns of behavior, beliefs, and values that a group, organization, or society adopts to solve problems (Ahmed et al., 1999). It includes both formal systems and underlying norms that influence behavior. Quality culture plays a crucial role in driving commitment to change (Kotter & Heskett, 1992). A strong quality culture is essential for the success of quality management (Westbrook, 1993). An organization with a quality culture is one that has clear values and beliefs that promote total quality behavior. Changing an organization’s culture is increasingly seen as a key requirement for successfully implementing quality management

practices (Hildebrandt et al., 1991). Leading quality experts emphasized the need to transform cultural elements to support continuous quality improvement and highlighted the importance of shifting perceptions and attitudes toward quality as a foundation for major quality improvements (Sommerville & Sulaiman, 1997). In fact, quality management itself aims to change quality culture, but in many cases, cultural change is also a necessary first step before implementing quality management practices (Hildebrandt et al., 1991).

2.3 Firm Performance

Firm performance can be defined and measured in terms of profitability, growth, market value, total return on shareholder, economic value added, customer satisfaction, based on the stakeholder's expectations (Carroll, 2004). Traditionally, financial analysis has been used to measure firm performance, as it helps investors, decision-makers, and other stakeholders assess how well a company is doing (Delen et al., 2013). Many experts see firm performance as mainly financial performance, but others argue that stakeholders care about more than just finances (Harrison & Wicks, 2013). Firm performance includes the total value created for all legitimate stakeholders (Freeman et al., 2004). Hansen and Wernerfelt (1989) identified that firm performance depends on organizational, environmental, and human factors that shape the workplace atmosphere, which influences behavior and performance.

Firm performance is defined as the total value created by the firm through its activities, which is the sum of the utility created for each of a firm's legitimate stakeholders (Freeman et al., 2004). While quality management practices are linked to better firm performance, researchers have different views on their impact. Some believe only soft quality management practices improve performance while others argue that hard quality management practices work independently (Agyei et al., 2021). Implementing all quality management practices helps organizations improve effectiveness and quality performance (Sharma & Joshi, 2020). Good firm performance gives companies a competitive advantage in a highly competitive market (Psomas & Kafetzopoulos, 2012). Firm performance means how well a firm is doing in reaching its goals, which are based on its vision, mission, and strategy. It shows how effectively the firm uses its resources. Firm performance measurement helps check how successful the firm is in meeting its targets, based on set standards. This process also helps identify any issues and make continuous improvements (Hery, 2017).

High firm performance is the result of the effective integration of quality management practices and strong organizational capabilities (Tantalo & Priem, 2016). Quality management practices—such as continuous improvement, customer focus, top management commitment, and process control—help organizations maintain high standards, reduce errors, and enhance customer satisfaction (Iazzolino et al., 2014). Organizational capabilities, including process orientation, quality culture, innovation capacity, and adaptive learning, enable firms to effectively implement and sustain these quality initiatives (Kaplan & Norton, 1996). According to Kaynak (2003), there is a positive relationship between total quality management practices, firm performance, and organizational effectiveness, especially when supported by internal capabilities. Firms that build strong capabilities and embed quality practices into their core operations are better positioned to achieve sustained competitive advantage and high performance (Saeidi et al., 2015).

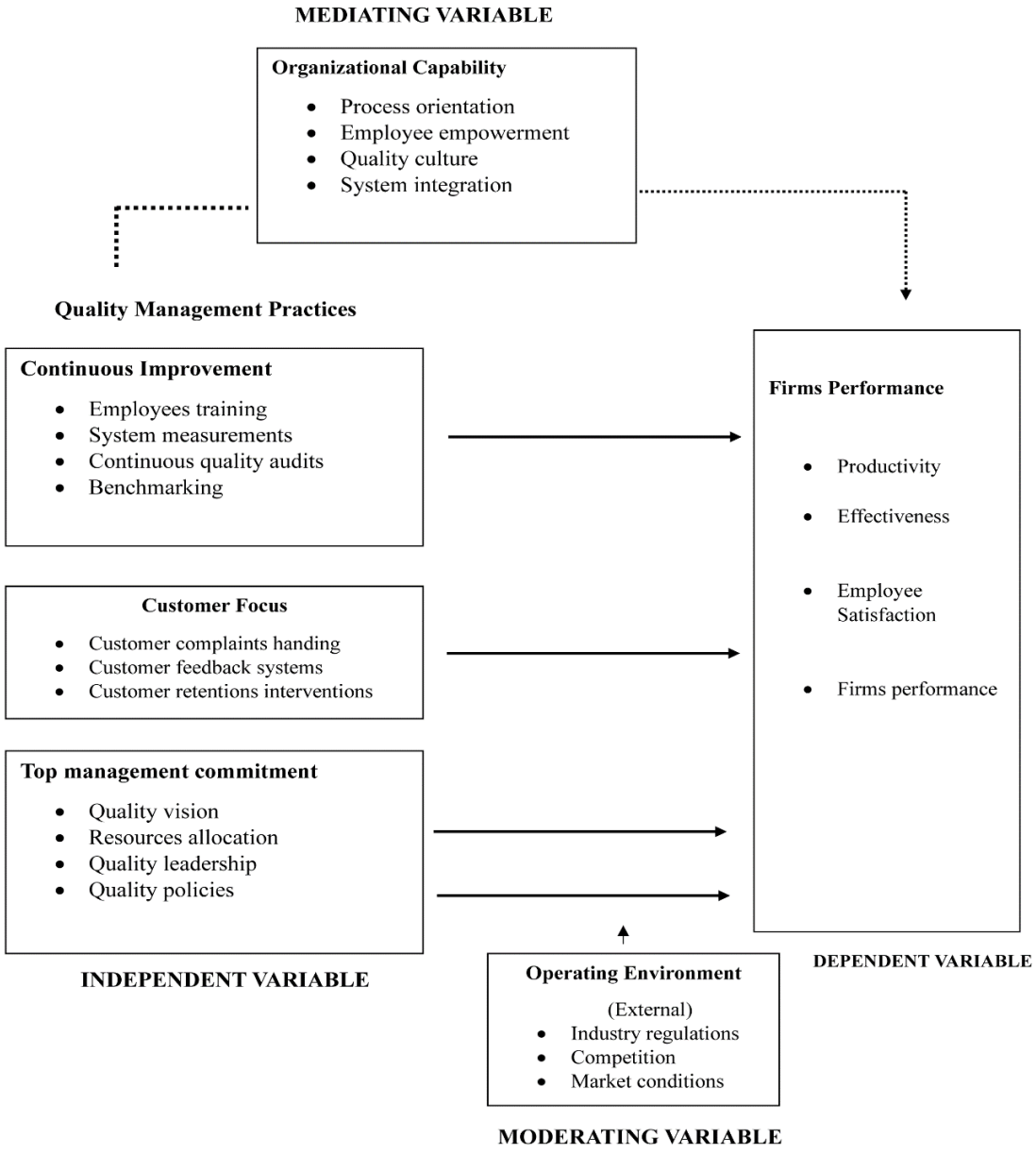
2.4 Previous Study

Several researchers studied about quality management practices, and organizational performance. Wanyoike (2016) conducted "Quality Management Practices and Firm Performance among Manufacturing Firms in Kenya". This study examined the effect of quality management practices and the performance of manufacturing firms in Kenya.

The study focused on 60 ISO-certified firms in Kenya, encompassing diverse industries such as consumer goods, agriculture, horticulture, and manufacturing. Due to the relatively small population size, a census approach was adopted, selecting two respondents from each firm—namely, quality assurance managers and internal auditors—resulting in a total of 120 participants. These respondents were chosen based on their expertise in policy formulation and the implementation of quality management practices. Data collection was conducted using structured, self-administered questionnaires designed to capture first-hand insights. The questionnaire was systematically divided into six sections, addressing general information, continuous improvement, customer focus, top management commitment, operating environment, organizational capability, and firm performance.

The following Figure (2.1) shows the conceptual framework of Wanyoike (2016).

Figure (2.1) Conceptual Framework of Wanyoike



Source: Wanyoike (2016)

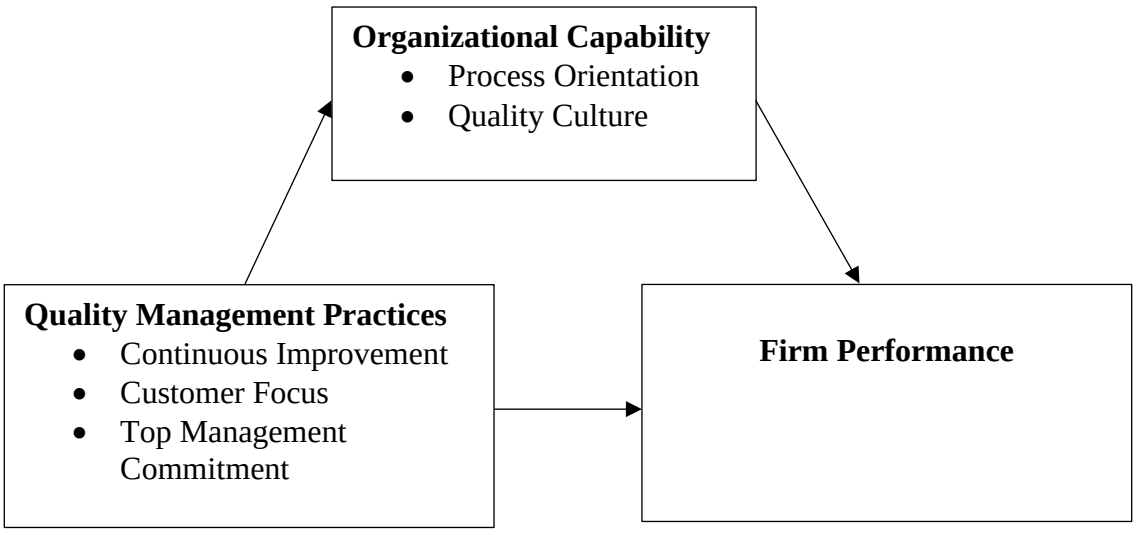
The result of this study showed that quality management practices had a significant effect on various performance results. The results showed that the main obstacles faced by the companies in Kenya were lack of employee participation, employee awareness and commitment, inadequate company structure and lack of resources. Additionally, organizational capability partially mediated this relationship, emphasizing the importance of employee empowerment and systems integration. The study also found that the operating

environment moderated the effect of quality management practices on performance, stating that firms must proactively adapt to changes for sustained success.

2.5 Conceptual Framework of the Study

This study focuses how quality management practices effect firm performance of pharmaceutical Factory (Insein) under Ministry of Industry. The objectives of this framework are to analyze the effect of quality management practices on firm performance at Pharmaceutical Factory (Insein) and to analyze the mediating effect of the organizational capability on the relationship between quality management practices and firm performance at Pharmaceutical Factory (Insein). The following Figure (2.2) shows the conceptual framework of the study.

Figure (2.2) Conceptual Framework of the Study



Source: Adapted from Wanyoike (2016)

This study has adapted from Wanyoike (2016), the framework represents two objectives of the study. For the first objective, three variables of quality management practices (continuous improvement, customer focus and top management commitment) are considered as independent variables, while firm performance as dependent variable. In second objective, the quality management practices serve as the independent variables, while firm performance acts as the dependent variable with the consideration of organizational capability (process orientation and quality culture) as a mediating variable.

CHAPTER 3

PROFILE AND QUALITY MANAGEMENT PRACTICES AT PHARMACEUTICAL FACTORY (INSEIN)

This chapter presents the profile and the organizational chart of Pharmaceutical Factory (Insein). Additionally, it explores the quality management practices and organizational capability of Pharmaceutical Factory (Insein), providing a foundation for understanding the firm's performance. In addition, this chapter also demonstrates the respondent's profile and reliability test according to the survey data results.

3.1 Profile of the Pharmaceutical Factory (Insein)

During world war II, many people in Myanmar suffered not only from the war itself but also from malnutrition and a severe shortage of medicines. These hardships highlighted the need for a local pharmaceutical factory. After Myanmar gained independence in 1948, building a pharmaceutical factory could help prevent the loss of foreign currency. It would help reduce reliance on foreign medicines, save foreign currency, and ensure a stable supply of essential drugs. The factory would also help the country prepare for emergencies, prevent shortages of rare medicines, and provide local people with the skills needed for pharmaceutical production. In August 1952, medicine and health were included as one of the 10 major projects in the first Pyi Taw Thar Conference.

In 1953, a team from the Ministry of Health was sent to England and other European countries to study the pharmaceutical industry. Based on their report, the national government council of ministers decided to form a special project implementation group that same year to carry out the plan. On October 20, 1953, Evans Medical Supplies Ltd., a well-known pharmaceutical company from Liverpool, England, signed a contract with the Union of Myanmar government to build a pharmaceutical factory in Myanmar. The contract included constructing and maintaining a modern facility. The factory aimed to produce a variety of medicines, including methylated spirit and yeast nutritional tablets.

In 1954, they decided to build a factory on 90 acres of land in the west ward of Gyogone, Insein Township, Yangon. On April 23rd, the Prime Minister laid the foundation stone of Pannetrai, and construction began in May of that year. The main pharmaceutical production building was completed in May. Part of the factory was used as a temporary

production unit, and some medicines were already being made. In January 1957, the biology department was established, followed by the distillery in February. The yeast factory was completed in July, and by August, all factory buildings were finished. The total construction cost was over 40 million kyats, with an additional 20 million kyats spent on machines and equipment, bringing the total to over 60 million kyats. By 1957, the factory began producing 41 types of medicines, 6 types of preventive and curative drugs, as well as alcohol, yeast, and yeast tablets.

The government of the Union of Myanmar signed a seven-year contract with Evan Pharmaceutical Supply Limited to supervise and manage the factory. The contract was set to last until October 20, 1960, but due to unavoidable circumstances, it was terminated early on January 31, 1959. In October 1960, the factory came under the supervision of the Myanmar Economic Development Corporation. After being nationalized in October 1964, it was managed by the Ministry of Industry under the industrial development corporation. From March 1972, it was placed under the supervision of the pharmaceutical and household appliances corporation.

According to the agreement between the Government of the Union of Myanmar and Evan Medical Supply Limited, foreign experts were first appointed as senior administrative officials. To replace them with Burmese experts in the future, scholars were sent abroad for training. The scholars were sent in three batches. The first batch, consisting of seven administrative-level employees, was sent abroad in July 1954 to gain expertise in high-level administration. In November 1954, three employees were sent as the second batch for supervisory-level training. The third batch, consisting of seven employees, was sent in April 1955.

Since 1975, the factory has been producing 41 types of medicines and 6 types of preventive treatments. Due to efforts of Burmese pharmacists, production improved, meeting quality standards. In addition to medicines, the factory expanded to produce household items, cosmetics, and premium alcohol. It also developed high-quality snake venom antidotes, rabies vaccines, antibiotics, and life-saving drugs to meet public needs. During this time, it became widely known as "Health Pillar BPI" among the people. Efforts are being made to replace imported pharmaceutical raw materials with locally sourced ones. Since 1980, sterile bandages have been sold to meet the needs of the Ministry of Military. In the same year, a project in Pakokku Township's Horse Breeding Division began, followed by the contact Lens Division in 1982. In 1985-86, Myanmar Traditional Medicine production started, and in 1988, the microbial medicine project expanded in Twintaung

Camp, Butalin Township, Sagaing Division, leading to the production of Provimin natural energy pills. Since the late 2000s, special pharmaceutical factory projects have focused on producing essential medicines. Pharmaceutical Factory No. 2 was established in 2002 in Pyin Oo Lwin, and a disposable needle and injection manufacturing factory Inyaung was launched in 2003. By the year 2000, a total of 246 medicines, including traditional medicines, had been produced. Some less effective drugs were discontinued. At that time, 184 types of western medicines and 11 types of traditional medicines were available.

The Pharmaceutical Factory (Insein) was established in 1954. Since 2016, new facilities — including the Snake Antivenom Plant, Warehouse, Cephalosporin Plant, and Small Volume Parenterals, Tablet, and Capsule Plants — have been constructed as part of the New BPI Projects, which were completed in 2018. Currently, the factory produces 200 types of Western medicines. Myanmar's pharmaceutical experts continue to work on developing more effective Western medicines to treat and prevent major diseases. The Pharmaceutical Factory (Insein) now manufactures tablets, capsules, syrups, creams, powders, injections, intravenous fluids, preventive treatments, and antibiotics.

Medicines produced by the Pharmaceutical Factory (Insein) are sold and distributed through the Ministry of Defense, the Ministry of Health, the Ministry of Labour, as well as to the public through sole agents and Win Thuzar shops. The Pharmaceutical Factory (Insein) produces medicines required by government ministries and the public, consistently setting and exceeding annual project targets. The factory follows good manufacturing practices (GMP) to ensure quality, safety, and compliance with established standards. The state's pharmaceutical needs are funded by the government budget. The factory is also certified with ISO 9001:2015 and ISO 45001:2018 and accredited with ISO/IEC 17025:2017. The factory’s motto, vision, and mission are defined as follows:

3.1.1 Vision

The visions of Pharmaceutical Factory (Insein) are

- to stand as a model pharmaceutical factory in pharmaceutical production sector in Myanmar.
- to be number one leading in pharmaceutical sector and integrated innovation in compliances with global standard and sustainable good governance.
- to provide safe work environment through implementation of proper occupational health and safety management system.

3.1.2 Mission

The missions of Pharmaceutical Factory (Insein) are

- to provide effective leadership for the pharmaceutical production sector by focusing on evidence-based policymaking, planning, monitoring, evaluation, collaboration and regulation.
- to promote knowledge and skills of employees by giving continuous training and making research.
- to conduct with leaders who have impeccable moral values.
- to supply efficiency, potentiality and quality in compliance with international standards.
- to promote and support the occupational health and safety at work continuously.
- to operate and manage the business in transparency, honestly, equitable and accountable manners to maximize the sustainable benefits to customers, employees, organization, society and environment.
- to promote knowledge of occupational health and safety through available methods such as awareness training, tool box meeting, display at notice board, etc.
- to provide necessary personal protective equipment.

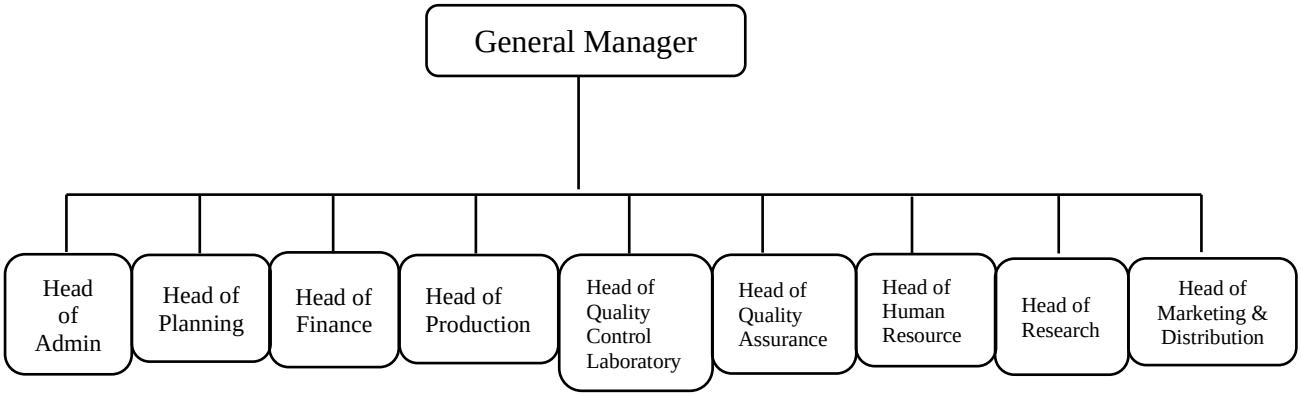
3.1.3 Motto

The Motto of Pharmaceutical Factory (Insein**)** is **"**Excellence through Competence''.

3.2 Organizational Structure of Pharmaceutical Factory (Insein)

The organizational structure of Pharmaceutical Factory (Insein) is shown in the following Figure (3.1).

Figure (3.1) Organizational Structure of Pharmaceutical Factory (Insein)



Source: Pharmaceutical Factory (Insein) (2025)

At the Pharmaceutical Factory (Insein), there are nine main departments working under the supervision of the general manager, who is responsible for the overall operation and performance of the factory. Each department is led by a deputy general manager (head of department), supported by an assistant general manager (assistant head). Below them are managers, who oversee the daily activities of their teams. Supervisors and assistant supervisors manage the frontline staff, while technicians and other employees carry out practical tasks.

(a) Administration Department

The administration department plays a key role in supporting the daily operations of the Pharmaceutical Factory (Insein). It is responsible for managing general office work such as handling correspondence, organizing meetings, maintaining office records, and filing important documents. This department also takes care of the maintenance of factory buildings, including regular repairs, sanitation, and ensuring a clean and safe working environment. It supervises security services to protect factory premises, assets, and employees, including managing security staff and CCTV systems. In addition, the department handles the transportation needs of the factory, such as arranging vehicles for staff, distribution, and official travel, and ensuring vehicle maintenance and fuel

management. The administration department also supports interdepartmental coordination by helping to organize meetings between departments, distributing official notices, and ensuring smooth internal communication. It works closely with other departments to provide logistical support and supplies, making sure that each unit has the necessary materials and resources to carry out its functions effectively. By managing these essential services, the administration department ensures the factory runs smoothly and efficiently on a daily basis.

(b) Planning Department

The planning department plays a vital role in ensuring that pharmaceutical production runs smoothly and on time. This department is responsible for preparing detailed production schedules based on product demand, available resources, and delivery timelines. It carefully plans how much of each product needs to be manufactured and when, while also making sure that the required equipment, labor, and materials are available. One of its key tasks is forecasting the quantity of raw materials and packaging materials needed for upcoming production batches. This includes reviewing past consumption trends, current stock levels, production plans, and expiry dates of raw materials. The planning department regularly communicates with the Procurement Unit to ensure that all necessary materials are ordered and delivered in advance, helping to prevent stockouts or overstocking. It works closely with the production department to align manufacturing schedules with factory capacity and with the quality assurance (QA) and quality control (QC) departments to ensure timely quality checks and product releases. The Planning team also updates and adjusts plans as needed if there are changes in market demand, supply issues, or equipment breakdowns. By coordinating with multiple departments and carefully managing time and resources, the planning department helps the factory maintain efficiency, reduce downtime, and meet delivery deadlines for essential medicines.

(c) Finance Department

The finance department is responsible for managing all financial activities of the Pharmaceutical Factory (Insein) in a transparent, accurate, and timely manner. One of its main duties is to prepare and manage the factory's annual budget, which includes estimating income and expenses, allocating funds to each department, and monitoring how the money is used throughout the year. It ensures that the budget supports production needs, maintenance, staff welfare, procurement, and other operational costs. The department is

also responsible for processing employee salaries, allowances, overtime payments, and benefits according to government salary structures and factory policies. The finance department maintains detailed financial records and accounting documents, including receipts, vouchers, and ledgers, in accordance with government financial regulations. It also prepares monthly, quarterly, and annual financial reports for internal management review and for submission to the relevant government authorities. These reports help track the financial health of the factory and support decision-making. Furthermore, the department plays an important role in ensuring compliance with national financial rules and audit requirements, coordinating with government auditors, and making sure all financial transactions follow public sector accounting standards. By carefully managing funds, supporting procurement and payroll processes, and ensuring proper financial reporting, the finance department helps maintain the factory's financial stability and accountability, handles the factory's budget, employee salaries, payments to suppliers, financial reports, and ensures that all money-related activities follow government rules.

(d) Production Department

The production department is responsible for the efficient and compliant manufacturing of a wide range of pharmaceutical products, including tablets, capsules, injectable formulations, and anti-snake venom. This department plays a critical role in ensuring that all production activities strictly adhere to good manufacturing practices (GMP) as outlined by national and international regulatory standards. It oversees the entire manufacturing process to ensure product quality, safety, and consistency. In addition, the department is tasked with the proper operation, cleaning, maintenance, and calibration of all production equipment and machinery to prevent contamination and ensure process integrity. It collaborates closely with quality assurance, quality control, and engineering teams to troubleshoot issues, implement process improvements, and ensure validation and documentation of production activities. The production department also ensures that all personnel are adequately trained, follow standard operating procedures (SOPs), and maintain hygienic practices to uphold product quality and patient safety.

(e) Quality Control (QC) Department

The quality control (QC) department is a key pillar of the pharmaceutical manufacturing process, responsible for ensuring that all materials and products meet the established quality standards before they are approved for use or release. This department

conducts thorough testing and analysis of raw materials, packaging components, in-process materials, and finished pharmaceutical products using a combination of chemical, physical, and microbiological methods. In the QC laboratory, sophisticated analytical techniques—such as high-performance liquid chromatography (HPLC), UV-visible spectrophotometry, pH measurement, dissolution testing, and microbial limit testing—are employed to verify the identity, purity, potency, and safety of materials and products. The department also performs environmental monitoring and water quality testing to ensure a clean and compliant production environment. Additionally, the QC department ensures that all laboratory equipment and instruments are properly maintained, regularly calibrated, and qualified to guarantee the accuracy and reliability of test results. Standard operating procedures (SOPs), good laboratory practices (GLP), and data integrity principles are strictly followed to maintain traceability and regulatory compliance. The QC team works in close coordination with the quality assurance (QA) department to review test data, investigate out-of-specification (OOS) or out-of-trend (OOT) results, and provide analytical support for product development, stability studies, and validation activities. By maintaining stringent quality controls throughout the production cycle, the QC department plays a critical role in safeguarding product quality, regulatory compliance, and ultimately, patient safety.

(f) Quality Assurance (QA) Department

The quality assurance (QA) department plays a critical role in maintaining and enhancing the quality systems of the pharmaceutical manufacturing process. It is responsible for ensuring that all departments consistently comply with good manufacturing practices (GMP), ISO standards (such as ISO 9001:2015, ISO 45001:2018, and ISO 17025:2017), and regulatory requirements established by the Myanmar food and drug administration (FDA) and other certification bodies. QA oversees the entire product life cycle from a compliance and quality perspective. This includes the thorough review and approval of batch manufacturing records, packaging records, and testing data to ensure completeness, accuracy, and adherence to approved specifications prior to product release. QA is also accountable for approving product release only when all quality criteria have been met. The department manages and evaluates changes through a structured change control system, ensuring that any modifications to processes, equipment, materials, or documentation are properly assessed and implemented without compromising product quality. Additionally, QA handles deviations and non-conformances by conducting root

cause investigations and implementing corrective and preventive actions (CAPA) to prevent recurrence. QA is also responsible for executing and coordinating validation activities, including equipment qualification, cleaning validation, and process validation, to ensure that all systems and processes consistently produce high-quality results. The department conducts internal audits to assess compliance with SOPs, regulatory guidelines, and quality systems, and it facilitates external audits and inspections by regulatory authorities and certification bodies. By fostering a culture of continuous improvement, documentation control, and regulatory compliance, the QA department ensures the integrity, safety, and efficacy of pharmaceutical products, thereby protecting patient health and supporting organizational excellence.

(g) Human Resource Department

The human resource department plays a vital role in managing the workforce and supporting the overall organizational structure. Its responsibilities encompass a wide range of functions, including recruitment, onboarding, staff training and development, performance evaluation, and employee relations. The department ensures that qualified and competent personnel are recruited through a structured selection process to meet the organization's operational and strategic needs. The human resource department organizes and facilitates continuous training and capacity-building programs to enhance employee skills, ensure compliance with regulatory requirements, and support career development. It manages employee leave, attendance, and disciplinary actions in accordance with factory policies and labor laws, ensuring fairness, transparency, and legal compliance. It is also committed to promoting employee welfare through various initiatives, including health benefits, counseling services and staff engagement activities. In collaboration with the safety and administration teams, the human resource department ensures workplace safety by implementing occupational health and safety policies, organizing safety training, and maintaining a safe and conducive working environment for all staff.

(h) Research Department

The research department is responsible for the development of new pharmaceutical formulations and the continuous improvement of existing products. It plays a critical role in scaling up laboratory processes for full-scale production, ensuring smooth technology transfer.

(i) Marketing and Distribution Department

The marketing and distribution department promotes the factory's products, plans how to meet market demand, and ensures that medicines are delivered on time to hospitals and other healthcare centers. It also gathers feedback from the market to help improve future products. All departments work together under the leadership of the general manager to make sure the factory produces safe, effective, and good-quality medicines, while meeting national and international standards.

3.3 Quality Management Practices at Pharmaceutical Factory (Insein)

To gain a competitive advantage and the trust of the Myanmar people, the Pharmaceutical Factory (Insein) focuses on improving the quality and performance of its employees. The Pharmaceutical Factory (Insein) consistently strives to practice quality management practices— especially customer focus, continuous improvement, and top management commitment—to provide pharmaceutical products that are high in quality, safety, and efficacy.

3.3.1 Continuous Improvement at the Pharmaceutical Factory (Insein)

The Pharmaceutical Factory (Insein) is deeply committed to fostering a culture of continuous improvement in all aspects of its operations. As a government-owned pharmaceutical manufacturer, the factory recognizes the critical importance of maintaining high standards in product quality, safety, and regulatory compliance. To this end, the factory actively engages in ongoing training and development initiatives aimed at enhancing the capabilities and performance of its workforce.

A key component of the factory's improvement strategy is the implementation of regular training programs. These include good manufacturing practice (GMP) training, which is essential for ensuring that manufacturing processes consistently produce products of the required quality. In addition to GMP, staff receive specialized training in production management, quality management systems, occupational health & safety and the requirements of ISO 17025:2017, which governs the competence of testing and calibration laboratories. These training sessions are designed not only to improve technical skills but also to foster a shared understanding of regulatory expectations and quality culture among employees at all levels—from technicians to senior management.

The leadership at the factory, particularly the general manager, plays a central role in driving continuous improvement. The general manager ensures that the factory is

adequately staffed and that human resource requirements are met in a timely and strategic manner. Furthermore, the factory prioritizes the regular maintenance and upgrading of facilities, equipment, and infrastructure to ensure a safe, efficient, and compliant production environment. These efforts help create the foundation necessary for consistent product quality and operational excellence.

External oversight and assessment are also crucial elements of the factory's quality improvement framework. The Pharmaceutical Factory (Insein) undergoes routine inspections by the Myanmar food and drug administration (FDA), which evaluates compliance with national pharmaceutical regulations. In addition, the factory is subject to audits by external certification bodies for ISO 9001:2015 (Quality Management System) and ISO 45001:2018 (Occupational Health and Safety Management System), as well as assessments by external assessors for ISO 17025:2017. These audits and assessments provide valuable feedback and benchmarking opportunities.

Following each external audit or inspection, the factory takes proactive steps to address any identified nonconformities or areas for improvement. Corrective and preventive actions (CAPA) are developed and implemented based on the auditors' findings and recommendations. These actions are carefully monitored to ensure effectiveness and to prevent recurrence. By responding promptly and constructively to audit outcomes, the factory demonstrates its commitment to continual enhancement of its systems and practices.

Overall, the Pharmaceutical Factory (Insein) maintains a forward-looking approach to quality and operational excellence. Through a combination of ongoing staff development, leadership commitment, infrastructure support, and regulatory compliance, the factory continuously strengthens its performance and aligns itself with both national and international standards. This dedication to continuous improvement not only ensures the delivery of safe and effective medicines but also enhances the factory's reputation and long-term sustainability.

3.3.2 Customer Focus at the Pharmaceutical Factory (Insein)

At Pharmaceutical Factory (Insein), customer focus is at the heart of factory's operations. As a government-owned pharmaceutical factory under the Ministry of Industry, factory is committed to improving the health and well-being of the people of Myanmar. The factory understands that customers—ranging from healthcare professionals and public

hospitals to regulatory authorities and ultimately the patients—rely on the factory to provide high-quality, safe, and effective pharmaceutical products.

The factory continuously strives to meet and exceed customer expectations by ensuring product quality, consistency, and compliance with national and international regulatory standards. The factory's customer-centric approach means factory keeps up with the changing needs of the healthcare system and adjust production and quality systems as needed. The factory actively engages with key stakeholders, including the Myanmar FDA, ministry of health, and healthcare institutions, to align the products with public health priorities and essential medicine requirements.

To support factory's customer focus, the factory follows ISO 9001:2015 in quality management system and have earned additional certifications, including ISO 45001:2018 and ISO/IEC 17025:2017 for quality control lab. These show factory's strong commitment to quality, safety, and ongoing improvement—leading to better customer satisfaction. The factory values customer feedback and treat all complaints and questions seriously, using them to improve factory products and services. The factory's internal audits, corrective and preventive actions, and staff training are all aimed at giving the best service and value to the customers.

Ultimately, the Pharmaceutical Factory (Insein) is committed to being a reliable and trusted partner in the healthcare system—producing essential medicines that support public health, foster trust, and demonstrate the unwavering dedication to the customers.

3.3.3 Top Management Commitment at the Pharmaceutical Factory (Insein)

The top management of the Pharmaceutical Factory (Insein) plays a crucial leadership role in ensuring the efficient operation, strategic direction, and regulatory compliance of the organization. As a government-owned facility, the factory operates under the supervision of the Ministry of Industry and adheres to national policies and international standards in pharmaceutical manufacturing. The general manager stands at the highest level of authority within the factory and is responsible for overall decision-making, organizational performance, and the successful implementation of quality management systems.

Under the leadership of the general manager, the heads of departments work collaboratively to manage the factory's diverse functions. These departments include administration, planning, finance, production, human resources, quality control (QC), quality assurance (QA), research, and marketing & distribution. Each head of department

is responsible for the daily management of their respective areas, ensuring that departmental objectives align with the factory's mission and strategic goals. The management structure also includes assistant heads of departments, managers, supervisors, and assistant supervisors who support operational execution and contribute to leadership at different levels.

Top management demonstrates its commitment to quality, safety, and continuous improvement through active involvement in policy development, strategic planning, and monitoring key performance indicators (KPIs). They ensure the implementation of international standards such as ISO 9001:2015 (Quality Management Systems), ISO 45001:2018 (Occupational Health and Safety), and ISO 17025:2017 (Laboratory Competence). The top management also initiates and supports internal and external audits, management review meetings, risk assessments, and corrective and preventive actions (CAPA), ensuring that all systems are functioning effectively and compliant with regulatory expectations.

The general manager and the leadership team prioritize the development of human resources, ensuring adequate staffing, training, and skill enhancement. Through regular GMP, production, and quality training, staff at all levels are empowered to maintain high standards in their work. In addition, top management ensures the proper maintenance and upgrading of infrastructure, equipment, and facilities to support productivity and regulatory compliance. In fulfilling their leadership role, top management also fosters a culture of open communication, teamwork, and accountability. This approach helps build trust, motivates employees, and ensures that quality and safety are not only the responsibility of one department but are integrated throughout the organization.

Overall, the top management of the Pharmaceutical Factory (Insein) plays a pivotal role in fostering a high-performing, quality-oriented organization. Through visionary leadership, interdepartmental collaboration, and strategic planning, they steer the factory toward fulfilling its mission of manufacturing safe, efficacious, and affordable pharmaceutical products to meet the healthcare needs of the population of Myanmar.

3.4 Organizational Capability at Pharmaceutical Factory (Insein)

The success of any pharmaceutical factory depends on how well it is organized, how its people work together, and how it ensures the quality of its products. At the Pharmaceutical Factory (Insein)**,** organizational capability is built on two important strengths—process orientation and a strong quality culture**.** These factors support the

production of safe and effective medicines, ensure compliance with regulatory requirements, and promote ongoing improvement in all aspects of operation.

3.4.1 Process Orientation

Process orientation is to carry out in a structured, step-by-step manner. The Pharmaceutical Factory (Insein) follows detailed procedures to ensure that each activity is completed correctly and consistently. This approach supports efficient operations and helps maintain high-quality standards. Departments within the factory—such as production, engineering, quality control, and quality assurance—operate according to clearly defined procedures. These processes are documented in standard operating procedures (SOPs) and follow international standards, including good manufacturing practices (GMP) and quality management practices**.** This structured system helps reduce errors and promotes teamwork across departments. All equipment and processes are qualified and validated before use, including installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ).

The factory uses risk assessment tools such as root cause analysis (RCA) to identify and resolve potential issues before they impact product quality. Key manufacturing steps, such as tablet compression and coating, are monitored in real-time. Data is collected and analyzed using statistical process control methods to ensure that processes remain stable and within acceptable limits. Early detection of process trends supports continuous improvement and helps maintain consistent output. The factory applies 5S to eliminate waste and increase productivity. Small, daily improvements through Kaizen activities are encouraged. Cross-functional teams are formed to review performance and suggest improvements to make processes more efficient and reduce cycle times. From material receipt to final product release, every step is recorded and documented in real-time. This ensures full traceability during audits or investigations.

3.4.2 Quality Culture

All employees of Pharmaceutical Factory (Insein) value and prioritize quality in their daily work. Quality is considered a shared responsibility that extends across all departments and roles. The leadership team at the factory plays an important role in building and supporting a quality-focused environment. Clear quality objectives are set, resources are allocated appropriately, and regular management reviews are conducted to track progress and ensure that quality goals align with the factory’s overall mission.

Employees are trained regularly in areas such as good manufacturing practices (GMP), regulatory guidelines, and data integrity.

Staff are encouraged to report deviations, offer suggestions, and take part in quality improvement activities. Clear job responsibilities and open communication help foster a sense of ownership and accountability. The factory uses a quality by design (QbD) approach, where quality is planned and built into the process from the beginning. Critical quality attributes (CQAs) and critical process parameters (CPPs) are identified and controlled throughout development and manufacturing. Regular audits and quality risk management further support proactive quality practices. The factory maintains high standards for regulatory compliance, including adherence to Myanmar FDA requirements, international pharmacopeias, and global guidelines. Internal audits are conducted to maintain a state of readiness. The quality assurance team oversees compliance and ensures that all corrective and preventive actions (CAPA) are implemented effectively. Excellence performance related to quality is acknowledged through internal awards and benchmarking activities. The factory also participates in external certification programs such as ISO 9001:2015**,** ISO 45001:2018**,** and ISO 17025:2017**,** demonstrating a strong commitment to quality excellence and continuous learning.

The Pharmaceutical Factory (Insein) demonstrates strong organizational capability through process orientation and a well-developed quality culture. These strengths support the production of reliable pharmaceutical products, ensure compliance with strict regulations, and build trust with healthcare providers and patients. By maintaining a focus on process orientation and quality at every level, the factory is well-positioned to meet future challenges, adopt new technologies, and contribute to public health in Myanmar and beyond.

3.5 Demographic Profile of Respondents

In this study, the sample size is 81 respondents. Profile of respondents includes demographic factors such as gender, age, marital status, education level, position, income and experience. Each characteristic has been analyzed in terms of absolute value and percentage. Table (3.1) shows the results of the analysis on the respondent's demographic profile, as follows:

Table (3.1) Demographic Profile of Respondents

Sr. No.	Demographic Profile	Description	Number of Respondents	Percentage
1	Gender	Male	8	9.88
		Female	73	90.12
2	Age Level (Years)	Below 30	7	8.64
		30 – 40	12	14.81
		41 – 51	45	55.56
		51 and above	17	20.99
3	Marital Status	Single	63	77.78
		Married	18	22.22
4	Highest Education Level	Bachelor	54	66.67
		Master	27	33.33
5	Position	General Manager	1	1.23
		Deputy General Manager	3	3.70
		Assistant General Manager	6	7.41
		Manager	10	12.35
		Assistant Manager	61	75.31
7	Income (MMK)	Below 300,000	50	61.73
		300,000 – 400,000	30	37.04
		400,001 – 500,000	1	1.23
8	Experience (Years)	Below 5	10	12.35
		5 – 10	3	3.70
		11 – 20	29	35.80
		Above 20	39	48.15
Total Respondents			**81**	**100.00**

Source: Survey Data (2025)

According to the results of Table (3.1), 73 respondents (90.12%) are female and only 8 respondents (9.88%) are male. This shows Pharmaceutical Factory (Insein) has a higher women participation in the workforce. For age distribution, 7 respondents (8.64%) age below 30 years old, 12 respondents (14.81%) fall within 30 to 40 years age range. 45 respondents (55.56%) age between 41 to 51 years and 17 respondents (20.99%) respondents age above 51 years. This indicates that most of the respondents are in the mid stages of their careers as only employees with assistant manager position and above participate in the survey and since government organizations promote employees mostly based on seniority, the data aligns with this factor.

For marital status, 63 respondents (77.78%) are single while 18 respondents (22.22%) are married. This states the employees at Pharmaceutical Factory (Insein) may have other priorities like career developments, work life balance expectations and other personal priorities instead of building families. It can also be explained that factory employees need more commitment to work than relationships, and they need to spend more time in their work taking care of consumers.

For education level, 54 respondents (66.67%) have a bachelor degree and 27 respondents (33.33%) have a masters' degree. The majority of the workforce are educated individuals, and the education level may also influence the advancement of career position also. The data highlights that the majority of respondents possess a bachelor's degree, with a significant proportion holding a master's degree. This reflects a highly educated workforce, suggesting that higher education levels may contribute positively to career advancement opportunities within the organization.

As for employment positions, only 1 respondent (1.23%) holds general manager position, 3 respondents (3.70%) are deputy general managers, 6 respondents (7.41%) are assistant general managers, 10 respondents (12.35%) are managers and 61 respondents (75.31%) are assistant managers. According to the data, it indicates that Pharmaceutical Factory (Insein) has a hierarchical culture, common for most government organizations for operational efficiency.

For income level, 50 respondents (61.73%) earn below 300,000 MMK, 30 respondents (37.04%) earn between 300,000 to 400,000 MMK, and only 1 respondent (1.23%) earns between 400,001 and 500,000 MMK. It is common for government organization's employees to earn a certain level of income with additional benefits like housing, transportation and others.

As for experience, 10 respondents (12.35%) have below 5 years of service, 3 respondents (3.70%) have 5 to 10 years of experience, 29 respondents (35.80%) have 11 to 20 years of experience and 39 respondents (48.15%) have above 20 years of experience. This shows that the majority of workforce has stayed with the organization for long-term, indicating their loyalty.

In summary, most of the respondents are women, showing that there is strong female participation at Pharmaceutical Factory (Insein). Many employees are in the middle stage of their careers, which fits with the organization's system of promoting people based on their years of service. A lot of employees are single, which may mean they are focusing

more on their jobs and personal goals rather than starting families. The respondents are well-educated, with most having either a bachelor's or master's degree, which can help them move forward in their careers. Most of them hold assistant manager positions, showing that the factory has a clear management structure. Their income levels are similar to what is usually seen in government organizations, where workers also receive other benefits like housing or transportation. Many employees have worked at the factory for a long time, showing strong loyalty to the organization.

3.6 Reliability Analysis

Reliability is a measure of how consistently a research instrument provides results following repeated trials. Reliability refers to the internal consistency of research instruments; it is their capacity to deliver similar results over and over under consistent settings. Cronbach alphas allow us to measure the reliability of different variables. It consists of estimates of how much variation in scores of different variables is attributable to chance or random errors (Selltiz et al. 1976). The Cronbach's alpha statistic was used in this study to assess reliability. The Cronbach's alpha coefficient typically runs from 0 to 1, with higher coefficients indicating greater reliability. The responses to 35 questions were evaluated for appropriateness and internal consistency. Cronbach's alpha was calculated using the Statistical Package for Social Sciences (SPSS) to establish reliability. The variables measured by the survey questionnaire in this study included continuous improvement, customer focus, top management commitment, process orientation, quality culture, and firm performance.

Table (3.2) Coefficient Alpha and Consistency

Alpha Coefficient Range	Strength of Association
<0.6	Poor
0.6 to < 0.7	Moderate
0.7 to < 0.8	Good
0.8 to < 0.9	Very Good
0.9>	Excellent

Source: Sekaran & Bougie (2017)

Table (3.3) displays the calculated Cronbach's alpha for all study variables based on a sample of 81 employees who took part in the study.

Table (3.3) Reliability Analysis

Sr. No.	Variable	No. of items	Cronbach's Alpha	Interpretation
1	Continuous Improvement	5	0.895	Very Good
2	Customer Focus	5	0.858	Very Good
3	Top Management Commitment	5	0.669	Moderate
4	Process Orientation	5	0.829	Very Good
5	Quality Culture	5	0.880	Very Good
6	Firm Performance	10	0.837	Very Good

Source: Survey Data (2025)

According to the result of Table (3.3), continuous improvement, quality culture, customer focus, process orientation, and firm performance all exhibit very good internal consistency, with Cronbach's Alpha values ranging from 0.829 to 0.895. Since all values fall within the accepted range of 0.8 to less than 0.9, this confirms that the measurement items are consistent and reliable in assessing their respective constructs.

However, top management commitment shows a lower Cronbach's Alpha value of 0.669, indicating moderate reliability. While this suggests some variability among the items, it still provides acceptable consistency for exploratory analysis.

Overall, the reliability analysis presented in Table (3.3) highlights the strength of the measurement tools used in this study. The generally high Cronbach's Alpha values across most factors underscore the internal consistency of the data, supporting the validity of conclusions drawn about the relationships between continuous improvement, customer focus, top management commitment, process orientation, quality culture, and firm performance at Pharmaceutical Factory (Insein).

CHAPTER 4

ANALYSIS ON THE EFFECT OF QUALITY MANAGEMENT PRACTICES ON FIRM PERFORMANCE AT PHARMACEUTICAL FACTORY(INSEIN)

This chapter includes employee perception on quality management practices, employee perception on organizational capability, employee perception on firm performance at Pharmaceutical Factory (Insein), analysis on the effect of quality management practices on firm performance and analysis on the mediating effect of organizational capability on the relationship between quality management practices and firm performance at Pharmaceutical Factory (Insein).

According to Best (1977), the mean values of five-point Likert scale items are interpreted as follows.

The score among 1.00 – 1.80 means strongly disagree.

The score among 1.81 – 2.60 means disagree.

The score among 2.61 – 3.40 means neutral.

The score among 3.41 – 4.20 means agree.

The score among 4.21 – 5.00 means strongly agree.

The mean score provides an overall measure of the respondents' collective sentiment or opinion on the set of items.

4.1 Employee Perception on Quality Management Practices at Pharmaceutical Factory (Insein)

This section examines the quality management practices of Pharmaceutical Factory (Insein). Quality management practices include aspects such as continuous improvement, customer focus and top management commitment. A structured questionnaire with a five-point Likert scale (1: strongly disagree, 2: disagree, 3 neutral, 4: agree, 5: strongly agree) is used to collect the primary data.

4. 1.1 Continuous Improvement

Continuous improvement is measured with five structured questions. The mean values, standard deviations, and overall mean value for continuous improvement are shown in Table (4.1) as follows:

Table (4.1) Continuous Improvement

Sr. No.	Description	Mean	Standard Deviation
1	Employees are continuously trained to enhance internal quality performance.	3.73	0.74
2	There is continuous monitoring and improvement of quality systems and procedures to enhance performance.	3.85	0.69
3	Quality audits are carried out continuously as per ISO certification requirements.	3.68	0.95
4	There are continuous improvement reviews through internal quality audits.	3.84	0.82
5	There is a policy for making continuous improvement of products quality for every individual in the company.	3.69	0.80
Overall Mean Value		**3.76**	

Source: Survey Data (2025)

According to the mean values (including overall mean) between 3.41 and 4.20, most respondents agree with statements of continuous improvement as shown in Table (4.1). Employees agree that there is continuous monitoring and improvement of quality systems and procedures to enhance performance, highlighting their focus on compliance and product quality. They also agree that internal quality audits are carried out to perform continuous improvement reviews as part of a proactive continuous improvement approach. The employees also express that they are provided with necessary training to improve internal quality performance, showing that the factory is committed to maintaining manufacturing and operating standards. They also agree that the factory has a policy to conduct continuous improvement for product quality improvement. Lastly, they agree that at the factory, quality audits are performed in a continuous manner as required by ISO

certification requirement which is one of the initiatives of the factory in maintaining international quality standards.

4.1.2 Customer Focus

Customer focus is measured with five structured questions. The mean values, standard deviations, and overall mean value for customer focus are shown in Table (4.2) as follows:

Table (4.2) Customer Focus

Sr. No.	Description	Mean	Standard Deviation
1	The factory has customer complains procedure where customers are attended to.	4.00	0.72
2	Factory is committed to customer retention by ensuring quality products.	3.90	0.80
3	The factory conducts customer feedback surveys regularly.	3.72	1.00
4	The factory stresses the importance on obtaining feedback on its quality control systems from customers.	3.84	0.83
5	The factory undertakes market-based research annually on quality issues.	3.65	0.85
Overall Mean Value		**3.82**	

Source: Survey Data (2025)

According to the mean values (including the overall mean) between 3.41 and 4.20, most respondents agree with the statements related to customer focus, as shown in Table (4.2). The employees agree that the factory has a procedure to handle customer complaints and assist them. This shows that the factory values the needs and expectations of its customers and always strives to improve quality. They also agree that factory is committed to customer retention by ensuring quality products. They also agree that the factory emphasizes getting feedback from customers about its quality control systems, showing the factory's commitment to customer satisfaction regarding product quality. The employees agree that the factory conducts customer feedback surveys regularly, which means the factory understands customer needs in a timely manner and can produce pharmaceutical products that meet requirements for quality, efficacy, and safety. Lastly, the employees

agree that the factory conducts market research every year to identify quality issues, showing the factory's dedication to maintaining high product quality.

4.1.3 Top Management Commitment

Top management commitment is measured with five structured questions. The mean values, standard deviations, and overall mean value for top management commitment are shown in Table (4.3) as follows:

Table (4.3) Top Management Commitment

Sr. No.	Description	Mean	Standard Deviation
1	Top management reviews organizations QMS at planned intervals to ensure continuity, adequacy and effectiveness.	3.90	0.62
2	Top management devotes resources for development and support for ISO certification.	3.78	0.70
3	Quality policies and procedures are documented and communicated to all employees.	3.84	0.58
4	Top management establish trust and commitment to quality improvement by eliminating fear.	3.88	0.65
5	The management allows participative and engagement of employees in making decisions on quality issues.	3.94	0.73
Overall Mean Value		**3.87**	

Source: Survey Data (2025)

According to the mean values (including the overall mean) between 3.41 and 4.20, most respondents agree with the statements related to top management commitment, as shown in Table (4.3). The employees agree that management allows them to take part in making decisions about quality issues. This shows that top management ensures employees are satisfied with their roles and encourages active participation. Employees also agree that top management checks the organization's QMS regularly to ensure it stays effective and suitable. This means that top management wants the factory's QMS to be effectively implemented. Employees agree that top management builds trust and supports quality improvement by removing fear. This shows that top management values the trust between leadership and employees, and by doing so, employees view the factory as their own and strive to improve quality. Employees also agree that quality policies and procedures are documented and communicated to all staff. This indicates that all employees are aware of

the factory's quality policies and can work to achieve its objectives. Lastly, employees agree that top management provides resources to develop and support ISO certification, reflecting top management's commitment.

4.2 Employee Perception on Organizational Capability at Pharmaceutical Factory (Insein)

This section examines the organizational capability at Pharmaceutical Factory (Insein). Organizational capability includes process orientation and quality culture. Employee perception on process orientation and quality culture is shown in the following Table (4.4) and Table (4.5).

4.2.1 Process Orientation

Process orientation is measured with five structured questions. The mean values, standard deviations, and overall mean value for process orientation are shown in Table (4.4) as follows:

Table (4.4) Process Orientation

Sr. No.	Description	Mean	Standard Deviation
1	Process are structured to achieved factory efficiency.	4.02	0.85
2	The factory structures facilitate high performance.	3.64	0.87
3	Production procedures are efficient for quality products.	3.90	0.68
4	Processes are well-defined and documented for all key activities.	3.69	0.84
5	Key performance indicators (KPIs) are established for monitoring process performance.	3.60	0.80
Overall Mean Value		**3.77**	

Source: Survey Data (2025)

According to the mean values (including the overall mean) between 3.41 and 4.20, most respondents agree with the statements related to process orientation, as shown in Table (4.4). The employees agree that processes are organized to improve factory efficiency. This shows that the factory can manufacture pharmaceutical products effectively and efficiently. Employees agree that the production procedures ensure the quality of products. This indicates that the factory validates production in accordance with

good manufacturing practices. Employees also agree that all key activities have clear and documented processes. This shows that the factory practices evidence-based decision-making. Employees agree that the factory structures facilitate high performance, meaning that pharmaceutical products can be produced in accordance with world health organization GMP guidelines and that the factory values product quality. Lastly, employees agree that key performance indicators (KPIs) are established for monitoring process performance. This shows that the factory has implemented the QMS system and measures its effectiveness by setting KPIs.

4.2.2 Quality Culture

Quality culture is measured with five structured questions. The mean values, standard deviations, and overall mean value for quality culture are shown in Table (4.5) as follows:

Table (4.5) Quality Culture

Sr. No.	Description	Mean	Standard Deviation
1	There is positive quality culture and cooperation within the factory.	3.95	0.58
2	There is culture of co-operation between management and employees for quality improvement.	4.08	0.61
3	The employees have positive culture change on QMS issues.	4.04	0.69
4	Standard operating procedures (SOPs) are strictly followed in daily operations.	3.84	0.79
5	The factory strictly adheres to regulatory requirements and standards.	4.02	0.68
Overall Mean Value		**3.97**	

Source: Survey Data (2025)

According to the mean values (including the overall mean) between 3.41 and 4.20, most respondents agree with the statements related to quality culture, as shown in Table (4.5). Employees agree that there is a culture of cooperation between management and staff for quality improvement. This indicates that both parties work together to enhance product quality. Employees also agree that there has been a positive cultural change regarding QMS issues. This demonstrates that the workforce is adapting well to quality management practices. Employees agree that the factory strictly adheres to regulatory requirements and standards. This reflects the factory's commitment to compliance and maintaining high-

quality production. Employees agree that there is a positive quality culture and cooperation within the factory. This shows that the factory fosters an environment where quality improvement is a shared responsibility. Lastly, employees also agree that standard operating procedures (SOPs) are strictly followed in daily operations. This shows that the factory ensures consistency and adherence to established procedures.

4.3 Employee Perception on Firm Performance at Pharmaceutical Factory (Insein)

This section examines the firm performance at Pharmaceutical Factory (Insein). Firm performance is measured with ten structured questions. The mean values for firm performance are shown in Table (4.6) as follows:

Table (4.6) Firm Performance

Sr. No.	Description	Mean	Standard Deviation
1	Factory provides quality products which are pocket friendly to customers.	3.90	0.70
2	There was less customers complaints after introduction of ISO certification.	3.90	0.60
3	The management ensures products meets customers' expectations through feedback.	4.14	0.64
4	The factory has high customer retention and growth after ISO certification.	3.75	0.75
5	The factory has fewer defects and less wastage after ISO certification.	3.68	0.52
6	There is improved lead time up to delivery.	3.90	0.58
7	There is high cost reduction after ISO certification.	3.78	0.61
8	High quality administrative systems are in place to support the efficiency of the factory.	3.78	0.61
9	There is improved information flow between top management and employee within the company.	4.37	0.48
10	Employee are well trained on quality matters to enhance efficiency.	4.32	0.46
Overall Mean Value		**3.95**	

Source: Survey Data (2025)

According to the mean values between 3.41 and 4.20, most respondents agree with the products meet customer's expectation, pocket friendly to customers, less customers complaints, improved lead time up to delivery, high cost reduction, high quality administrative systems are in place, high customer retention, fewer defects and less wastage related to firm performance, as shown in Table (4.6). Employees agree that management ensures products meet customers' expectations through feedback. This demonstrates the factory's commitment to customer satisfaction. Employees also agree that the factory provides quality products that are affordable for customers, showing its dedication to delivering value. Additionally, employees agree that there were fewer customer complaints after the introduction of ISO certification. This shows that quality improvements are effectively meeting customer needs. Employees also agree that lead time up to delivery has improved, indicating enhanced operational efficiency. Furthermore, employees agree that there has been significant cost reduction after ISO certification, demonstrating better resource management. Employees agree that high-quality administrative systems are in place to support the factory's efficiency. This shows that strong internal systems help maintain smooth operations. Lastly, employees agree that the factory has achieved high customer retention and growth, as well as fewer defects and less wastage, after ISO certification. This reflects the factory's strong commitment to quality, efficiency, and continuous improvement.

According to Table (4.6), the mean value for improved information flow and training on quality matters which ranges between 4.21 and 5.00, indicates strongly agree level. Employees strongly agree that there is improved information flow between top management and employees within the company. This shows that communication is strengthened, supporting better decision-making and coordination. Employees also strongly agree that they are well trained on quality matters to enhance efficiency. This indicates that the factory invests in building employee competencies to maintain high performance.

4.4 Analysis on the Effect of Quality Management Practices on Firm Performance at Pharmaceutical Factory (Insein)

This section presents an analysis on the effect of quality management practices on firm performance at Pharmaceutical Factory (Insein). The effect of quality management practices (independent variable) on firm performance (dependent variable) is analyzed. The result is shown in Table (4.7).

Table (4.7) Effect of Quality Management Practices on Firm Performance

Variables	Unstandardized Coefficients		Standardized Coefficients	t	Sig.	VIF
	B	Std. Error	Beta			
(Constant)	1.024	0.150		6.836	0.000	
Continuous Improvement	0.677***	0.033	0.854	20.613	0.000	1.546
Customer Focus	0.093***	0.025	0.164	3.686	0.000	1.783
Top Management Commitment	0.009	0.032	0.010	0.274	0.785	1.197
R	0.956					
R Square	0.915					
Adjusted R Square	0.911					
Durbin-Watson	2.034					
F Value	274.839***					

Source: Survey Data (2025)

Note: *Significant at 10% level, **Significant at 5% level, ***Significant at 1% level

According to the results of Table (4.7), R value is 0.956 and R square value is 0.915, meaning the model is able to explain the variance in firm performance of Pharmaceutical Factory (Insein) well. The adjusted R square value is 0.911, meaning the model explains 91.1% of the variance of both the independent and dependent variables. Durbin-Watson value is 2.034, which falls within an acceptable range (between 1.5 and 2.5). All the VIFs (Variance inflation factor) of independent variables are less than 10. Therefore, there is no multicollinearity (correlation between independent variables) in the survey.

The F value is 274.839 and the overall model is significant at 1% level and hence, the model can be regarded as valid. Among the variables, continuous improvement and customer focus have a positive significant effect on firm performance while top management commitment does not have significant effect on firm performance.

The coefficient value of continuous improvement on firm performance is 0.667 and it has a positive significant effect on firm performance at 1% significant level. This result states that efforts made by the factory in systematically enhancing processes, reducing waste, refining procedures, and investing in quality improvement initiatives are highly effective in enhancing overall firm performance. Continuous improvement directly

supports productivity, efficiency, and competitive advantage. The factory continues to invest in and strengthen continuous improvement practices—such as regular process audits, staff suggestions systems, lean manufacturing techniques, and corrective and preventive actions (CAPA). These strategies should be embedded into the factory's operational culture to sustain long-term performance gains.

The coefficient value of customer focus on firm performance is 0.093 and it has a positive significant effect on firm performance at 1% significant level. This shows that the factory's efforts in understanding and meeting customer needs—such as ensuring product quality, improving delivery timelines, responding to customer feedback, and maintaining regulatory compliance—play a vital role in enhancing performance. Satisfied and loyal customers often translate to repeat business, better market reputation, and higher revenues.

The factory prioritizes initiatives that enhance customer satisfaction. These may include strengthening the quality complaint handling system, conducting regular customer satisfaction surveys, improving after-sales support, and offering customized product solutions. Enhancing communication and responsiveness will further trust and customer loyalty.

The Pharmaceutical Factory (Insein) prioritizes and strengthen initiatives related to continuous improvement and customer focus to enhance overall organizational performance. These practices significantly contribute to improving firm performance. On the other hand, top management commitment shows a positive effect but is not statistically significant, indicating it is an area for potential improvement.

4.5 Analysis on the Mediating Effect of Organizational Capability on the Relationship between Quality Management Practices and Firm Performance at Pharmaceutical Factory (Insein)

To test the mediating effect of organizational capability on the relationship between quality management practices and firm performance, the following steps are followed:

1. Total effect thought regression analysis on the effect of the independent variable on the dependent variable.
2. Regression analysis on the effect of the independent variable on the mediating variable.
3. Regression analysis on the effect of the independent variable and the mediating variable on the dependent variable.
4. Sobel Test for the significance of mediating variable.
5. Finding indirect effect, direct effect, and total effect.

4.5.1 Analysis on the Mediating Effect of Process Orientation on the Relationship between Continuous Improvement and Firm Performance at Pharmaceutical Factory (Insein)

This section presents an analysis of the mediation effect of process orientation on the relationship between continuous improvement and firm performance at Pharmaceutical Factory (Insein). The effect of continuous improvement (independent variable) on firm performance (dependent variable) is analyzed. The result is shown in Table (4.8).

Table (4.8) Effect of Continuous Improvement on Firm Performance

Variables	Unstandardized Coefficients		Standardized Coefficients	t	Sig.	VIF
	B	Std. Error	Beta			
(Constant)	1.061	0.111		9.580	0.000	
Continuous Improvement	0.751***	0.029	0.947	26.320	0.000	1.000
R	0.947					
R Square	0.898					
Adjusted R Square	0.896					
Durbin-Watson	1.922					
F Value	692.767***					

Source: Survey Data (2025)

Note: *Significant at 10% level, **Significant at 5% level, ***Significant at 1% level

According to the results of Table (4.8), R value is 0.947 and R square value is 0.898, meaning the model explains 89.8% of variance of both independent and dependent variables. The adjusted R square value is 0.896. The VIF value is also under 10, indicating that there are no multicollinearity issues with the independent variables. With Durbin-Watson value of 1.922, the sample does not have autocorrelation issue. The F value is 692.767 and the overall model is positive significant at 1% level and hence, the model can be regarded as valid.

The significant value of continuous improvement is 0.000, it is significant at 1% level. The standardized coefficient (Beta) values of continuous improvement is also

positive, indicating that continuous improvement has a significant and positive effect on the dependent variable which is firm performance. It means continuous improvement has a positive and significant effect on firm performance.

The analysis results indicate that continuous improvement has a significant positive effect on firm performance at Pharmaceutical Factory (Insein). This implies and states that the factory focuses on enhancing its continuous improvement initiatives to drive better organizational performance.

Table (4.9) Effect of Continuous Improvement on Process Orientation

Variables	Unstandardized Coefficients		Standardized Coefficients	t	Sig.	VIF
	B	Std. Error	Beta			
(Constant)	2.011	0.181		11.133	0.000	
Continuous Improvement	0.524***	0.047	0.785	11.264	0.000	1.000
R	0.785					
R Square	0.616					
Adjusted R Square	0.611					
Durbin-Watson	1.749					
F Value	126.871***					

Source: Survey Data (2025)

Note: *Significant at 10% level, **Significant at 5% level, ***Significant at 1% level

According to the results of Table (4.9), R value is 0.785 and R square value is 0.616, meaning the model explains 61.1% of the variance of both the independent and dependent variables. The adjusted R square value is 0.611. The VIF value is also under 10, indicating that there are no multicollinearity issues with the independent variables. With Durbin-Watson value of 1.749, the sample does not have autocorrelation issue. The F value is 126.871 and the overall model is positive significant at 1% level and hence, the model can be regarded as valid.

The significant value of continuous improvement is 0.000, it is significant at 1% level. The standardized coefficient (Beta) values of continuous improvement is also

positive, indicating that continuous improvement has a significant and positive effect on the dependent variable which is process orientation. It means continuous improvement has a positive and significant effect on process orientation.

The analysis results indicate that continuous improvement has a significant positive effect on process orientation at Pharmaceutical Factory (Insein). This implies and states that the factory focuses on strengthening its continuous improvement efforts to enhance the alignment and efficiency of its internal processes. After analysis on the effect of continuous improvement (independent variable) on process orientation (mediating variable), the third step of testing the mediating effect is continued. In this step, the independent variables are continuous improvement and process orientation and dependent variable is firm performance. The results are shown in Table (4.10).

Table (4.10) Effect of Continuous Improvement and Process Orientation on Firm Performance

Variables	Unstandardized Coefficients		Standardized Coefficients	t	Sig.	VIF
	B	Std. Error	Beta			
(Constant)	0.217	0.130		1.667	0.100	
Continuous Improvement	0.531***	0.034	0.670	15.712	0.000	2.606
Process Orientation	0.419***	0.051	0.353	8.290	0.000	2.606
R	0.972					
R Square	0.946					
Adjusted R Square	0.944					
Durbin-Watson	1.977					
F Value	677.701***					

Source: Survey Data (2025)

Note: *Significant at 10% level, **Significant at 5% level, ***Significant at 1% level

According to the result of Table (4.10), the coefficient value of process orientation is 0.419 with standard error value 0.051. To test the mediating effect of process orientation on the relationship between continuous improvement and firm performance, the Sobel test is conducted. The result is shown in Table (4.11).

Table (4.11) Sobel Test Result for Mediating Effect of Process Orientation on the Relationship between Continuous Improvement and Firm Performance

Input			**Test Statistic:**	**Std. Error:**	**p-value:**
a	0.524	**Sobel Test:**	6.61389335	0.03319618	0.00000000
b	0.419	**Aroian Test:**	6.59671851	0.03328261	0.00000000
S_a	0.047	**Goodman Test:**	6.63120304	0.03310953	0.00000000
S_b	0.051	**Reset all**	**Calculate**		

Source: Survey Data (2025)

According to the result of Table (4.11), p value 0 is less than 0.01. Thus, there is a mediating effect of process orientation on the relationship between continuous improvement and firm performance at the 1% significant level. The total effect, direct effect, and indirect effect are as follows:

Total Effect = 0.751

Direct Effect = 0.531

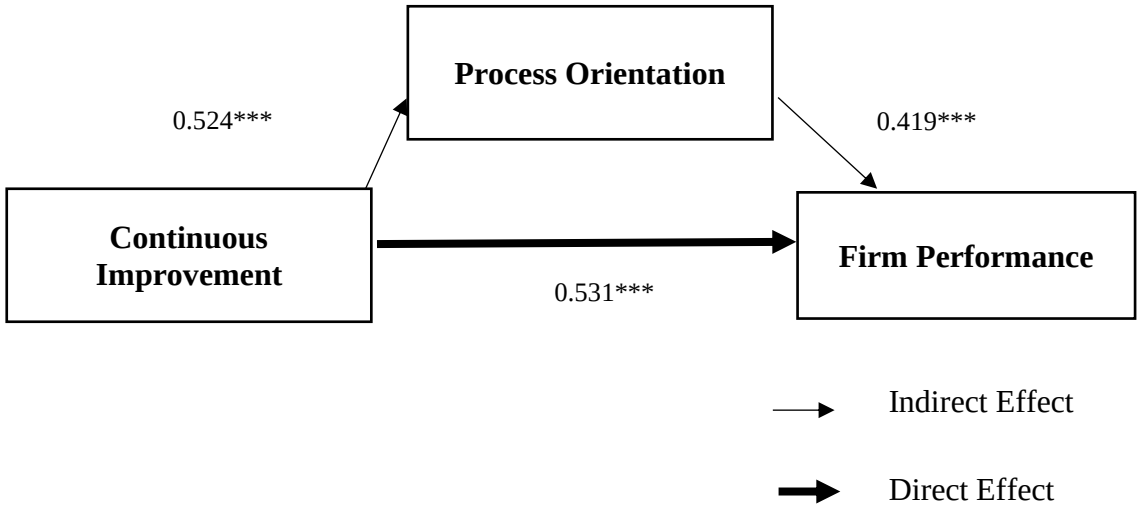
Indirect Effect = 0.524 x 0.419 = 0.220

Direct Effect + Indirect Effect = Total Effect

0.531 + 0.220 = 0.751

The direct effect and indirect effect can be seen in Figure (4.1).

Figure (4.1) Mediating Effect of Process Orientation on the Relationship between Continuous Improvement and Firm Performance



Source: Survey Data (2025)

Notes: ***Significant at 1% level, **Significant at 5% level, *Significant at 10% level

Based on Figure (4.1), the result shows that there is a positive and significant effect of continuous improvement on firm performance. For the indirect effect, the result indicates that there is a positive and significant effect of continuous improvement on process orientation and a positive and a significant effect of process orientation on firm performance as well. Therefore, there is a mediation effect of process orientation found on the relationship between continuous improvement and firm performance.

The analysis results indicate that continuous improvement has a significant positive effect on firm performance at Pharmaceutical Factory (Insein), and this relationship is mediated by process orientation. This implies and states that the factory is not only on continuous improvement initiatives but also on developing a strong process orientation to achieve maximum performance outcomes. It means firm performance increases when there is a strong focus on continuous improvement, as it leads to increased process orientation. When there is continuous improvement, the factory is able to systemize its operations to become consistent and efficient which influences performance. As process orientation is a mediator, it enhances the relationship between the continuous improvement and firm performance. That means, the factory is able to perform better when it focuses on both continuous improvement and process orientation compared to when it is only focusing on

continuous improvement. For that reason, Pharmaceutical Factory (Insein) strives to develop continuous improvement and process orientation initiatives in order to achieve maximum firm performance.

4.5.2 Analysis on the Mediating Effect of Process Orientation on the Relationship between Customer Focus and Firm Performance at Pharmaceutical Factory (Insein)

This section presents an analysis of the mediation effect of process orientation on the relationship between customer focus and firm performance at Pharmaceutical Factory (Insein). The effect of customer focus (independent variable) on firm performance (dependent variable) is analyzed. The result is shown in Table (4.12).

Table (4.12) Effect of Customer Focus on Firm Performance

Variables	Unstandardized Coefficients		Standardized Coefficients	t	Sig.	VIF
	B	Std. Error	Beta			
(Constant)	2.531	0.188		13.450	0.000	
Customer Focus	0.372***	0.048	0.653	7.663	0.000	1.000
R	0.653					
R Square	0.426					
Adjusted R Square	0.419					
Durbin-Watson	2.031					
F Value	58.719***					

Source: Survey Data (2025)

Note: *Significant at 10% level, **Significant at 5% level, ***Significant at 1% level

According to the results of Table (4.12), R value is 0.653 and R square value is 0.426, meaning the model explains 42.6% of the variance of both the independent and dependent variables. The adjusted R square value is 0.419. The VIF value is also under 10, indicating that there are no multicollinearity issues with the independent variables. With Durbin-Watson value of 2.031, the sample does not have autocorrelation issue. The F value

is 58.719 and the overall model is highly significant at 1% level and hence, the model can be regarded as valid.

The significant value of customer focus is 0.000, it is significant at 1% level. The standardized coefficient (Beta) values of customer focus is also positive, indicating that customer focus has a significant and positive effect on the dependent variable which is firm performance. It means customer focus has a positive and significant effect on firm performance.

The analysis results indicate that customer focus has a significant positive effect on firm performance at Pharmaceutical Factory (Insein). This implies and states that the factory continues to enhance its customer-focused strategies to further improve overall performance. Additionally, the results highlight the importance of customer focus as a critical factor in enhancing firm performance and states that maintaining and strengthening this practice further supports the factory's strategic objectives.

Table (4.13) Effect of Customer Focus on Process Orientation

Variables	Unstandardized Coefficients		Standardized Coefficients	t	Sig.	VIF
	B	Std. Error	Beta			
(Constant)	3.011	0.174		17.296	0.000	
Customer Focus	0.267***	0.045	0.556	5.944	0.000	1.000
R	0.556					
R Square	0.309					
Adjusted R Square	0.300					
Durbin-Watson	1.930					
F Value	35.328***					

Source: Survey Data (2025)

Note: *Significant at 10% level, **Significant at 5% level, ***Significant at 1% level

According to the result of Table (4.13), R value is 0.556 and R square value is 0.309, meaning the model explains 30.9% of the variance of both the independent and dependent variables. The adjusted R square value is 0.300. The VIF value is also under 10, indicating

that there are no multicollinearity issues with the independent variables. With Durbin-Watson value of 1.930, the sample does not have autocorrelation issue. The F value is 35.328 and the overall model is highly significant at 1% level and hence, the model can be regarded as valid.

The significant value of customer focus is 0.000, it is significant at 1% level. The standardized coefficient (Beta) values of customer focus is also positive, indicating that customer focus has a significant and positive effect on the dependent variable which is process orientation. It means customer focus has a positive and significant effect on process orientation.

The analysis results indicate that customer focus has a significant positive effect on process orientation at Pharmaceutical Factory (Insein)**.** This implies and states that the factory can prioritize and strengthen its continuous improvement initiatives to enhance its process orientation. After analysis on the effect of customer focus (independent variable) on process orientation (mediating variable), the third step of testing the mediating effect is continued. In this step, the independent variables are customer focus and process orientation and dependent variable is firm performance. The results are shown in Table (4.14).

Table (4.14) Effect of Customer Focus and Process Orientation on Firm Performance

Variables	Unstandardized Coefficients		Standardized Coefficients	t	Sig.	VIF
	B	Std. Error	Beta			
(Constant)	0.139	0.237		0.586	0.560	
Customer Focus	0.135***	0.034	0.238	4.025	0.000	1.447
Process Orientation	0.887***	0.070	0.747	12.666	0.000	1.447
R	0.901					
R Square	0.812					
Adjusted R Square	0.808					
Durbin-Watson	1.855					
F Value	168.817***					

Source: Survey Data (2025)

Note: *Significant at 10% level, **Significant at 5% level, ***Significant at 1% level

According to the result of Table (4.14), the coefficient value of process orientation on firm performance is 0.887 with standard error value 0.070. To test the mediating effect of process orientation between customer focus and firm performance, the Sobel test is conducted. The result is shown in Table (4.15).

Table (4.15) Sobel Test Result for Mediating Effect of Process Orientation on the Relationship between Customer Focus and Firm Performance

Input			**Test Statistic:**	**Std. Error:**	**p-value:**
a	0.267	**Sobel Test:**	5.37343203	0.04407407	0.00000000
b	0.887	**Aroian Test:**	5.35976052	0.04418649	0.00000000
S_a	0.045	**Goodman Test:**	5.38720871	0.04396136	0.00000000
S_b	0.070	**Reset all**	**Calculate**		

Source: Survey Data (2025)

According to the result of Table (4.15), p value 0 is less than 0.01. Thus, there is a mediating effect of process orientation between customer focus and firm performance at the 1% significant level. The total effect, direct effect, and indirect effect are as follows:

Total Effect = 0.372

Direct Effect = 0.135

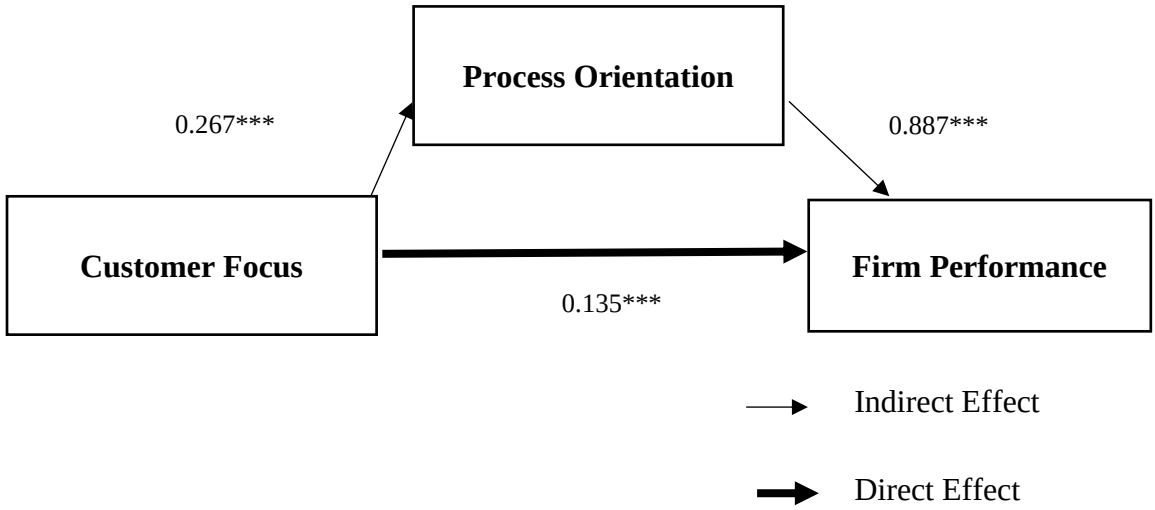
Indirect Effect = 0.267 x 0.887 = 0.237

Direct Effect + Indirect Effect = Total Effect

0.135 + 0.237 = 0.372

The direct effect and indirect effect can be seen in Figure (4.2).

Figure (4.2) Mediating Effect of Process Orientation on the Relationship between Customer Focus and Firm Performance



Source: Survey Data (2025)

Notes: ***Significant at 1% level, **Significant at 5% level, *Significant at 10% level

Based on Figure (4.2), the result shows that there is a positive and significant effect of customer focus on firm performance. For the indirect effect, the result indicates that there is a positive and significant effect of customer focus on process orientation and a positive and significant effect of process orientation on firm performance as well. Therefore, there is a mediation effect of process orientation found in the relationship between customer focus and firm performance.

This means firm performance improves when there is a strong emphasis on customer focus, as it leads to increased process orientation. When the factory prioritizes understanding and meeting customer needs, it is able to align its processes to deliver consistent value, which in turn boosts performance. Customer focus fosters a culture where the organization continuously seeks to understand customer expectations and adjust processes, quality, and services accordingly. With process orientation acting as a mediator, it strengthens the connection between customer focus and firm performance. This states that the factory achieves better performance when it concentrates on both customer focus and process orientation compared to focusing on customer focus alone. Therefore, Pharmaceutical Factory (Insein) can actively promote customer focus and process orientation initiatives to maximize its firm performance.

4.5.3 Analysis on the Mediating Effect of Quality Culture on the Relationship between Continuous Improvement and Firm Performance at Pharmaceutical Factory (Insein)

This section presents an analysis of the mediation effect of quality culture between continuous improvement and firm performance at Pharmaceutical Factory (Insein).

Table (4.16) Effect of Continuous Improvement on Quality Culture

Variables	Unstandardized Coefficients		Standardized Coefficients	t	Sig.	VIF
	B	Std. Error	Beta			
(Constant)	1.838	0.341		5.384	0.000	
Continuous Improvement	0.580***	0.088	0.596	6.590	0.000	1.000
R	0.596					
R Square	0.355					
Adjusted R Square	0.347					
Durbin-Watson	1.788					
F Value	43.426***					

Source: Survey Data (2025)

Note: *Significant at 10% level, **Significant at 5% level, ***Significant at 1% level

According to the result of Table (4.16), R value is 0.596 and R square value is 0.355, meaning the model explains 35.5% of the variance of the independent and dependent variables. The adjusted R square value is 0.347. The VIF value is also under 10, indicating that there are no multicollinearity issues with the independent variables. With Durbin-Watson value of 1.788, the sample does not have autocorrelation issue. The F value is 43.426 and the overall model is highly significant at 1% level and hence, the model can be regarded as valid.

The significant value of continuous improvement is 0.000, it is significant at 1% level. The Standardized Coefficient (Beta) values of continuous improvement is also positive, indicating that continuous improvement has a significant and positive effect on

the dependent variable which is quality culture. It means continuous improvement has a positive and significant effect on quality culture.

After analysis on the effect of continuous improvement (independent variable) on quality culture (mediating variable), the third step of testing the mediating effect is continued. In this step, the independent variables are continuous improvement and quality culture and dependent variable is firm performance. The results are shown in Table (4.17).

Table (4.17) Effect of Continuous Improvement and Quality Culture on Firm Performance

Variables	Unstandardized Coefficients		Standardized Coefficients	t	Sig.	VIF
	B	Std. Error	Beta			
(Constant)	0.859	0.123		7.006	0.000	
Continuous Improvement	0.687***	0.034	0.867	20.435	0.000	1.550
Quality Culture	0.110***	0.035	0.135	3.177	0.002	1.550
R	0.954					
R Square	0.909					
Adjusted R Square	0.907					
Durbin-Watson	2.105					
F Value	391.309***					

Source: Survey Data (2025)

Note: *Significant at 10% level, **Significant at 5% level, ***Significant at 1% level

According to the result of Table (4.17), the coefficient value of quality culture is 0.110 with standard error is 0.035. To test the mediating effect of quality culture on the relationship between continuous improvement and firm performance, the Sobel test is conducted. The result is shown in Table (4.18).

Table (4.18) Sobel Test Result for Mediating Effect of Quality Culture on the Relationship between Continuous Improvement and Firm Performance

Input			Test Statistic:	Std. Error:	p-value:
a	0.580	**Sobel Test:**	2.83683796	0.02248983	0.00455627
b	0.110	**Aroian Test:**	2.81060323	0.02269975	0.00494487
S_a	0.088	**Goodman Test:**	2.86382131	0.02227793	0.00418564
S_b	0.035	**Reset all**	**Calculate**		

Source: Survey Data (2025)

According to the result of Table (4.18), p value 0 is less than 0.01. Thus, there is a mediating effect of quality culture between continuous improvement and firm performance at the 1% significant level. The total effect, direct effect, and indirect effect are as follows.

Total Effect = 0.751

Direct Effect = 0.687

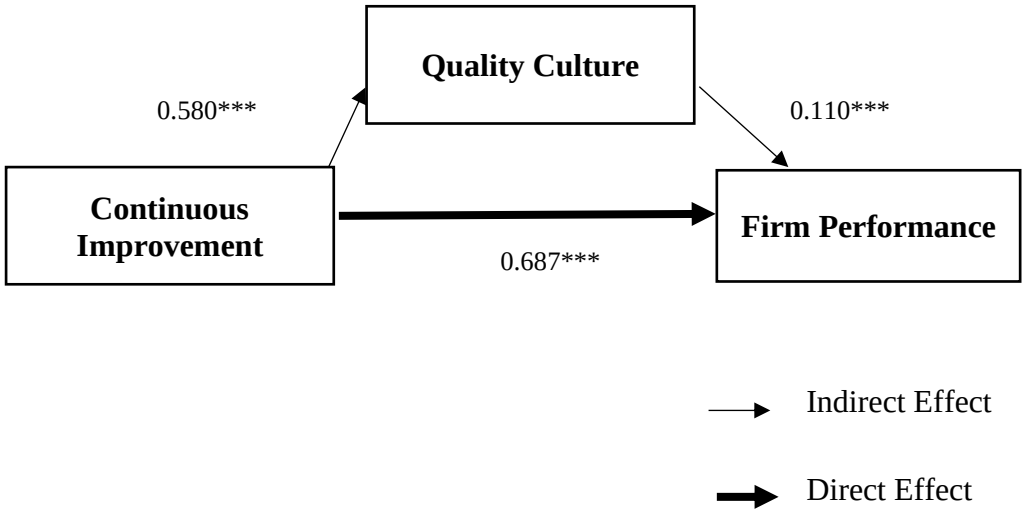
Indirect Effect = 0.580 x 0.110 = 0.064

Direct Effect + Indirect Effect = Total Effect

0.687 + 0.064 = 0.751

The direct effect and indirect effect can be seen in Figure (4.3).

Figure (4.3) Mediating Effect of Quality Culture between Continuous Improvement and Firm Performance



Notes: ***Significant at 1% level, **Significant at 5% level, *Significant at 10% level

Source: Survey Data (2025)

Based on Figure (4.3), the result shows that there is a positive and significant effect of continuous improvement on firm performance. For the indirect effect, the result indicates that there is a positive and significant effect of continuous improvement on quality culture and a positive and significant effect of quality culture on firm performance as well. Therefore, there is a mediation effect of quality culture found in the relationship between continuous improvement and firm performance.

This means firm performance improves when there is a strong focus on continuous improvement, as it leads to the strengthening of quality culture. When the factory emphasizes continuous improvement, it nurtures a culture where quality is prioritized at all levels, which directly enhances performance. Continuous improvement builds an environment where the organization is consistently seeking to improve quality standards, reduce errors, and enhance product reliability. With quality culture acting as a mediator, it amplifies the connection between continuous improvement and firm performance. This indicates that the factory achieves better performance when it focuses on both continuous improvement and developing a strong quality culture, compared to focusing on continuous improvement alone.

4.5.4 Analysis on the Mediating Effect of Quality Culture between Customer Focus and Firm Performance at Pharmaceutical Factory (Insein)

This section presents an analysis of the mediation effect of quality culture between customer focus and firm performance at Pharmaceutical Factory (Insein).

Table (4.19) Effect of Customer Focus on Quality Culture

Independent Variables	Unstandardized Coefficients		Standardized Coefficients	t	Sig.	VIF
	B	Std. Error	Beta			
(Constant)	2.455	0.243		10.099	0.000	
Customer Focus	0.422***	0.063	0.604	6.739	0.000	1.000
R	0.604					
R Square	0.365					
Adjusted R Square	0.357					
Durbin-Watson	1.900					
F Value	45.416***					

Source: Survey Data (2025)

Note: *Significant at 1% level, **Significant at 5% level, ***Significant at 1% level

According to the result of Table (4.19), R value is 0.604 and R square value is 0.365, meaning the model explains 36.5% of the variance of the independent and the dependent variables. The adjusted R square value is 0.357. The VIF value is also under 10, indicating that there are no multicollinearity issues with the independent variables. With Durbin-Watson value of 1.9, the sample does not have autocorrelation issue. The F value is 45.416 and the overall model is highly significant at 1% level and hence, the model can be regarded as valid.

The significant value of customer focus is 0.000, it is significant at 1% level. The Standardized Coefficient (Beta) values of customer focus is also positive, indicating that customer focus has a significant and positive effect on the dependent variable which is quality culture. It means customer focus has a positive and significant effect on quality culture.

After analysis on the effect of customer focus (independent variable) on quality culture (mediating variable), the third step of testing the mediating effect is continued. In this step, the independent variables are customer focus and quality culture and dependent variable is firm performance. The results are shown in Table (4.20).

Table (4.20) Effect of Customer Focus and Quality Culture on Firm Performance

Independent Variables	Unstandardized Coefficients		Standardized Coefficients	t	Sig.	VIF
	B	Std. Error	Beta			
(Constant)	1.723	0.259		6.640	0.000	
Customer Focus	0.233***	0.055	0.409	4.196	0.000	1.575
Quality Culture	0.329***	0.079	0.404	4.152	0.000	1.575
R	0.728					
R Square	0.530					
Adjusted R Square	0.518					
Durbin-Watson	2.136					
F Value	44.013***					

Source: Survey Data (2025)

Note: *Significant at 10% level, **Significant at 5% level, ***Significant at 1% level

According to the result of Table (4.20), the coefficient value of quality culture is 0.329 with standard error is 0.079. To test the mediating effect of quality culture on the relationship between customer focus and firm performance, the Sobel test is conducted. The result is shown in Table (4.21).

Table (4.21) Sobel Test Result for Mediating Effect of Quality Culture on the Relationship between Customer Focus and Firm Performance

Input			Test Statistic:	Std. Error:	p-value:
a	0.422	**Sobel Test:**	3.53673641	0.04308557	0.00040510
b	0.329	**Aroian Test:**	3.50864981	0.04317388	0.00045039
S_a	0.063	**Goodman Test:**	3.56550849	0.04299708	0.00036315
S_b	0.079	**Reset all**	**Calculate**		

Source: Survey Data (2025)

According to the result of Table (4.21), p value 0 is less than 0.01. Thus, there is a mediating effect of quality culture between customer focus and firm performance at the 1% significant level. The total effect, direct effect, and indirect effect are as follows.

Total Effect = 0.372

Direct Effect = 0.233

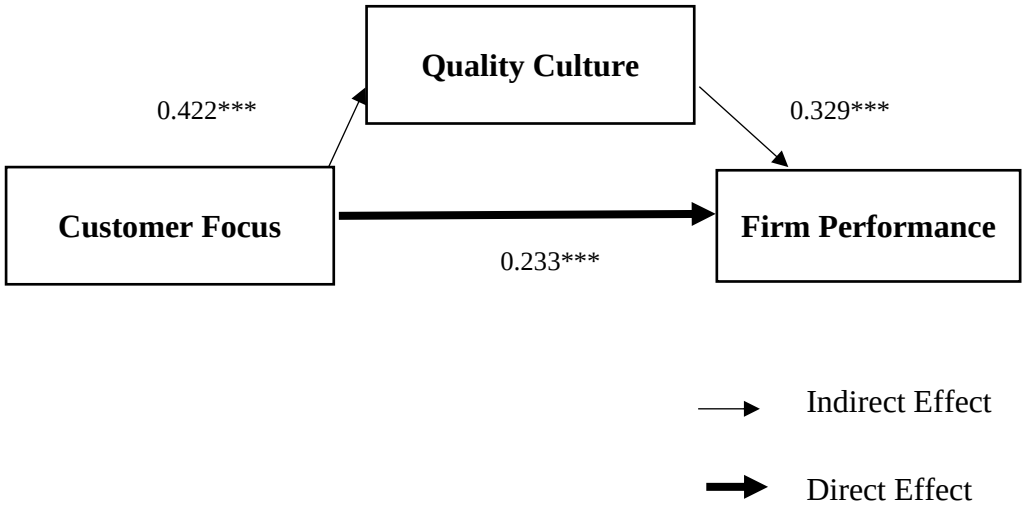
Indirect Effect = 0.422 x 0.329 = 0.139

Direct Effect + Indirect Effect = Total Effect

0.233 + 0.139 = 0.372

The direct effect and indirect effect can be seen in Figure (4.4).

Figure (4.4) Mediating Effect of Quality Culture on the Relationship between Customer Focus and Firm Performance



Notes: ***Significant at 1% level, **Significant at 5% level, *Significant at 10% level

Source: Survey Data (2025)

Based on Figure (4.4), the result shows that there is a positive and significant effect of customer focus on firm performance. For the indirect effect, the result indicates that there is a positive and significant effect of customer focus on quality culture and a positive and significant effect of quality culture on firm performance as well. Therefore, there is a mediation effect of quality culture found in the relationship between customer focus and firm performance.

This means firm performance improves when there is a strong emphasis on customer focus, as it leads to the strengthening of quality culture. When the factory prioritizes customer needs and expectations, it fosters a quality-driven environment where employees are committed to delivering high standards, which directly enhances performance. Customer focus builds a culture where the organization continually seeks to improve quality, reliability, and customer satisfaction. With quality culture acting as a mediator, it strengthens the relationship between customer focus and firm performance. This indicates that the factory performs better when it concentrates on both customer focus and cultivating a strong quality culture, compared to focusing on customer focus alone. Therefore, Pharmaceutical Factory (Insein) actively promotes customer focus alongside initiatives to enhance its quality culture in order to achieve maximum firm performance.

CHAPTER 5

CONCLUSION

In this chapter, a total of three parts are discussed findings and discussions of the study, suggestions and recommendations as well as the needs for further research based on this study of effect of quality management practices on firm performance at Pharmaceutical Factory (Insein) are presented in an organized manner.

5.1 Findings and Discussions

This study focuses on examining the effect of quality management practices on firm performance at the Pharmaceutical Factory (Insein). It is conducted with 102 respondents at manager level from the Pharmaceutical Factory (Insein). The sample size is determined to be 81 using the Raosoft sample size calculator. A simple random sampling method is applied to collect the data. Questionnaires are used for primary data collection, while secondary data is gathered from relevant textbooks, previous research papers, journals, articles, and other related resources from the pharmaceutical industry.

Based on the results of demographic profile, the gender distribution is skewed toward women, with the majority of respondents being female. Most employees are in the mid-stage of their careers, primarily between the ages of 41 and 51, reflecting the government organization's seniority-based promotion system. The marital status data shows that most respondents are single, suggesting a focus on career development and work commitments over family life. In terms of education, the workforce is highly educated, with most holding bachelor's degrees and a significant portion having master's degrees, which may positively influence career advancement. Employment positions are mostly at the assistant manager level, highlighting a hierarchical structure common in government organizations. Income levels are generally modest, consistent with typical government salaries supplemented by additional benefits. Finally, most respondents have long service durations, with many having worked over 20 years, indicating a loyal and stable workforce.

Based on the analysis, the respondents generally agree with the effect of quality management practices on firm performance. This indicates that the respondents are aware of effect of quality management practices of Pharmaceutical Factory (Insein). The mean value of continuous improvement indicates that respondents agree the factory consistently monitors and enhances its quality systems and procedures to improve performance, with a

strong focus on compliance and product quality. This states that the majority of respondents perceive the factory's efforts in continuous improvement as proactive and effective, particularly through regular internal quality audits and the provision of necessary training to enhance internal quality performance. The mean score also reflects that the factory has established policies for the continuous improvement of product quality and demonstrates a strong commitment to maintaining manufacturing standards, adhering to ISO certification requirements, and fostering a culture of ongoing quality enhancement.

The mean value of customer focus indicates that respondents agree the factory has established effective procedures for handling customer complaints, reflecting its commitment to meeting customer needs and expectations. They also agree that the factory is committed to customer retention by ensuring the delivery of quality products and prioritizing the collection of customer feedback on its quality control systems, emphasizing its focus on customer satisfaction and product quality. Furthermore, employees agree that annual market research is carried out to identify and address quality issues, highlighting the factory's ongoing dedication to maintaining high product quality.

The mean value of top management commitment indicates that respondents agree management actively involves employees in decision-making on quality issues, fostering satisfaction with their roles and encouraging active participation. They also agree that top management regularly reviews the quality management system (QMS) to ensure its effectiveness and relevance. The mean score states that employees believe management builds trust and supports quality improvement by removing fear and promoting a sense of ownership. Employees also agree that the factory's quality policies and procedures are clearly documented and communicated, ensuring that all staff understand the factory's quality objectives. Furthermore, they agree that top management provides sufficient resources to develop and maintain ISO certification, reflecting strong leadership commitment to quality excellence.

The mean value of process orientation indicates that respondents agree the factory's processes are well-structured to enhance efficiency and support effective pharmaceutical production. This states that the majority of respondents perceive the factory's operations as aligned with validated procedures and good manufacturing practices, ensuring consistent product quality. The mean score reflects that key activities are supported by clearly documented processes, and the organizational structure promotes high performance in accordance with WHO GMP guidelines. Additionally, the establishment and monitoring of

key performance indicators (KPIs) demonstrate the factory's active approach to measuring and improving the effectiveness of its quality management system.

The mean value of quality culture indicates that respondents agree there is a cooperative environment between management and staff focused on quality improvement, reflecting a shared commitment to enhancing product quality. This states that the majority of employees perceive a positive cultural shift in quality management system (QMS) practices, highlighting adaptability and engagement with quality initiatives. The mean score reflects the factory's strong adherence to regulatory requirements and standards, as well as the presence of a supportive quality culture that fosters continuous improvement. It also indicates that standard operating procedures (SOPs) are consistently followed in daily operations, ensuring process consistency and reinforcing the factory's dedication to quality excellence.

The mean values of firm performance indicate that respondents agree the factory is performing well in key areas such as meeting customer expectations, offering affordable products, reducing customer complaints, improving lead time, achieving cost reduction, maintaining high-quality administrative systems, retaining customers, and minimizing defects and wastage. This states that the majority of employees perceive the factory's efforts—particularly after ISO certification—as effective in enhancing quality, efficiency, and customer satisfaction. The mean scores also reflect the factory's strong commitment to continuous improvement and operational excellence, contributing positively to overall firm performance. In addition, the mean values for improved information flow and training on quality matters indicate that respondents strongly agree these areas are well-managed. This suggests that employees experience strengthened communication between top management and staff, supporting better coordination and decision-making. Employees also feel well-trained on quality matters, indicating that the factory invests in building employee competencies. These mean scores also reflect the effectiveness of the factory's communication and training practices in supporting high performance and fostering a strong quality culture.

To achieve the first objective, which is to analyze the effect of quality management practices on firm performance at the Pharmaceutical Factory (Insein), the study found that among the quality management variables, continuous improvement and customer focus have a positive and significant effect on firm performance. However, top management commitment does not show a significant effect in this model. This states that the main drivers of improved performance at the Pharmaceutical Factory (Insein) are its focus on

continuous improvement and customer-centered practices. To strengthen top management commitment, the factory can enhance leadership visibility, ensure the active participation of senior leaders in quality initiatives, provide a clear strategic direction aligned with quality goals, and foster a culture where management consistently supports, communicates, and rewards quality improvement efforts. These steps help close the gap and amplify the positive effect of other quality management practices on overall firm performance.

To achieve the second objective which is to analyze the mediating effect of organizational capability on the relationship between quality management practices and firm performance at Pharmaceutical Factory (Insein), the study found that continuous improvement and customer focus both have positive and significant effect on performance. Process orientation plays a key mediating role, by strengthening the connection between quality management practices and performance outcomes. Continuous improvement enhances efficiency and consistency, while customer focus ensures alignment with customer needs and expectations. When these practices are supported by a strong process orientation, they become embedded in the factory's daily operations, resulting in sustained and measurable improvements in performance.

In addition, quality culture serves as another important mediator. Continuous improvement and customer focus contribute to cultivating a culture that emphasizes excellence, error prevention, and product reliability. This culture not only reinforces high-quality standards but also enhances employee engagement, accountability, and commitment. A robust quality culture thus acts as a catalyst, translating quality management efforts into tangible performance gains.

The study states that optimal performance is achieved when continuous improvement and customer focus are effectively integrated with strong process orientation and a deeply embedded quality culture. These organizational capabilities amplify and sustain the positive effects of quality management practices, leading to long-term improvements in firm performance at Pharmaceutical Factory (Insein).

Therefore, to maximize performance, Pharmaceutical Factory (Insein) is not only continue its efforts in continuous improvement and customer focus but also actively invest in developing and reinforcing organizational capability.

5.2 Suggestions and Recommendations

Based on the findings of this study, which examined the effect of quality management practices on firm performance at Pharmaceutical Factory (Insein) and

highlighted the mediating roles of process orientation and quality culture, several strategic recommendations are proposed to strengthen organizational capabilities and optimize performance outcomes.

Pharmaceutical Factory (Insein) should sustain and intensify its commitment to continuous improvement by embedding structured mechanisms for employee-driven innovation, proactive problem-solving, and cross-departmental collaboration, ensuring that improvements are systematically identified, implemented, and sustained over time. For continuous improvement, the factory needs to carry out quality audits continuously and establish a policy that encourages every individual to contribute to the ongoing improvement of product quality.

To strengthen customer focus, the organization should formalize comprehensive feedback mechanisms, enhance responsiveness to customer needs, and integrate client insights directly into product development, service delivery, and quality improvement initiatives, thereby strengthening market competitiveness and customer satisfaction. Specifically, the factory needs to undertake market-based research annually on quality-related issues and conduct regular customer feedback surveys.

Recognizing the critical mediating roles of process orientation and quality culture, the factory should prioritize initiatives that map, standardize, and continuously refine operational processes while simultaneously fostering a shared organizational mindset that values compliance, excellence, and collective responsibility for quality. In this regard, the factory should establish key performance indicators (KPIs) for monitoring process performance and ensure that factory structures are designed to facilitate high performance. To support a strong quality culture, it is essential to follow standard operating procedures (SOPs) strictly in daily operations.

Importantly, although top management commitment is not found to have a significant direct effect on firm performance in the current model, it remains essential that senior leaders adopt a more visible, engaged, and strategic role in actively supporting quality initiatives, aligning organizational goals with quality objectives, and fostering an environment where quality achievements are recognized and rewarded. Additionally, top management needs to devote resources to the development and ongoing support of ISO certification efforts. Moreover, investing in ongoing workforce development—particularly in areas related to good manufacturing practices (GMP), regulatory compliance, and ISO standards—will equip employees with the competencies needed to sustain high-quality outcomes. Finally, the establishment of comprehensive monitoring systems using KPIs,

internal audits, and continuous feedback mechanisms will ensure that quality management practices are effectively assessed and refined, driving continuous organizational learning and performance enhancement. To improve firm performance after ISO certification, the factory needs to aim for fewer product defects and reduced waste, cut down on high operational costs, and implement a high-quality administrative system to support overall factory efficiency. By implementing these targeted recommendations, Pharmaceutical Factory (Insein) can strengthen its organizational capabilities, enhance the positive impact of quality management practices, and achieve sustained improvements in firm performance.

5.3 Needs for Further Research

This study has provided valuable insights into the effect of quality management practices on firm performance at Pharmaceutical Factory (Insein), further research is required to enhance comprehension and inform subsequent advancements. First, future research should explore how other factors, such as organizational leadership styles, employee engagement levels, or technological adoption, interact with quality management practices to influence performance. This could help identify additional drivers or barriers that were not covered in the current analysis. Secondly, it would be useful to conduct longitudinal studies to assess how the long-term implementation of continuous improvement, customer focus, quality culture, and process orientation initiatives affects performance over time. Thirdly, further research could investigate the role of external factors, such as regulatory changes, market competition, or supply chain dynamics, and how these external pressures impact the relationship between internal quality practices and organizational outcomes. Additionally, future studies could apply comparative research by examining similar pharmaceutical factories or manufacturing organizations, both locally and internationally, to benchmark practices and performance outcomes. This would help determine whether the findings at Pharmaceutical Factory (Insein) are broadly applicable or context-specific. Finally, more qualitative research, such as employee interviews or focus groups, could provide deeper insights into the perceptions, challenges, and cultural aspects that influence the success of quality management initiatives. By addressing these areas, future research can build a more comprehensive understanding of how to optimize quality management practices for sustained organizational success at Pharmaceutical Factory (Insein) and beyond.

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APPENDIX - A

QUESTIONNAIRE

Section (A) Demographic Factors

Please put a tick mark on the box which is suitable to you.

(1) Gender

- ☐ Male
- ☐ Female

(2) Age

- ☐ Below 30 Years
- ☐ 30 Years - 40 Years
- ☐ 41 Years - 51 Years
- ☐ 51 Years - and above

(3) Marital Status

- ☐ Single
- ☐ Married

(4) Education

- ☐ Master
- ☐ Bachelor

(5) Position

- ☐ General Manager
- ☐ Deputy General Manager
- ☐ Assistant General Manager
- ☐ Manager
- ☐ Assistant Manager

(6) Income

- ☐ Below -300,000
- ☐ MMK 300,000 -400,000
- ☐ MMK 400,001 -500,000
- ☐ Above -500,000

(7) Experience

- ☐ Below 5 Years
- ☐ 5 Years -10 Years
- ☐ 11 Years – 20 Years
- ☐ Above 20 Years

Section (B)

Interpretations of the Scale: Strongly disagree=1, Disagree=2, Neutral =3, Agree=4, Strongly agree = 5

(1) Continuous Improvement

Sr. No	Statements	1	2	3	4	5
1	Employees are continuously trained to enhance internal quality performance.					
2	There is continuous monitoring and improvement of quality systems and procedures to enhance performance.					
3	Quality audits are carried out continuously as per ISO certification requirements.					
4	There is continuous improvement reviews through internal quality audits.					
5	There is a policy for making continuous improvement of products quality for every individual in the company.					

(2) Customer Focus

Sr. No	Statements	1	2	3	4	5
1	The factory has customer complains procedure where customers are attended to.					
2	Factory is committed to customer retention by ensuring quality products.					
3	The factory conducts customer feedback surveys regularly.					
4	The factory stresses the importance on obtaining feedback on its quality control systems from customers.					
5	The factory undertakes market based research annually on quality issues.					

(3) Top Management Commitment

Sr. No	Statements	1	2	3	4	5
1	Top management reviews organizations QMS at planned intervals to ensure continuity, adequacy and effectiveness.					
2	Top management devotes resources for development and support for ISO certification.					
3	Quality policies and procedures are documented and communicated to all employees.					
4	Top management establish trust and commitment to quality improvement by eliminating fear.					
5	The management allows participative and engagement of employees in making decisions on quality issues.					

Section (C)

Interpretations of the Scale: Strongly disagree=1, Disagree=2, Neutral =3, Agree=4, Strongly agree = 5

(1) Process Orientation

Sr. No	Statements	1	2	3	4	5
1	Process are structured to achieved factory efficiency.					
2	The factory structures facilitates high performance.					
3	Production procedures are efficient for quality products.					
4	Processes are well-defined and documented for all key activities.					
5	Key performance indicators (KPIs) are established for monitoring process performance.					

(2) Quality Culture

Sr. No	Statements	1	2	3	4	5
1	There is positive quality culture and cooperation within the factory.					
2	There is culture of co-operation between management and employees for quality improvement.					
3	The employees have positive culture change on QMS issues.					
4	Standard operating procedures (SOPs) are strictly followed in daily operations.					
5	The factory strictly adheres to regulatory requirements and standards.					

Section (D)

Interpretations of the Scale: Strongly disagree=1, Disagree=2, Neutral =3, Agree=4, Strongly agree = 5

(3) Firm performance

Sr. No	Statements	1	2	3	4	5
1	Factory providers quality products which are pocket friendly to customers.					
2	There was less customers complaints after introduction of ISO certification.					
3	The management ensures products meets customers expectations through feedback.					
4	The factory has high customer retention and growth after ISO certification.					
5	The factory has fewer defects and less wastage after ISO certification.					
6	There is improved lead time up to delivery.					
7	There is high cost reduction after ISO certification.					
8	High quality administrative systems are in place to support the efficiency of the factory.					
9	There is improved information flow between top management and employee within the company.					
10	Employee are well trained on quality matters to enhance efficiency.					

APPENDIX - B

STATISTICAL OUTPUT

Continuous Improvement

Reliability Statistics

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.895	.896	5

Item Statistics

	Mean	Std. Deviation	N
CI1	3.7284	.74183	81
CI2	3.8519	.69121	81
CI3	3.6790	.95952	81
CI4	3.8395	.82850	81
CI5	3.6914	.80066	81

Customer Focus

Reliability Statistics

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.858	.860	5

Item Statistics

	Mean	Std. Deviation	N
CF1	4.0000	.72457	81
CF2	3.9012	.80008	81
CF3	3.7160	1.00293	81
CF4	3.8395	.82850	81
CF5	3.6543	.85382	81

Top Management Commitment

Reliability Statistics

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.669	.661	5

Item Statistics

	Mean	Std. Deviation	N
TMC1	3.9012	.62460	81
TMC2	3.7778	.70711	81
TMC3	3.8395	.58002	81
TMC4	3.8765	.65922	81
TMC5	3.9383	.73051	81

Process Orientation

Reliability Statistics

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.829	.834	5

Item Statistics

	Mean	Std. Deviation	N
PO1	4.0247	.85111	81
PO2	3.6420	.87047	81
PO3	3.9012	.68200	81
PO4	3.6914	.84620	81
PO5	3.6049	.80123	81

Quality Culture

Reliability Statistics

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.880	.883	5

Item Statistics

	Mean	Std. Deviation	N
QC1	3.9506	.58952	81
QC2	4.0864	.61639	81
QC3	4.0370	.69722	81
QC4	3.8395	.79776	81
QC5	4.0247	.68875	81

Firm Performance

Reliability Statistics

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.837	.814	10

Item Statistics

	Mean	Std. Deviation	N
FP1	3.9012	.70009	81
FP2	3.9012	.60425	81
FP3	4.1358	.64717	81
FP4	3.7531	.75051	81
FP5	3.6790	.52027	81
FP6	3.9012	.58320	81
FP7	3.7778	.61237	81
FP8	3.7778	.61237	81
FP9	4.3704	.48591	81
FP10	4.3210	.46976	81

Analysis of the Effect of Quality Management Practices on Firm Performance

Model Summary[b]

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics					Durbin-Watson
					R Square Change	F Change	df1	df2	Sig. F Change	
1	.956[a]	.915	.911	.11461	.915	274.839	3	77	.000	2.034

a. Predictors: (Constant), TMCM, CIM, CFM

b. Dependent Variable: FPM

ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	10.831	3	3.610	274.839	.000[b]
	Residual	1.011	77	.013		
	Total	11.842	80			

a. Dependent Variable: FPM

b. Predictors: (Constant), TMCM, CIM, CFM

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95.0% Confidence Interval for B		Correlations			Collinearity Statistics	
		B	Std. Error	Beta			Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF
1	(Constant)	1.024	.150		6.836	.000	.726	1.323					
	CIM	.677	.033	.854	20.613	.000	.611	.742	.947	.920	.687	.647	1.546
	CFM	.093	.025	.164	3.686	.000	.043	.144	.653	.387	.123	.561	1.783
	TMCM	.009	.032	.010	.274	.785	.073	.055	.123	.031	.009	.835	1.197

a. Dependent Variable: FPM

Mediating Effect of Process Orientation on the Relationship between Continuous Improvement and Firm Performance

Model Summary[b]

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics					Durbin-Watson
					R Square Change	F Change	df1	df2	Sig. F Change	
1	.947[a]	.898	.896	.12387	.898	692.767	1	79	.000	1.922

a. Predictors: (Constant), CIM

b. Dependent Variable: FPM

ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	10.630	1	10.630	692.767	.000[b]
	Residual	1.212	79	.015		
	Total	11.842	80			

a. Dependent Variable: FPM

b. Predictors: (Constant), CIM

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95.0% Confidence Interval for B		Correlations			Collinearity Statistics	
		B	Std. Error	Beta			Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF
1	(Constant)	1.061	.111		9.580	.000	.840	1.281					
	CIM	.751	.029	.947	26.320	.000	.694	.808	.947	.947	.947	1.000	1.000

a. Dependent Variable: FPM

Model Summary[b]

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics					Durbin-Watson
					R Square Change	F Change	df1	df2	Sig. F Change	
1	.785[a]	.616	.611	.20210	.616	126.871	1	79	.000	1.749

a. Predictors: (Constant), CIM

b. Dependent Variable: POM

ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	5.182	1	5.182	126.871	.000[b]
	Residual	3.227	79	.041		
	Total	8.409	80			

a. Dependent Variable: POM

b. Predictors: (Constant), CIM

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95.0% Confidence Interval for B		Correlations			Collinearity Statistics	
		B	Std. Error	Beta			Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF
1	(Constant)	2.011	.181		11.133	.000	1.651	2.370					
	CIM	.524	.047	.785	11.264	.000	.432	.617	.785	.785	.785	1.000	1.000

a. Dependent Variable: POM

Model Summary[b]

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics					Durbin-Watson
					R Square Change	F Change	df1	df2	Sig. F Change	
1	.972[a]	.946	.944	.09089	.946	677.701	2	78	.000	1.977

a. Predictors: (Constant), POM, CIM

b. Dependent Variable: FPM

ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	11.198	2	5.599	677.701	.000[b]
	Residual	.644	78	.008		
	Total	11.842	80			

a. Dependent Variable: FPM

b. Predictors: (Constant), POM, CIM

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95.0% Confidence Interval for B		Correlations			Collinearity Statistics	
		B	Std. Error	Beta			Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF
1	(Constant)	.217	.130		1.667	.100	-.042	.476					
	CIM	.531	.034	.670	15.712	.000	.464	.598	.947	.872	.415	.384	2.606
	POM	.419	.051	.353	8.290	.000	.319	.520	.879	.684	.219	.384	2.606

a. Dependent Variable: FPM

Sobel Test Result for Mediating Effect of Process Orientation on the Relationship between Continuous Improvement and Firm Performance

Input			Test Statistic:	Std. Error:	p-value:
a	0.524	Sobel Test:	6.61389335	0.03319618	0.00000000
b	0.419	Aroian Test:	6.59671851	0.03328261	0.00000000
S_a	0.047	Goodman Test:	6.63120304	0.03310953	0.00000000
S_b	0.051	Reset all	Calculate		

Mediating Effect of Process Orientation on the Relationship between Customer Focus and Firm Performance

Model Summary[b]

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics					Durbin-Watson
					R Square Change	F Change	df1	df2	Sig. F Change	
1	.653[a]	.426	.419	.29324	.426	58.719	1	79	.000	2.031

a. Predictors: (Constant), CFM

b. Dependent Variable: FPM

ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	5.049	1	5.049	58.719	.000[b]
	Residual	6.793	79	.086		
	Total	11.842	80			

a. Dependent Variable: FPM

b. Predictors: (Constant), CFM

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95.0% Confidence Interval for B		Correlations			Collinearity Statistics	
		B	Std. Error	Beta			Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF
1	(Constant)	2.531	.188		13.450	.000	2.157	2.906					
	CFM	.372	.048	.653	7.663	.000	.275	.468	.653	.653	.653	1.000	1.000

a. Dependent Variable: FPM

Model Summary[b]

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics					Durbin-Watson
					R Square Change	F Change	df1	df2	Sig. F Change	
1	.556[a]	.309	.300	.27120	.309	35.328	1	79	.000	1.930

a. Predictors: (Constant), CFM

b. Dependent Variable: POM

ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	2.598	1	2.598	35.328	.000[b]
	Residual	5.810	79	.074		
	Total	8.409	80			

a. Dependent Variable: POM

b. Predictors: (Constant), CFM

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95.0% Confidence Interval for B		Correlations			Collinearity Statistics	
		B	Std. Error	Beta			Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF
1	(Constant)	3.011	.174		17.296	.000	2.664	3.357					
	CFM	.267	.045	.556	5.944	.000	.177	.356	.556	.556	.556	1.000	1.000

a. Dependent Variable: POM

Model Summary[b]

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics					Durbin-Watson
					R Square Change	F Change	df1	df2	Sig. F Change	
1	.901[a]	.812	.808	.16880	.812	168.817	2	78	.000	1.855

a. Predictors: (Constant), POM, CFM

b. Dependent Variable: FPM

ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	9.620	2	4.810	168.817	.000[b]
	Residual	2.222	78	.028		
	Total	11.842	80			

a. Dependent Variable: FPM

b. Predictors: (Constant), POM, CFM

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95.0% Confidence Interval for B		Correlations			Collinearity Statistics	
		B	Std. Error	Beta			Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF
1	(Constant)	-.139	.237		-.586	.560	-.611	.333					
	CFM	.135	.034	.238	4.025	.000	.068	.202	.653	.415	.197	.691	1.447
	POM	.887	.070	.747	12.666	.000	.748	1.026	.879	.820	.621	.691	1.447

a. Dependent Variable: FPM

Sobel Test Result for Mediating Effect of Process Orientation on the Relationship between Customer Focus and Firm Performance

Input			Test Statistic:	Std. Error:	p-value:
a	0.267	Sobel Test:	5.37343203	0.04407407	0.00000000
b	0.887	Aroian Test:	5.35976052	0.04418649	0.00000000
S_a	0.045	Goodman Test:	5.38720871	0.04396136	0.00000000
S_b	0.070	Reset all	Calculate		

Mediating Effect of Quality Culture on the Relationship between Continuous Improvement and Firm Performance

Model Summary[b]

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics					Durbin-Watson
					R Square Change	F Change	df1	df2	Sig. F Change	
1	.947[a]	.898	.896	.12387	.898	692.767	1	79	.000	1.922

a. Predictors: (Constant), CIM

b. Dependent Variable: FPM

ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	10.630	1	10.630	692.767	.000[b]
	Residual	1.212	79	.015		
	Total	11.842	80			

a. Dependent Variable: FPM

b. Predictors: (Constant), CIM

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95.0% Confidence Interval for B		Correlations			Collinearity Statistics	
		B	Std. Error	Beta			Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF
1	(Constant)	1.061	.111		9.580	.000	.840	1.281					
	CIM	.751	.029	.947	26.320	.000	.694	.808	.947	.947	.947	1.000	1.000

a. Dependent Variable: FPM

Model Summary[b]

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics					Durbin-Watson
					R Square Change	F Change	df1	df2	Sig. F Change	
1	.596[a]	.355	.347	.38187	.355	43.426	1	79	.000	1.788

a. Predictors: (Constant), CIM

b. Dependent Variable: QCM

ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	6.333	1	6.333	43.426	.000[b]
	Residual	11.520	79	.146		
	Total	17.853	80			

a. Dependent Variable: QCM

b. Predictors: (Constant), CIM

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95.0% Confidence Interval for B		Correlations			Collinearity Statistics	
		B	Std. Error	Beta			Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF
1	(Constant)	1.838	.341		5.384	.000	1.158	2.517					
	CIM	.580	.088	.596	6.590	.000	.405	.755	.596	.596	.596	1.000	1.000

a. Dependent Variable: QCM

Model Summary[b]

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics					Durbin-Watson
					R Square Change	F Change	df1	df2	Sig. F Change	
1	.954[a]	.909	.907	.11730	.909	391.309	2	78	.000	2.105

a. Predictors: (Constant), QCM, CIM

b. Dependent Variable: FPM

ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	10.769	2	5.384	391.309	.000[b]
	Residual	1.073	78	.014		
	Total	11.842	80			

a. Dependent Variable: FPM

b. Predictors: (Constant), QCM, CIM

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95.0% Confidence Interval for B		Correlations			Collinearity Statistics	
		B	Std. Error	Beta			Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF
1	(Constant)	.859	.123		7.006	.000	.615	1.103					
	CIM	.687	.034	.867	20.435	.000	.620	.754	.947	.918	.697	.645	1.550
	QCM	.110	.035	.135	3.177	.002	.041	.179	.651	.339	.108	.645	1.550

a. Dependent Variable: FPM

Sobel Test Result for Mediating Effect of Quality Culture on the Relationship between Continuous Improvement and Firm Performance

Input			Test Statistic:	Std. Error:	p-value:
a	0.580	Sobel Test:	2.83683796	0.02248983	0.00455627
b	0.110	Aroian Test:	2.81060323	0.02269975	0.00494487
S_a	0.088	Goodman Test:	2.86382131	0.02227793	0.00418564
S_b	0.035	Reset all	Calculate		

Mediating Effect of Quality Culture on the Relationship between Customer Focus and Firm Performance

Model Summary[b]

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics					Durbin-Watson
					R Square Change	F Change	df1	df2	Sig. F Change	
1	.653[a]	.426	.419	.29324	.426	58.719	1	79	.000	2.031

a. Predictors: (Constant), CFM

b. Dependent Variable: FPM

ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	5.049	1	5.049	58.719	.000[b]
	Residual	6.793	79	.086		
	Total	11.842	80			

a. Dependent Variable: FPM

b. Predictors: (Constant), CFM

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95.0% Confidence Interval for B		Correlations			Collinearity Statistics	
		B	Std. Error	Beta			Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF
1	(Constant)	2.531	.188		13.450	.000	2.157	2.906					
	CFM	.372	.048	.653	7.663	.000	.275	.468	.653	.653	.653	1.000	1.000

a. Dependent Variable: FPM

Model Summary[b]

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics					Durbin-Watson
					R Square Change	F Change	df1	df2	Sig. F Change	
1	.604[a]	.365	.357	.37881	.365	45.416	1	79	.000	1.900

a. Predictors: (Constant), CFM

b. Dependent Variable: QCM

ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	6.517	1	6.517	45.416	.000[b]
	Residual	11.336	79	.143		
	Total	17.853	80			

a. Dependent Variable: QCM

b. Predictors: (Constant), CFM

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95.0% Confidence Interval for B		Correlations			Collinearity Statistics	
		B	Std. Error	Beta			Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF
1	(Constant)	2.455	.243		10.099	.000	1.971	2.939					
	CFM	.422	.063	.604	6.739	.000	.297	.547	.604	.604	.604	1.000	1.000

a. Dependent Variable: QCM

Model Summary[b]

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics					Durbin-Watson
					R Square Change	F Change	df1	df2	Sig. F Change	
1	.728[a]	.530	.518	.26707	.530	44.013	2	78	.000	2.136

a. Predictors: (Constant), QCM, CFM

b. Dependent Variable: FPM

ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	6.279	2	3.139	44.013	.000[b]
	Residual	5.564	78	.071		
	Total	11.842	80			

a. Dependent Variable: FPM

b. Predictors: (Constant), QCM, CFM

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95.0% Confidence Interval for B		Correlations			Collinearity Statistics	
		B	Std. Error	Beta			Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF
1	(Constant)	1.723	.259		6.640	.000	1.206	2.239					
	CFM	.233	.055	.409	4.196	.000	.122	.343	.653	.429	.326	.635	1.575
	QCM	.329	.079	.404	4.152	.000	.171	.487	.651	.425	.322	.635	1.575

a. Dependent Variable: FPM

Sobel Test Result for Mediating Effect of Quality Culture on the Relationship between Customer Focus and Firm Performance

Input			Test Statistic:	Std. Error:	p-value:
a	0.422	Sobel Test:	3.53673641	0.04308557	0.00040510
b	0.329	Aroian Test:	3.50864981	0.04317388	0.00045039
S_a	0.063	Goodman Test:	3.56550849	0.04299708	0.00036315
S_b	0.079	Reset all	Calculate		