



Addis Ababa University College
Of Business and Economics
M.Sc in Management (Extension)

The Effect of Quality Management System on Organizational Performance:
The Case of EPHARM Ethiopia

A Thesis Submitted to Addis Ababa University College of Business and Economics in partial fulfillment of the requirements for the Degree of Master of Science (M.Sc.) in Management Specialized in Quality Management and Organizational Excellence

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Addis Abeba, Ethiopia

Declaration

I, the undersigned, endorse that this thesis is entirely original with guidance from my advisor, Assistant Professor **Tewodros Wuhib**, and that all sources of information used in its preparation have been properly cited. I also prove that the thesis has not been submitted, in whole or in part, to any other higher education institution for credit toward a degree.

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This thesis has been submitted to Addis Ababa University College of Business and Economics for examination with my approval as a university thesis advisor.

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The Effect of Quality Management System on
Organizational Performance:
*The Case of Ethiopian Pharmaceutical Manufacturing
(EPHARM) S.C*

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Acronym

QMS	Quality Management System
ISO	International Organization for Standardization
QM	Quality Management
JIT	Just in Time
UNIDO	United Nations Industrial Development Organization
EPHARM	Ethiopian Pharmaceutical Manufacturing

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Abstract

This research has been conducted to examine the effect of QMS (Quality Management System) on organizational performance in the case of Ethiopian Pharmaceutical Manufacturing (EPHARM) S.C. This is due to the reason that companies frequently assume QMS practices and ISO certification can improve organization performances. An explanatory research design and mixed approach has been employed to investigate the effect of QMS on the Ethiopian Pharmaceutical Manufacturing (EPHARM) S.C organizational performance. Audit Report & Annual performance reports are used as secondary data and Questioners & interview are used as primary data. These data were collected from the case company managers, division heads, experts and staffs. Purposive sampling used to select the interviewees and respondents for the questionnaire. The collected data was analyzed using descriptive statistics and SPSS version 26 software was used to test for its significance. The results showed that Implementation of quality management systems has positive effect on the performance of the company. Organization performance dimensions such as business performance, product quality and operational performance are positively affected by the quality management system practices. The research finding has also showed that the major challenges in the course of quality management systems implementation process are gaining the work force commitment, top management commitment, lack of QMS knowledge and experience, insufficient time and limited budget. This research has surfaced the effect of quality management system on organizational performance, and so the case company, researchers, practitioners, affiliated institutes and organizations will be benefited from the research findings.

Key words: Quality management system, organizational performance, manufacturing industr

CHAPTER ONE

INTRODUCTION

1.1 Back ground of the study

This time, the major challenge for organizations is to meet the demands of the customer (Patyal & Koilakuntla, 2017). According to Patyal, Vishal Singh and Koilakuntla, Maddulety customers are powerful and organizations are working in stiff competition. The customers need them to produce their products in an environmental friendly way. It imposes additional pressure to produce with efficiency and effectiveness. The products should also be supplied with minimum cost, high quality, in speedy situations with variety in number and type of products to meet the varied requirements of customers, to have increased market share and to remain competitive. Organizations are, therefore, continuously enhancing their performance by improving quality of their products and services through various quality management (QM) practices (Patyal & Koilakuntla, 2015b).

In the past few decades, companies in the world have been trying to survive these challenges and a rapidly changing business environment in which management have to be more and more intelligent in finding ways to sustain or gain competitive advantage. Among the measure that have been taken to withstand these challenges, most manufacturing organizations have chosen to implement and use new improvement philosophies such as quality management systems, concurrent Engineering, Lean Production, Just-In Time (JIT) strategies, Business Process Re-engineering (BPR) and others, to become more effective in the way they conduct business (Ngambi & Nkemkiafu, 2015) . The optimization of the organization's performance is the main driver behind these philosophies both internally and externally within its respective market targets strategies.

According to the International Organization for Standardization (ISO), quality management system (QMS) is defined as coordinated activities to direct and control an organization with regard to quality. It is a standard developed by the International Organizations for Standardization and act as a framework for organizational quality management systems (Bell & Omachonu, 2011). The framework is popularly understood by organizations and governments around the world and consequently used as standard for management systems. The ISO 9000 family addresses various issues of quality management and holds

some of ISO's best known standards. The standards provide guidance and tools for companies and organizations who want to ensure that their products and services consistently meet customer's requirements, and that quality is consistently improved (ISO, 2017).

Several researches have shown quality management systems (QMS) have been widely applied successfully by many manufacturing companies to improve their process, increase profits and organizational performance (Awoku, 2012). Among the most applied quality improvement programs, ISO 9001 is the popular one. A large number of current literatures have, in common, the general assumption on the adoption of QMS to result in firm's performance improvement (Karipidis, et al., 2009; Marin & Ruiz-Olalla, 2011).

1.2 Statement of the problem

Many researchers tried to figure out how the QMS helps organizations increase their organizational processes and their corresponding performance. Any initiative aimed at continuous improvement must always be implemented with the goal of improving a portion or the entirety of the organizational performance as seen from various angles. Performance and QMS practices have been measured in a number of empirical studies (Patyal and Koilakuntla 2015 b). Numerous empirical investigations have been shown that QMS directly affects organizational performance (Powell, 1995; Patyal and Koilakuntla, 2017).

Ethiopian Pharmaceutical Manufacturing S.C (EPHARM) is currently implementing quality management systems (QMSs). QMSs have been widely adopted in the global manufacturing arena, despite occasional criticism regarding the standard's capacity to help manufacturing companies operate quality procedures and produce quality products. Nevertheless, the presence of quality documentation alone such as quality plans, procedures, and work instructions, as well as a top management system does not always indicate the existence of ingrained operational practices and procedures required to guarantee the eventual delivery of a well-functioning QMS that can provide customer satisfaction in accordance with ISO 9001's stated values (Al-Rawahi and Bashir, 2011). Furthermore, it seems that there are still unanswered questions about EPHARM's comprehensive understanding of QMS implementation procedures

Implementing a QMS goes beyond simply earning a certificate; it shows that the real goals of quality management have been met. This information motivates businesses to voluntarily manage quality and after it is put into place, it helps them to fully utilize the System (Leonardo, 2011). Remarkable rise in the

number of businesses obtaining ISO 9001 certification globally further implies that certification will benefit the company (Tulu, 2011).

At the end of this research, the following research questions will be answered.

1. Does the Top Management commitment have an effect on organizational performance?
2. Does Supplier relationship management have an effect on organizational performance?
3. Does customer relationship management have an effect on organizational performance?
4. Does Work force management have an effect on organizational performance?
5. Does Process management have an effect on organizational performance?
6. Do Product /Service design have an effect on organizational performance?
7. Does Quality Information & analysis have an effect on organizational performance?

1.3 Objectives

1.3.1 General objective

The general objective of the study was to determine the effect QMS implementation on organizational performance of Ethiopian pharmaceutical manufacturing company (EPHARM).

1.3.2 Specific Objectives

1. To Assess the effect of Top Management commitment on organizational performance
2. To Assess Supplier relationship management effect on organizational performance
3. To Assess Customer relationship management effect on organizational performance.
4. To Assess Work force management effect on organizational performance
5. To Assess Process management effect on organizational performance
6. To Assess effect of Product /Service design on organizational performance
7. To Assess effect of Quality Information & analysis on organizational performance

1.4 Scope of the study

The study focused on the effects of the Quality Management System (QMS) on the performance of the company. It looked at aspects like business performance, product quality, and operational performance to measure this effect. Various performance indicators were used, including operational revenue, transactions, market share, industrial prices, incomes, durability, consistency, perceived quality and

productivity, compliance with the given standard, process effectiveness, and competitive advantage. These indicators helped assess how QMS implementation influenced the organization's performance.

The research was conducted in Addis Ababa. A sample of Production Department, Research and Development Department, Engineering Department, Quality Assurance Department and other Managers who serves for the last two years and above who have significant role in designing, planning, implementation, controlling and evaluation of ISO 9001:2015 QMS system will be selected.

This study aimed to assess how the Quality Management System (QMS) affects the performance of the Ethiopian pharmaceutical manufacturing company (EPHARM). The company adopted the ISO 9001:2015 QMS as a method for ongoing improvement in performance through quality management standards. It also looks at various performance factors that can be examined in relation to the QMS implementation.

1.5 Significance of the study

The company will gain internal benefits from this research, including increased control confidence, better understanding of the company's goal, improved communication, and clearly defined authority and responsibility. The company's external benefits from this research output include increased customer satisfaction, enhanced brand recognition, and increased consumer confidence.

1.6 Limitations of the Study

The exclusion of other pharmaceutical factories from the current study was a limitation that might have affected the conclusions drawn about the quality management system (QMS) across the nation's pharmaceutical industry. The researcher's limited budget, convenience, and time constraints served as the justification for the participant selection process. In addition, there are time and logistical resource limitations, as well as challenges with data access.

Additionally, due to a confidentiality issue, access to financial annual report data was restricted; making it impossible to compare net profit before and after the QMS was implemented. It should be mentioned that Ethiopian Pharmaceutical Manufacturing Share Company is a well-known pharmaceutical production and manufacturing facility in Ethiopia with years of experience in the field. It offers a variety of products as well as facilities for research and development.

1.7. Organization of the study

The research has been structured in to 5 chapters. One introduce the general concept , outlines the problem statement, details the study's objectives, defines the scope and limitations. Chapter two covered the literature review concerning the conceptual definitions of the terms as well as previous theoretical and empirical findings from various researchers. Chapter three outlined the approach to achieve the specified objective and respond to the research questions posed, focusing entirely on research methodology. Chapter four provided the data analysis and interpretation section of the study. Lastly, chapter five presented the conclusion, summary, and findings of the research.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

Organizations must compete for survival. As customers gain more options for their needs and expectations manufacturers are constantly faced with the need to meet ever increasing consumer demands. As the interests of various shareholders, their respective benefits, effects, and demands grow, so do operational performance indicators. In response to these challenges, various concepts and related systems, tools, and technologies have been developed to support organizational growth and competitiveness. Among these concepts, the concept of quality is one of them. “Meeting customer requirements” is the simplest definition of the quality concept. As a result, the quality of manufactured products today has become one of the most important factors influencing local, regional and global business and economic models (Aggelogiannopoulos, et al., 2007). Over the years, several quality standards have been developed and adopted. The quality management system is one of the ISO management systems developed and applied worldwide

2.2. The concept of quality and QMS

Quality has enhanced a usual strategic arm by trades contemporary. Companies with better characteristic likely to have a best market share than their contestants (Awoku, 2012). According to Awoku and Rachel Yetunde-Abiodun, many production companies have earned the significance of status. This time, quality has enhanced the gist of contest for companies to beat their favorites and extend their market share. There are various habits to decide quality. Today, skilled is no distinct universal description of character. Quality is seen differently by various families.

However, everyone knows what “quality” means (University of Cambridge, 2017). For manufactured products, the user, the customer, perceives the quality of fit, finish, appearance, function, and performance. Service quality can be assessed based on the satisfaction of the customer receiving the service. Some people see quality as compliance with standards. Others see it as customer satisfaction or customer satisfaction (Awoku, 2012).

To ensure overall quality in production, it must be defined from the customer's perspective. Compliance means meeting consumer and governing requirements. Differences between one organization and another,

or between one product and another, are usually perceived in relation to the company's products or services.

In manufacturing, quality is product conformity, reliability, performance, durability, and serviceability (Awoku, 2012). Conformity is the extent to which a product's characteristics meet established standards, while performance measures how effectively a product functions. Reliability is the likelihood that a device will perform its required functions under specified conditions for a specified period of time. In 1930, Walter Schuhart of Bell Labs decided to use statistics to determine "best practices" in the United States. Over the years, these findings were translated into control charts and adopted by the American manufacturing industry in the 1950s (Goef, 2001, p. 34). In the 1950s and 1960s, W. Edwards Deming and Joseph Juran recognized the importance of using quality standards and processes to ensure processes and control performance. The United States, being the world leader in manufacturing, did not pay much attention to quality assurance. Deming and Juran were invited to Japan to give a lecture on quality management (Goeff, 2001). During the 1970s and 1980s, many American companies lost business to foreign competitors. Foreign companies produced cheaper and better products. While Western countries focus on luxury goods to sell products at higher prices and increase profits, Eastern countries focus on product development to create better and cheaper products (Goeff, 2001). ISO standards and the Malcolm Baldrige National Quality Award were established in 1987 to recognize quality that products manufactured are not only effective but also durable and easy to repair.

A Quality Management System is a set of tools for driving and controlling an organization, considering all different Quality aspects (ISO-9000 2000) including human resources, know-how and technology, working practices, methodologies and procedures (Franceschini, et al., 2007). According to Franceschini Fiorenzo, Galetto Maurizio and Masan Domenici a quality system with its resources and processes should accomplish specific planned targets such as production, cost, time, and return of investment, stakeholders' exigencies or expectations.

2.3. Brief review of QMS

A quality management system (QMS) is a formalized system that defines and documents an organization's processes, procedures, and responsibilities for achieving quality policies, practices, and objectives. It helps an organization coordinate and direct its activities to meet customer and regulatory requirements, as well as continuously improve its effectiveness and efficiency.

Implementing a QMS affects every aspect of an organization's performance. Benefits of a documented QMS include:

Meeting customer requirements, this helps instill confidence in the organization, in turn leading to more customers, sales, and repeat business

Meeting the organization's requirements, which ensures compliance with applicable regulations and provides products and services in the most cost and resource-efficient manner, creating room for expansion, growth, and profit

Furthermore, several industries also have developed standards, built upon ISO 9001, that offer specific direction regarding additional expectations that are uniquely associated with their operations. ISO 9001 is the most recognized and implemented quality management system standard in the world. ISO 9001 specifies the requirements for a QMS that organizations can use to develop their own programs.

The standard is structured around seven quality management principles. Quality management principles are the guiding beliefs that, when used for organizational decision-making, ensure long-term success from the perspective of customers, employees, and other stakeholders. The quality management principles demonstrate the depth of the organization's commitment to quality. Well-formulated principles should be timeless, not dependent on temporary circumstances.

In general, an organization's management system is how it oversees the interconnected aspects of its operations to meet its goals (ISO, 2017). Quality of the product or service, operational effectiveness, environmental performance, workplace health and safety, and many other areas can all be related to these goals, according to ISO. A bulletin issued by the International Organization for Standardization in 1987 served as the foundation for the ISO 9000 standards (Ferguson, 1996). Its objective was to offer a set of global standards pertaining to quality systems that could be applied to external quality assessments (Aggelogiannopoulos, et al. (2007). Educating organizations on how to create their own quality systems according to the demands of their respective markets was the other goal.

The ISO 9000 series of standards is designed as a general standard for quality management and

quality assurance. Regardless of the type of organization, these standards apply to all types and types of organizations, including private and public organizations, government agencies, and regardless of the size of the organization or the types of products produced or services provided.

The ISO standards covers a wide range of quality management topics and includes some of the most important one is (ISO, 2017). It provides guidance and tools for companies and organizations that want to ensure that their goods and facilities continue to meet customer needs and expectations.

This standard is implemented with the goal of ensuring those customers' demands for goods and services are met. Consequently, the ISO concept's goal of standardizing a few essential aspects of a quality management system and generating benefits for both suppliers and customers will be considered. It also makes it possible to establish a contractual standard between these parties that evaluates whether the goods or services that producers provide will meet the needs and specifications of buyers (Yahya and Goh, 2001).

A status administration structure (QMS) is delimited for one International Organization for Standardization (ISO) as a set of matched conduct to guide and manage an arranging's characteristic. It serves as a foundation for administrative value administration schemes and was founded apiece International Organizations for Standardization (Bell and Omachonu, 2011). Organizations and governments general use the foundation as a standard for administration plans because it is widely implicit.

Goetsch and Davis, on the other hand, define QMS as a quality management system that includes all of the organization's policies, plans, resources, processes, and authority and responsibility delineation. These are all purposefully designed to achieve product or service quality levels that are in line with customer satisfaction and the organization's goals. When these plans, policies, and procedures, etc. are combined, they establish the organization's operations and quality control procedures (Goetsch and Davis, 2005). The most well-known quality management system is probably the ISO 9000 series standard (Al-Rawahi & Bashir, 2011).

In the 1980s, American companies were facing fierce competition from Japanese competitors in the global market. Japanese companies played a significant role in the past trade with the United States in products such as automobiles, electronics, and mechanical equipment. NBC TV

explained this fact well in its program "If Japan Can Do It. Why Can't We" (Samson and Terziovski, 1999, p. 394).

Table2.1: There are now seven (7) quality management system principles (QMSPs)

No	QMSP	Statement
1	Customer focus	Fulfill customers need and expectation
2	Leadership	A function of Leading group of peoples to achieve common goals
3	Engagement of people	Participation of employees for each activities
4	Process approach	Managing and organizing a business activities as a system of process
5	Improvement	Making the system or the working environment better than the previous one
6	Evidence-based decision- making	Make decision based on tangible data or analysis
7	Relationship management	Building strong relationship with customers ,clients and with co-workers

Sources: ISO 9000:2015: Quality Management System-Fundamentals and Vocabulary (2015) and Fonseca & Domingues (2016)

1. Customer Focus

Surpassing consumer expectations and including their needs. This involves energetically hearing to customer response. Additionally, it demands making necessary adaptations to products or aids. Moreover, stopping updated accompanying innovations is owned by improving customer delight. Ultimately, a customer-directed approach guarantees commitment to providing profit and supporting enduring relates with customers.

Advantages:

- **Increased Customer Loyalty:** Building tighter connect customers by accompanying to their needs and beliefs spurs better customer faithfulness and repeat trade.
- **Better Brand Reputation:** an extreme arrangement on customer delight upgrades the company's prestige, illustration in new clients and acquiring allure place as a trustworthy display leader.

2. Leadership

It refers to the responsibilities and responsibilities of upper administration in forming and maintaining an atmosphere inside the association namely timely to accomplishing the organization's characteristic aims and pledging the efficiency of the kind administration whole.

Advantages:

- **Improved Organizational Alignment:** Skilled guidance form sure that all stick appendages share the unchanging view for the organization's quality aims and hook up to accomplish bureaucracy.
- **Enhanced Employee Morale:** Good guidance founds a supportive work air, bestowing staff appendages more expert and enhancing confidence, that raises engagement and output

3. Engagement of People:

The term "engagement of people" describes by means of what population at all administrative levels agree to attain quality aims and set the quality administration structure (QMS) into place. Moreover, this law acknowledges the significance of bestowing workers the finishes they need to favorably contribute to the advance and continuous growth of the company

Advantages:

- **Enhanced Departmental Collaboration:** Including stick members when carrying out company aims increases ideas and creates a strong crew environment.
- **Increased Retention Rates:** Involving stick appendages actively in condition administration constitute a sense of dependability and ownership with bureaucracy that lowers turnover and keeps top ability in the party.

4. Process Approach

It is a theme that stresses directing possessions and exercises as connected processes so that capably and efficiently achieves asked results. The process approach sees an institution as a network of pertain

processes that agree to realize the institution's aims, as opposite to observing it as a group of separate areas or functions

Advantages:

- **Streamlined Operations:** By streamlining movements and lowering wrongs, the process approach increases effectiveness and minimizes wrongs.
- **Enhanced Compliance:** Processes that are agreeing ISO 9001 flags guarantee supervisory compliance while threatening risks and reconstructing administrative conduct

5. Improvement:

Improving the adeptness of organizational process and the characteristic administration system (QMS) this idea is implanted in the idea of continuous bettering. It includes labeling areas for augmentation, making adaptations, and judging the outcomes to support continuous progress

Advantages:

- **Enhanced Productivity and Efficiency:** Continual bettering leads to sleek procedures and optimum capital distribution, which raises adeptness and output
- **Competitive Edge:** providing better output and services, that increase client happiness and faithfulness, arrangements that prioritize bettering achieve a strategic benefit.

6. Evidence-Based Decision Making

Making educated conclusions based on objective evidence and dossier reasoning as opposed to resting on particularly on gut feelings or emotional fate is famous as "evidence-based in charge." This law highlights the meaning of acquiring, assessing, and requesting relevant dossier to assist organizational administrative processes

Advantages:

- **Improving Problem-Solving:** Organizations grant permission fast identifies the center causes of questions with the use of evidence-located administrative. This promotes focused and effective logical activities.
- **Strategic Adaptability:** Organizations can guarantee deftness and resilience in vital frameworks by fast regulating plans and tactics in reaction to changeful chances and resorting to objective data

7. Relationship Management

The planning used by activities to handle their business with relevant curious parties these bodies contain suppliers, employees, clients, managers, and other partners. This standard acknowledges the need for beginning and maintaining good relationships. It aims to boost consumer satisfaction and obey allowable obligations. Additionally, it is important for favorably accomplishing allied aims

Advantages:

- **Improved Risk Management:** Since shareholders are more willing to share concerns and agree to evolve risk management plans, productive connection administration furthers upgraded risk discovery and mitigation.
- **Improved Customer Retention:** Happy clients are more inclined wait and use the company's goods and duties repeated. Therefore, nurturing stable friendships with ruling class increases

As seen in Figure 2.1, QMS follows a process based on a conceptual model. In the continuous improvement process, customers and standards should be followed, and ideas and customer satisfaction should be included in the product development process.

Figure 2.1: A process based quality management system Model



Source: (INTRA.ITILTD-India, 2017)

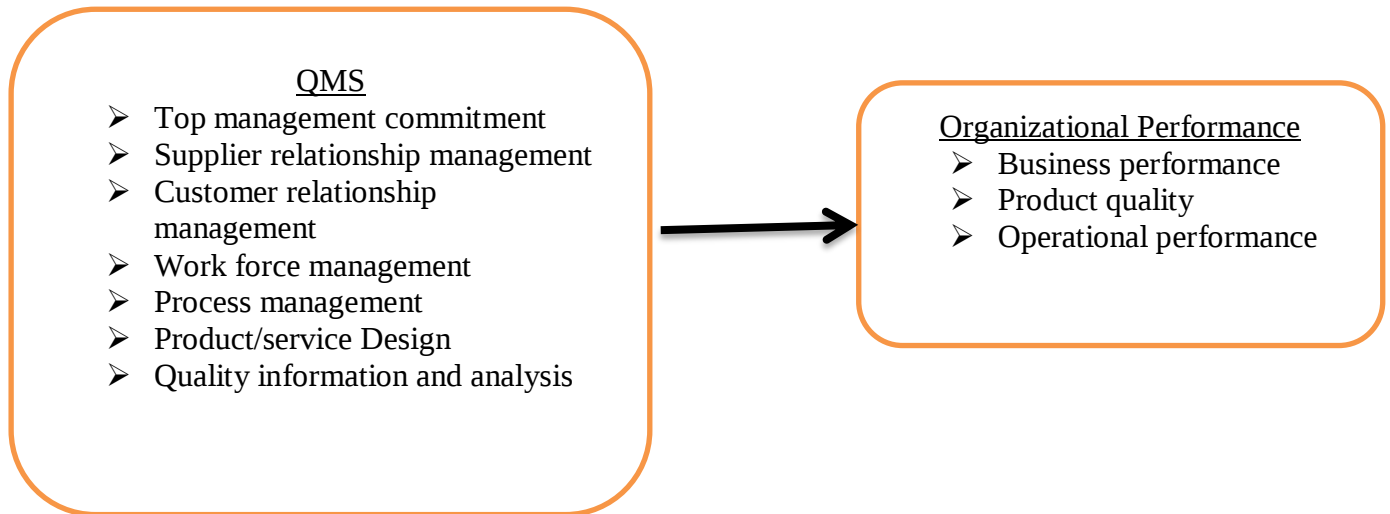
2.4 Empirical Review

Table 2.2: The Relationship between QMS Practices and Organizational Performance

Source: - Shafiq, Muhammad Lasrado, Flevy Hafeez, Khalid 20

Study	Country	Nature of organizations	Research method	Findings
Tan (2013)	Malaysia	Family business	Survey	Organizational performance and QMS has positive relationship
Louise et al. (2013)	USA	American awarded companies	Observation of firms over 11 years	Positive relationship of QMS and OP
Corredor and Goni (2010)	Spain	Manufacturing and service provider	Secondary data of financial report and quality award	There is no significance difference before and after implementation of QMS
Bou-Llusor et al. (2009)	Spain	Manufacturing and service provider	Questionnaire for top managers	Strong positive relationship
Macinati (2008)	Italy	Health center	Questionnaire for top managers	QMS has no significant relationship between financial results. But it has positively associated with subjective performance.
Tari, Molina and Castejon (2007)	Spain	Manufacturing and services provider	Questionnaire for top managers	QMS have direct and indirect effect on organizational performance.
Feng et al. (2006)	Australia and Singapore		Questionnaire for top managers	QMS and OP has relationship
Sila and Ebrahimpur (2005)	USA	Manufacturer	Questionnaire for top managers	Among different constructs of TQM, only leadership and process management have a direct positive relationship with business results.
Rahman and Bullock (2005)	Australia	Manufacturer	Questionnaire for top managers	QMS has direct and indirect effect on organizational performance
Kaynak (2003)	USA	Manufacturing and services provider	Questionnaire for top managers	QMS practices have a positive direct and indirect effect on organizational performance.
Prajogo and Sohal (2003)	Australia	Manufacturing and services provider	Questionnaire for top managers	QMS are positive relation with product quality and innovation
Douglas and Judge (2001)	USA	Health center	Questionnaires' and secondary data	QMS has positively and significant related to financial and other related performance

Conceptual Frame work



Source: International Journal of Academic Research

Figure 2.2 Conceptual framework of the study

2.5. Organizational Performance Measures

The most important idea that must be understood before taking any control or improvement measures is measurement. Given the well-known adage, "what you cannot measure, you cannot manage," measurement is crucial (Hauser and Katz, 1998). Performance measurement is a universal measurement system of an organization that is dependent on the individual or collection of measures that make up the measurement system.

A factory can't be successful by all measures. Manufacturing performance can be measured using a variety of common standards (Neely, 2007). Short delivery cycles, excellent product quality and dependability, trustworthy delivery assurances, the capacity to swiftly develop new products, adaptability to volume fluctuations, low investment and, consequently, a higher return on investment, and low costs are a few of these. These manufacturing performance metrics require trade-offs; some tasks must be sacrificed in order to fulfill others. The unavoidable limitations of process technology and equipment mean that they cannot all be completed to the same standard. Trade-offs like low inventory investment versus short delivery cycles or costs versus quality are fairly obvious. Even though they are less evident, other trade-offs exist. When creating manufacturing policies, they entail making implicit decisions (Skinner, 1969).

However, it may be questioned to create, implement, and judge acting metrics that really show the value of an institution's management wholes. Some trades just consider the cost of dawdling condition administration systems working expected an overhead payment that is repeatedly hidden within additional budgets (Bell and Omachonu, 2011). The increasing number of certifications accepted annually, still, displays that the ISO 9000 quality administration scheme and the connected industry-distinguishing guidelines are still established (ISO Central Secretariat, 2008). Even certified institutions, in accordance with critics of the ISO 9000 standard, create inferior yield (Johannsen, 1996) Proving the pointlessness of confirmation. Nonetheless, a more persuasive system may be completed by collect on the quality administration structure certification process accompanying the aid of appropriate trade efficiency metrics. Implementing a characteristic administration foundation can have significant costs in addition to benefits.

To evaluate the organizational performance of a company implementing a quality management system, various researchers use a wide range of performance measures. Kafetzopoulos and Dimitrios P. conducted a study on the evaluation of quality management implementation. ; Evangelos L. Psomas. According to Kafetzopoulos et al., Gotzamani, Katerina D. classified operational performance, business performance, and product quality as the three main performance metrics. 2014). Performance metrics like dependability, durability, perceived quality, performance, and specification compliance are all taken into account under the operational performance dimension in their study. They use financial results, cash flow, profitability, net profit margin, company sales growth, and company market growth as indicators of business performance. Similar to this, the operational performance dimension considers the company's competitive advantage, productivity, efficiency, and process effectiveness as well as its capacity to access new domestic and international markets.

Ali Uyar working 11 administrative performance measures, two together fiscal and non-commercial, in welcome survey study on quality efficiency calculation practices in the top 500 production companies in Turkey. The commercial measures contain equating characteristic costs to industry flags, resolving feature cost components, calculating for condition costs, and resolving variances. Trend analysis of value costs over diversified periods. The allotment of produce reworks, the rate of material spoilage, the rate of result product defects, the capacity of returned merchandise amount to buying, the appropriate delivery of merchandise or duties to clients, and so on are instances of non-fiscal versification, total number of illnesses from customers, several investigators, including Feng and others have checked the effect of implementing an QMS character management system on administrative efficiency.

To evaluate by virtue of what the kind management method distressed different arranging, they employed a difference of efficiency metrics.

2.6 Quality management systems and organizational performance

In contemporary's competitive atmosphere, transferring high-quality, fairly priced merchandise and services in the abridged amount momentary is essential to accomplishing, improving, and asserting competitiveness (Al-Rawahi and Bashir, 2011). As a result, businesses use a variety of management techniques and concepts, such as quality management systems. In addition to lowering costs, these systems are crucial for improving quality, safety, efficiency, dependability, productivity, and job satisfaction.

According to earlier research in the field of quality, there are components of the quality system that affect the performance of organizations. Additionally, empirical data shows that a number of organizations are compelled to register and implement ISO as a result of external pressures like market-related factors and customer needs, need for process or plan bettering, the desire for worldwide arrangement, and a lack of within focus (Aggelogiannopoulos, et al. 2007; Goh and Yahya, 2001).

On the contrary, skilled is evidence that within factors, like reinforcing the overall act of the association, are main in determining either to command ISO enrollment and implement ISO management arrangements. Periodic review, stiff healing operation, and process focus are important parts of kind administration systems that influence the acting of arrangements, in accordance with Tsiotras and Gotzamani (1996). Better customer connections and upgraded processes were eminent by Carlsson and Carlsson as advantages of achieving ISO 9000 in Swedish trades (Carlsson & Carlsson, 1996). Monitoring often agreement with settled pacts and including the corrective operation process are two big barriers, in accordance with Lee and Palmer (Lee & Palmer, 1999). These ISO 9000 system parts have existed picked for additional research in this place study on account of their distinction in the characteristic literature.

According to ISO 9000 confirmation guidelines, quality administration methods maybe focused to gain asked and necessary results accompanying the aid of appropriate trade act measures (Bell and Omachonu, 2011). According to Lassâad Lakhal, Federico Pasin, and Mohamed Limam, quality administration methods and administrative performance are absolutely compared (Lakhal, et al. (2006). Furthermore, their verdicts show that center practices have a direct affect product characteristic and foundation practices have a direct affect operational accomplishment. Mei Feng, Milé Terziovski, and Danny Samson demanded that certification practices (exercise, administrative assurance, and planning) and functional act

have a definite and significant connection (Feng and others. (2008). However, out of the variables they look at, the friendship betwixt these practices and business acting was erect expected positive but not important. According to their research, functional and trade performance was still most carefully correlated accompanying administrative obligation to certification.

According to the findings of their empirical study, ChingI Lin and Woan Yuh Jang found a positive correlation between business performance and QMS (Lin and Jang, 2008). Four essential components for the successful implementation of quality management systems have also been identified by them. These were determined to be a sequence of chains rather than parallel elements and included employee involvement, quality planning, top management support, and continuous improvement. Michael Bell and Vincent Omachonu stressed that the return on assets financial metric, which gauges business performance, is correlated with the adoption of a documentation system (Bell & Omachonu, 2011). According to an empirical study on 288 Spanish companies, 65 percent of those certified by quality management system standards have experienced extremely high levels of both internal and external benefits (CasadesuÂs & GimeÂnez, 2000)

CHAPTER THREE

RESEARCH DESIGN AND METHODOLOGY

3.1 Research Design and Approach

Research design shows the various stages of a research accompanying the matching projects. This research was planned to examine and interpret the Effect of QMS on administrative Performance in the Ethiopian drug production association (EPHARM).

This research design used explanatory and explanatory study variables. In line with this, two together subjective and comprehensive procedures will be employed. The comprehensive dossier composed through questionnaire maneuvered to answer questions formal on the effect of QMS inside the determinable variables and with a goal to justify and anticipate the existing phantasms. The subjective dossier was composed through Semi-structured interview from mark things is win to be checked qualitatively to analyze the effect QMS on administrative acting in Ethiopian pharmaceutical production association (EPHARM).

3.2 Source & Type of Data

Source of Data: Two beginnings of dossier collection arrangement were used for this research that is to say primary and subordinate beginning of data. Secondary beginnings by refer to earlier researches, books, journals articles, conduct reports of Ethiopian drug production company (EPHARM) for various age, and different necessary beginnings concern the exercise of QMS. Regarding to primary beginnings, the analyst used the organized and self- executed inquiry technique to accumulate dossier necessary for the research and the interview as well. In line with this, the main mechanism in dossier accumulation is through questionnaires targeting top administration and agents to supply information by information or happening of Ethiopian pharmaceutical production association (EPHARM) and the concerning qualities not quantities data assembled through interview from Ethiopian drug production company (EPHARM)

Data collection Method:

A questioner was the basic data group finish that is self-executed by the accused. A questioner is a research finish that used to draw data over a big sample (Kombo, 2006). With the questioner, the facts

assembled from individual respondents waited secret. It has the benefits for conditional time and services. Thus, it authorizes experts to cover abundant sample with short range.

Table 3.1: The constructs and variables for the study

Objective	Constructs	Variable	References
1.To identify the organization performance variables affected by QMS 2. To analyze the Effect of QMS on the case company performance	Business performance	Operating income	(Kafetzopoulos, et al., 2014) (Uyar, 2009), (Feng, et al., 2008), (Lin & Jang, 2008), (Su, et al., 2008), (Lakhal, et al., 2006)
		Market share	
		Sales	
		Profits	
		Unit cost of manufacturing	
	Product Quality	performance	
		Reliability	
		durability	
		perceived quality	
		conformance to specifications	
	Operational performance	productivity	
		process effectiveness	
		competitive advantage	
		Company's ability to have access to new domestic and foreign markets	
		Efficiency	

3.3 Sampling Technique and Sample size:

In this study the analyst use intentional sampling method means was used to select the interviewers and accused of the questionnaire. Purposive examining method, otherwise known as judgment savoring, is

completely set, the researcher ends what needs expected popular and sets out to find folk the one can and are not quite provide facts by information or happening.

Accordingly, from the total constant workers as a Purposive Sampling rules pronounced that, the scientist uses welcome or her own doom about that accused to select, and picks those one best meets the purposes of the study. From those point reviewed above the investigator was picked accused for a inquirers and interviewers from middle level administration appendages, and senior specialists to describe the Effect of QMS on administrative Performance and to answer the break of inquirers to reveal defect that has picked for this particular research.

In relation to sample breadth perseverance, the scientist has followed controlled processes and tests. Mugenda (2003) states place time and possessions admit a grown sample concede possibility be taken. This authorizes judgments expected a valid representative of the whole public.

Table: 3.2 Sample Size

Department	Sample Size
Production Department	9
Quality Assurance	6
Finance Department	4
Administration and Human Resource	4
Marketing and Sales Department	7
Research and Development Department	4
Procurement Department	5
Total	39

3.3.1 Inclusion Criteria

Employees, specialists, division heads, directors, and managers from EPHARM S.C who were willing and played a big part in the planning, execution, and assessment of the QMS implementation are included.

3.3.2Exclusion Criteria

For the QMS implementations, EPHARM S.C staffs who were allotted as field workers and had been on the job for less than two years lacked sufficient information.

3.4 Statistical analysis

Qualitative data analysis (QDA) is the process of arranging, analyzing, and defining concerning qualities not quantities research dossier—non-mathematical, abstract information, and consumer feedback—to capture ideas and patterns, answer research questions, and recognize conduct to improve your arrangement..

3.5 Sampling Design

Target population: The study community was attendants of EPHARM in Addis Ababa and sample is discriminating. The option of sample accused who supply facts is by information or occurrence. The total number of respondents for this study was 39 for inquiry and 5 for interviews. In this regard, accused are specialists, Divisional heads, section head, service head and Managers the one have important part in crafty, planning, exercise, ruling and judgment of QMS but those workers, the one has assign as untrained traders (amateur members such as guards, motorists, cleaners, welders, etc.) and recently staff member inferior two years do the guest has incompetent facts for the QMS implementation and arm peasants are prohibited.

3.6 Data Analysis and Interpretation Techniques

SPSS version 26 software was used to test the quantitative data got from the questioner using probable enumerations. By the reference of the sampled data assembled, the efficiency measurement variables and their influence on the management conduct ranges have also happened checked using the correct parametric mathematical methods to ascertain the quality of company and the route of the relationship. Additionally, the explanatory mathematical principles of the five-point Likert scale data have existed presented using tables. After assemblage subjective data from interviews, narrative analysis was used.

3.7. Reliability and validity

Using Cronbach Alpha, the reliability of the items in the questionnaire and the corresponding scale has been examined. The measuring variables' internal consistency was made possible as a result. Using the judgment of researchers and experts as well as pertinent literature reviews, the validity of the variables and the data gathered has been established.

Perceptual questions on a 5-point Likert scale, with the end points being "strongly disagree (1)" and "strongly agree (5)," were used to calculate the measurement items. The organization's performance can be measured and reflected by the ten latent variables that were created from a total of 67 variables

The validity and reliability of the survey measures were assessed before the research questions were put to the test. Given the features of the instrument employed in this investigation, its reliability was assessed using the inter-item reliability consistency (alpha). The degree to which particular constructs can account for the variation in responses to a set of survey items is known as construct validity.

Table 3.3: Reliability analysis test result and descriptive statistics

No	Constructs	Item	Cronbach's α	N
1	Top Management Commitment	TM1	0.796	37
		TM2		
		TM3		
		TM4		
		TM5		
		TM6		
		TM7		
		TM8		
		TM9		
		TM10		
2	Supplier Relationship Management	SR1	0.788	37
		SR2		
		SR3		
		SR4		
		SR5		
		SR6		
		SR7		
3	Customer Relationship Management	CR1	0.841	37
		CR2		

		CR3		
		CR4		
		CR5		
		CR6		
4	Workforce Management	WM1	0.836	37
		WM2		
		WM3		
		WM4		
		WM5		
		WM6		
		WM7		
5	Process Management	PM1	0.791	37
		PM2		
		PM3		
		PM4		
		PM5		
		PM6		
		PM7		
6	Product/Service Design	PSD1	0.775	37
		PSD2		
		PSD3		
		PSD4		
7	Quality Information and analysis	QI 1	0.778	37
		QI 2		
		QI 3		
		QI 4		
		QI 5		
8	Business Performance	BP1	0.830	37
		BP2		
		BP3		

		BP4		
		BP5		
9	Product Quality	PQ1	0.757	37
		PQ2		
		PQ3		
		PQ4		
		PQ5		
10	Operational Performance	OP1	0.513	37
		OP2		
		OP3		
		OP4		
		OP5		
		OP6		
		OP7		
11	Implementation Challenge	IC 1	0.710	37
		IC 2		
		IC 3		
		IC 4		
		IC 5		

Source: Data Survey, 2024

A reliability test was conducted on both performance metrics and QMS procedures. The degree to which scales are error-free thus, consistent is a broad definition of reliability. The reliability of the instrument and consistency of the measurement scale created based on the respondents' responses were assessed in this study using Cronbach's α . Cronbach's alpha should have a threshold value of at least 0.60 (Patyal and Koilakuntla, 2017), and if it is higher than 0.70, it is regarded as highly reliable. Each construct's initial Cronbach's α is shown in Table 3.3, and the total Cronbach's α for all 67 items combined is Cronbach's α 0.872. The reliability test analysis's value was sufficient for additional investigation.

3.8. Ethical consideration

The case company's private facts is protected in this place study similarly the guidelines contained in the i questionnaire, and no information will be joint outside the company's authorization. The research's differentness has also happened maintained, and all facts and former findings have existed accordingly acknowledged accompanying the equivalent authors.

CHAPTER 4

DATA ANALYSIS AND INTERPRETATION

4.1. Introduction

Experimental result gathered using Survey will be presented in this chapter. The data was triangulated by interviewing top management of the case company. SPSS 26 is a data processing program that was used for the data analysis. In order to address the stated research objectives and provide answers to the research questions, the results of the data collection were carefully examined and discussed. 37 respondents, out of the 39 questioners, responded from the case company that was contacted directly for data collection, as outlined in the research methodology. It was requested that these responders fill out the questionnaire. A 95 % response rate was obtained from the 37 respondents who agreed and replied out of the 39 total.

4.2. Profile of Respondents

The standard survey was given to the 39 respondents following content validity testing. Thankfully, every questionnaire was filled out. As a result, the information gathered from 37 respondents was examined.

Table 4.1 Education Qualification of the respondents

Qualification		Frequency	Percent
Valid	Diploma	2	5.4%
	BA/BSC	28	75.7%
	Master & above	7	18.9%
	Total	37	100%

Source: Own survey, 2024

According to the respondents' qualifications, 5.4% of them had a diploma, 75.7% had a BA or BSC, and 18.9% had a master's degree or higher. Based on these findings, we can assume that the employees have simply understanding the system.

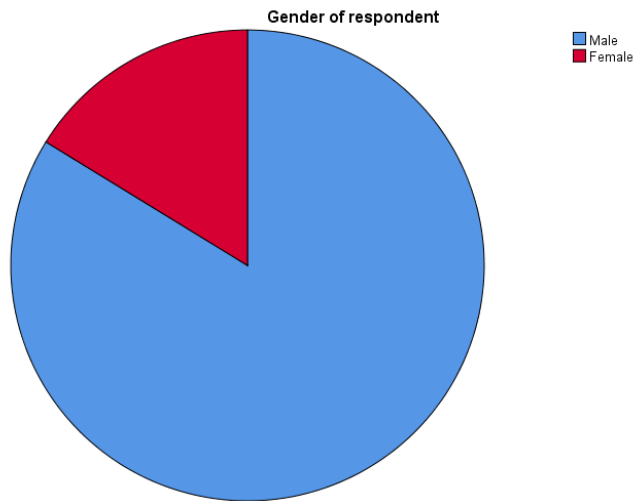
Table 4.2 Work Experience (Year) of the Respondent

Work Experience (Year)		Frequency	Percent
Valid	2-8	14	37.8%
	9-15	4	10.8%
	16-25	16	43.2%
	26-40	3	8.1%
	Total	37	100.0%

Source: Own survey, 2024

43.2 % of the respondents have 16–25 years of work experience. The respondents' minimum work experience ranged from 26 to 40. It may be advantageous to maintain the Quality Management System in place if we assume that many employees are motivated to work hard.

Figure 4.1: Gender profile of Respondents



Source: Own survey, 2024

From the Descriptive statistics result, we can understand that the organization is composed of more male than females.

Table 4.3 Ages of the Respondents

Ages		Frequency	Percent
Valid	18-29	7	18.9%

	30-45	17	45.9%
	46-60	9	24.3%
	Above 60	4	10.8%
	Total	37	100%

Source: Own survey, 2024

According to the descriptive statistics table, the majority of employees (45.9%) are between the ages of 30 and 45. We can assume that many of these employees are in their prime working years, which may give the company a significant advantage when it comes to adopting new systems and maintaining the ones that are already in place.

4.3. Descriptive analysis of major quality management practices

All independent variables of the quality management system practices taken into consideration in this study as stated in the standard questionnaire and covered in the conceptual frame work. The minimum score value for constructs is greater than the mean value, 3.0, as indicated in Table 4.4. On the other hand, the maximum mean value for everyone exceeds 4.064. This shows that, in a comparatively small variation, the respondents concur that the organization's performance was improved by the quality management system practices.

Table 4.4: Descriptive Statistics for quality management practices

Statements	N	Minimum	Maximum	Mean	Std. Deviation
Top Management Commitment	37	33	50	40.49	4.706
Supplier Relationship Management	37	17	31	26.19	3.726
Customer Relationship Management	37	18	30	23.68	3.559
Workforce Management	37	20	35	26.57	3.870
Process Management	37	24	35	29.11	3.462
Product/Service Design	37	12	20	16.95	2.210
Quality Information and Analysis	37	17	25	20.32	2.224

Source: Own survey, 2024

4.4. Descriptive analysis of major organizational performance constructs

According to the study essay portion and the conceptual frame work portion, trade act, fruit quality, and functional accomplishment are variables that show the act of the organizations.

Business Performance			
Statements	N	Mean	Std. Deviation
Your company operating income improved after implementation of QMS	37	4.05	.815
Your company Market share increased after implementation of QMS	37	4.11	.809
Sales of the company product improved after the implementation of QMS	37	4.35	.484
The implementation of QMS Increased Profits of the company	37	4.46	.505
After the implementation of QMS the manufacturing unit cost has been reduced	37	3.92	.722

Product Quality			
Statements	N	Mean	Std. Deviation
After the implementation of QMS the reliability of the product increased	37	4.43	.555
The implementation of QMS improved the consistency/durability of the product	37	4.41	.599
The implementation of QMS improved the perceived quality of the product	37	4.30	.571
the company's rate of product defect reduced and there was increased conformance to specifications after implementation of QMS	37	4.16	.898

Operation Performance			
Statements	N	Mean	Std. Deviation

There was labor productivity improvement observed after the implementation of QMS in the company.	37	3.86	.948
There was input material utilization rate improvement observed after the implementation of QMS in the company.	37	3.97	.687
The production process was capable of producing variety of products after establishments	37	3.95	.468
Cycle time (from receipt of raw materials to shipment of finished products) has decreased in your organization over the past three years	37	3.41	1.066
The implementation of QMS increased Company's ability to have access to new domestic and foreign markets	37	3.97	.645
There was machine efficiency improvement observed after the implementation of ISO QMS in the company	37	3.95	.848
Process variability in your organization has decreased after implementation of ISO QMS.	37	3.92	.759

Source: Own survey, 2024

According to the above table, the respondents agreed that implementing a QMS would improve organizational performance. Some variables in operational performance have a lower mean value, which suggests that operational performance is a crucial metric for ensuring quality control, guiding improvements, evaluating consistency, and assessing risks. In the end, this helps to improve decision-making, operational efficiency, and organizational performance.

4.5. Bivariate Correlation Test

To decide the course and strength of the connection middle from two points variables and with the construct, pairwise equating reasoning has been acted. Since we pretended that the dossier was normally delivered and constant accompanying parametric assumptions, the Pearson equating cooperative was secondhand as parametric correlation guess test for the variables in this place study.

Table 4.6 Correlations between constructs

		TM	SR	CR	WM	PM	PSD	QI	BP	PQ	OP
TM	Pearson Correlation	1									
	Sig. (2-tailed)										
	N	37									
SR	Pearson Correlation	.568**	1								
	Sig. (2-tailed)	.000									
	N	37	37								
CR	Pearson Correlation	.773**	.533**	1							
	Sig. (2-tailed)	.000	.001								
	N	37	37	37							
WM	Pearson Correlation	.849**	.576**	.788**	1						
	Sig. (2-tailed)	.000	.000	.000							
	N	37	37	37	37						
PM	Pearson Correlation	.926**	.569**	.785**	.862**	1					
	Sig. (2-tailed)	.000	.000	.000	.000						
	N	37	37	37	37	37					
PSD	Pearson	.579**	.258	.319	.468**	.658**	1				

	Correlation										
	Sig. (2-tailed)	.000	.124	.054	.003	.000					
	N	37	37	37	37	37	37				
QI	Pearson Correlation	.303	.194	.533**	.275	.410*	.422**	1			
	Sig. (2-tailed)	.068	.251	.001	.100	.012	.009				
	N	37	37	37	37	37	37	37			
BP	Pearson Correlation	.226	.124	.527**	.243	.276	.309	.585**	1		
	Sig. (2-tailed)	.178	.465	.001	.147	.099	.063	.000			
	N	37	37	37	37	37	37	37	37		
PQ	Pearson Correlation	.474**	.332*	.722**	.527**	.499**	.139	.413*	.622**	1	
	Sig. (2-tailed)	.003	.044	.000	.001	.002	.411	.011	.000		
	N	37	37	37	37	37	37	37	37	37	
OP	Pearson Correlation	.502**	.530**	.692**	.631**	.544**	.246	.340*	.360*	.618**	1
	Sig. (2-tailed)	.002	.001	.000	.000	.000	.142	.039	.028	.000	
	N	37	37	37	37	37	37	37	37	37	37
**. Correlation is significant at the 0.01 level (2-tailed).											
*. Correlation is significant at the 0.05 level (2-tailed).											

Source: Own survey, 2024

Additionally, the Pearson correlation analysis reveals a modest and positive correlation between company operational performance and supplier relationship management ($r=0.530$), customer relationship management ($r=0.692$), and top management commitment ($r=0.502$) at $p<0.01$. Additionally, there is a moderately positive correlation between the company's operational performance and quality information analysis ($r=0.340$), Process management ($r=0.544$), workforce management ($r=0.631$), and product or service design ($r=0.246$).

4.6. Regression analysis

Operational Performance, Product quality and Business performance are dependent scale variables whose values have been modeled using linear regression based on their linear relationship to the predictors. The conventional method for characterizing the connections in this issue is linear regression. The best popular metric for evaluating a regression model's fit to the data is R^2 . This statistic shows the proportion of the response's variance that can be accounted for by the weighted combination of the predictors, which include quality information and analysis, top management commitment, supplier and customer relationship management, workforce management, process management, and product or service management. The model fits better when R^2 is near 1

Table 4.7 Model Summary for Organizational Performance

Model Summary Business Performance				
Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.746 ^a	.556	.449	1.955
a. Predictors: (Constant), QI, SR, PSD, WM, CR, TM, PM				

Model Summary Product Quality				
Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.736 ^a	.541	.430	1.539
a. Predictors: (Constant), QI, SR, PSD, WM, CR, TM, PM				

Model Summary Operational Performance				
Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.754 ^a	.568	.464	2.060
a. Predictors: (Constant), QI, SR, PSD, WM, CR, TM, PM				

Source: Own survey, 2024

Table 4.8 ANOVA for Organizational Performance

ANOVA^a Business Performance						
Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	138.738	7	19.820	5.186	.001 ^b
	Residual	110.830	29	3.822		
	Total	249.568	36			
a. Dependent Variable: BP						
b. Predictors: (Constant), QI, SR, PSD, WM, CR, TM, PM						
ANOVA^a Product Quality						
Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	81.009	7	11.573	4.884	.001 ^b
	Residual	68.721	29	2.370		
	Total	149.730	36			
a. Dependent Variable: PQ						
b. Predictors: (Constant), QI, SR, PSD, WM, CR, TM, PM						

ANOVA^a Operational Performance						
Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	161.965	7	23.138	5.455	.000 ^b
	Residual	123.007	29	4.242		
	Total	284.973	36			
a. Dependent Variable: OP						
b. Predictors: (Constant), QI, SR, PSD, WM, CR, TM, PM						

Source: Own survey, 2024

Table 4.9 Coefficients^a Business Performance

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	10.133	3.983		2.544	.017
	TM	-.161	.201	-.288	-.800	.430

	SR	-.038	.110	-.054	-.346	.732
	CR	.779	.219	1.053	3.565	.001
	WM	-.078	.192	-.115	-.406	.688
	PM	-.421	.321	-.554	-1.314	.199
	PSD	.596	.246	.501	2.427	.022
	QI	.200	.216	.169	.925	.363

Coefficients^a Product Quality

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	8.958	3.136		2.856	.008
	TM	-.077	.159	-.178	-.488	.629
	SR	-.020	.087	-.037	-.236	.815
	CR	.465	.172	.812	2.702	.011
	WM	.032	.151	.061	.213	.833
	PM	.013	.252	.022	.052	.959
	PSD	-.064	.194	-.069	-.328	.745
	QI	.041	.170	.045	.241	.811

Coefficients^a Operational Performance

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	13.865	4.196		3.304	.003
	TM	-.257	.212	-.430	-1.212	.235
	SR	.180	.116	.239	1.552	.132
	CR	.534	.230	.676	2.319	.028
	WM	.279	.202	.384	1.380	.178
	PM	-.106	.338	-.130	-.312	.757
	PSD	.184	.259	.144	.709	.484

	QI	-.062	.227	-.049	-.272	.787
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The ANOVA table (Table 4.8) reports a significant F statistic, indicating that using the model is better than guessing the mean for the independent organizational performance.

4.7. ISO Quality Management Systems Implementation Challenges

Also it is clear that all of the issues that were tested, including "Gaining workforce commitment to QMS implementation" and "The lack of QMS knowledge and experience was a challenge during the course of implementation," contributed to the organization's difficulties in implementing the QMS system. Table 4.10 demonstrates that the primary challenges in the case company's QMS implementation were top management commitment, a lack of time, and a limited budget was a problem.

Table 4.10 Descriptive Statistics of QMS Implementation Challenges

Implementation Challenges	N	Mean	Std. Deviation
Gaining workforce commitment to QMS implementation was a problem	37	2.65	.824
The lack of QMS knowledge and experience was a challenge during the course of implementation	37	2.54	.803
There was insufficient time for QMS implementation in your organization	37	2.38	.861
There was limited budget to run the implementation of the QMS system	37	2.14	.918
Top management commitment was low while implementing QMS	37	2.14	.855

Source: Own survey, 2024

4.8 Interview Question Analysis

For the purpose of this study, five key informants including members of the case company's top management were interviewed from middle administration and experts. The interviewees stated that the company fulfilled the quality management system in order to improve product quality, decrease defects,

boost profit, expand market share, and improve customer satisfaction. The questions were nine, as shown in Appendix II.

Through the implementation of the system, top management members all aimed to increase the company's sales and market performance in order to improve its reputation. Additionally, the interviewees had a variety of experiences on implementing QMS in other sectors. However, some people lacked experience with the full management system implementation.

All of the interviewees gave the same response when asked how long it took to implement the QMS in their company: almost a year and a half. In light of this, the interviewer also asked them about the required steps that must be taken when putting the QMS into practice. Here, there were some modifications to clarify the processes based on their roles, responsibilities, and in-depth knowledge of the topic. According to their responses, raising awareness and creating working procedures and formats were the two main processes that every interviewee mentioned.

According to the interviewees, the company's improved sales performance and market share were the primary advantages of implementing the QMS. They also thought that the organization was performing better in performance indicators. In order to experience continuous improvement, the principles must be properly applied, starting with raising awareness and continuing through certification and implementation status maintenance. When the interviewees were asked, "What was your role to implement quality management systems in your organization?" their responses were largely similar, providing insight into their experiences with the procedures to be followed during QMS implementation. There were ensuing awareness-raising events following the management's commitment.

The interviewees were asked if they had a Quality Manual and what items were included in it. Nearly all of them said that they did. The primary guiding document was the QMS manual, which included the QMS map that illustrated the processes and how they interacted to produce customer satisfaction as well as the quality objective, policy, procedures, instructions, and specifications. The interviewee was also questioned about how they understood how to determine the current gap between the standards requirements. Similar answers were given to the question, "How do you conduct the required gap analysis of your organization?" Initially, they determined the resources and process, established criteria and particular KPIs, and verified that the right tools and techniques for measuring, tracking, evaluating, and controlling performance were in place. These would suggest that they understand gap analysis and how to do it fairly well. The

interviewees were also asked about the specific certification process: "Can a Company Actually Become Efficient Using QMS Certification?" Most of them responded in the affirmative, emphasizing that the system helps the company focus on product and service quality to improve customer satisfaction certification and increase market share.

CHAPTER FIVE

SUMMARY OF FINDINGS, CONCLUSION AND RECOMMENDATION

5.1. Summary of Findings

This study was accomplished to consider the effect of characteristic management order on administrative accomplishment. To gain the research aims, a scientific process was understood. The first was administered to believe the theoretical and practical facets of kind administration method. For this purpose, a review of the relevant composition was followed. The review concentrated on the abstract and practical linkages between character administration scheme practices and administrative performance ranges.

A total of seven Independent and three dependent variables have existed identified and resolved in this place study to decide the effect of quality management system practices on organizational performance. A questioner combining 67 parts was grown to assess the ranges of administrative acting, status management practices, and the challenges on the exercise. Out of 39 delivered questionnaires, 37 were achieved, yielding an answer rate of 95%. The dependability of articles and calculation scale was evaluated utilizing Cronbach's α cooperative, accompanying all sets achieving α value surpassing rude beginning of 0.6. The overall calculated α cooperative worth was 0.872 that is regarded acceptable for further reasoning.

The investigation of all dimensions of organizational performance has revealed that

- The lowest result for all constructs exceeds the mean value of 3.0.
- The highest mean value across all constructs is above 3.41.
- Additionally, the average mean value surpasses the overall average of 3.0 for all constructs.
- The deviation from the average mean value is below 1.066. Likewise, the minimum score for all organizational performance constructs is higher than the mean value.
- The average mean value is also greater than the average of 3.0.
- Additionally, correlation analysis demonstrate that at significance level of $p < 0.01$, all variables exhibited a positive interrelationship, except business performance and customer relationship management, which demonstrated either weak or modest correlations.
- The correlation between Product Quality, Quality Information and Analysis was found to be positive at significant level $p < 0.05$, although the relationship was weak.

The regression analysis indicates that when organizational performance was regressed on the independent predictor's variables, the R^2 value was 0.494. This suggests the predictor variables account for a substantial portion of the variance in the dependent variable within the linear regression model. Furthermore, the research highlighted the primary challenges encountered by the company during the implementation.

5.2 Conclusion

The aim concerning this study was to determine the effects of Quality Management System (QMS) on the organizational performance of Ethiopian Pharmaceutical Manufacturing S.C. Numerous studies in the literature have identified the implementation of quality management systems as a strategy for enhancing organizational performance. This research further confirms that the adoption of QMS positively influences organizational performance, as evidenced by findings from the case company. Descriptive analysis revealed that respondents generally agree that QMS practices underwrite to improve organizational performance. The dimensions used to measure organizational performance were all significantly influenced ($p < 0.05$) by the QMS practices.

Other finding from this research pertained to the difficulties faced during the implementation of the Quality Management System within the case company was securing the commitment of the workforce, obtaining support from top management, a deficiency in knowledge and experience related to QMS, as well as constraints related to time and budget.

5.3 Recommendations

Based on the decisions of the research judgments, the following recommendations were compiled:

- Risk-based thinking is one of the principles of QMS with a new identity and companies those who plan to implement QMS have to ensure that top management commitment is available in their organizations.
- Companies need to train their employees on process of QMS implementation well ahead of time before actually implementing QMS to gain the required experience and knowledge
- Commitment for the work force has to be achieved during the process of implementation as well. And to have employees with the implementation of QMS in line with the appropriate means of motivation scheme.

- Companies must have budget to implement the system standard
- Sufficient time was needed to establish successful quality management system.
- The company is now in a position that it can act allure result processes in a better habit than before and suitable way to solve better arrangement acting.

To experience this organizational performance it bear further claim the constant improvement and resultant reworking and restore of the QMS exercise process.

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Appendix –I

Questionnaire

ADDIS ABABA UNIVERSITY

College of Business and Economics

Department of Management

Dear Respondents,

The purpose of this survey question is to collect data related to quality management system implementation and it's Effect on organizational performance for the completion of Master Degree from Addis Ababa University. Your voluntary collaboration & accurate information is vital to complete this research.

Please be assured that information provided in this questionnaire is purely for academic purpose and therefore would be treated with utmost CONFIDENTIALITY.

Sincerely,

Name: Habtamnesh Bayissa

Tel. 0912720388

A. Demographic Characteristics

1. Current position: Manager ☐ Service Head ☐ Division Head ☐
 Section Head ☐ Expert ☐
2. Highest Qualification: Diploma ☐ BA/BSC ☐ Master & above ☐
3. Work experience [year] 2-8 ☐ 9-15 ☐ 16-25 ☐ 26-40 ☐
4. Sex: Male ☐ Female ☐
5. Age 18-29 ☐ 30-45 ☐ 46-60 ☐ Above 60 ☐

B. Management and Employees Opinion Measurement

The following items which are related to your organizations performance as measured from the contribution of ISO 9001 QMS implementation. It is based on your degree of agreement as rated from 1 to 5 from strong disagreement to strong agreement. Accordingly, please rate on the scale 1 to 5, with 1= strongly disagree; 2= disagree; 3= neither agree nor disagree; 4= agree; 5= strongly agree, and please tick “✓” sign in the corresponding cell provided.

Code	Items	Measurement scale				
		1	2	3	4	5
I	<i>Top management commitment</i>					
TM1	The top management of your organization (i.e. top executives and major department heads) assumes responsibility for quality performance					
TM2	The top management of your organization provides personal leadership for quality products and quality improvement					
TM3	Your organization's top management is evaluated for quality performance					
TM4	In your organization, major department heads participate in the quality improvement process					
TM5	In your organization, “Quality issues” are reviewed in top management meetings					
TM6	In your organization, top management views quality performance as a major objective					
TM7	In your organization, strategic decisions are affected by top management					
TM8	In your organization, quality policy is developed by top management					
TM9	In your organization information processing is efficient & effective					
TM10	Employees obtain timely, reliable, consistent & necessary data & information as they need to do their job					
II	<i>Supplier relationship management</i>					
SR1	Your organization believes in long-term relationships with suppliers and takes effort for the same					
SR2	Your organization trusts on a small number of high-quality suppliers					
SR3	Your organization allows supplier's active participation in product design/redesign process					
SR4	Your organization evaluates suppliers based on parameters related to quality, delivery and price					

SR5	Your organization has a systematic supplier rating system					
SR6	Your organization provides technical assistance to suppliers					
SR7	Your organization is working with suppliers to ensure that expectations met					
III	<i>Customer relationship management</i>					
CR1	Your organization believes in maintaining consistent contact with customers					
CR2	Your customers provide feedback on quality and delivery performance					
CR3	Your organization measures customer satisfaction of external customer					
CR4	Customer requirements are used as the basis for quality in your organization					
CR5	Your employees are aware about your customers					
CR6	Your customers visit your plant					
IV	<i>Workforce management</i>					
WM1	Your organization form teams to solve problems					
WM2	Your organization provides feedback to employees on their quality performance					
WM3	Employees are also involved in quality decisions in your organization					
WM4	Supervisors encourage teamwork in your organization					
WM5	Quality-related training is given to contractual employees					
WM6	Quality-related training is given to managers and supervisors in your organization					
WM7	Your organization provides quality training as “total quality concept” (i.e. philosophy of company-wide responsibility for quality)					
V	<i>Process management</i>					
PM1	Processes in your organization are designed to minimize the chances of errors					
PM2	Your organization meets daily production schedule					
PM3	In your organization, production is stopped immediately for quality problems					
PM4	Your organization conducts preventive equipment maintenance					
PM5	Your organization provides clear process instructions					

PM6	In your organization, shop floors are well organized and clean					
PM7	Your organization has adopted statistical process control					
VI	<i>Product/service design</i>					
PSD1	Your organization reviews new product/service designs in detail before the production of product/service					
PSD2	Various departments of your organization such as marketing, manufacturing, and purchasing, etc. coordinate in the product/service development process					
PSD3	In your organization, manufacturing and quality personnel are involved in the product/service development process					
PSD4	Your organization takes effort for clearly needed specifications in the design process					
VII	<i>Quality information and analysis</i>					
QI1	Your organization manages useful data pertaining to quality (such as error rates, defect rates, scrap, defects, cost of quality, etc.)					
QI2	In your organization, data are accessible to managers, supervisors, and engineers					
QI3	Your organization manages data timely					
QI4	Your organization use data for managing quality					
QI5	Your organization use data for evaluating supervisory as well as managerial performance					
VIII	<i>Business performance</i>					
BP1	Your company operating income improved after implementation of QMS					
BP2	Your company Market share increased after implementation of QMS					
BP3	Sales of the company product improved after the implementation of QMS					
BP4	The implementation of QMS Increased Profits of the company					
BP5	After the implementation of QMS the manufacturing unit cost has been reduced					
IX	<i>Product Quality</i>					
PQ1	After the implementation of QMS the reliability of the product increased					

PQ2	The implementation of QMS improved the consistency/durability of the product					
PQ3	The implementation of QMS improved the perceived quality of the product					
PQ4	the company's rate of product defect reduced and there was increased conformance to specifications after implementation of QMS					
X	<i>Operational performance</i>					
OP1	There was labor productivity improvement observed after the implementation of QMS in the company.					
OP2	There was input material utilization rate improvement observed after the implementation of QMS in the company.					
OP3	The production process was capable of producing variety of products after establishments					
OP4	Cycle time (from receipt of raw materials to shipment of finished products) has decreased in your organization over the past three years					
OP5	The implementation of QMS increased Company's ability to have access to new domestic and foreign markets					
OP6	There was machine efficiency improvement observed after the implementation of ISO QMS in the company					
OP7	Process variability in your organization has decreased after implementation of ISO QMS.					
XI	<i>Implementation challenges</i>					
IC1	Gaining workforce commitment to QMS implementation was a problem					
IC2	The lack of ISO 9001:2008 QMS knowledge and experience was a challenge during the course of implementation					
IC3	There was insufficient time for QMS implementation in your organization					
IC4	There was limited budget to run the implementation of the QMS system					
IC5	Top management commitment was low while implementing QMS					

Thank you for your valuable time

Appendix –II

Interview Questions

1. Why you are interested to implement QMS in your Company?
2. What is your QMS experience? Have you taken a company through registration?
3. How long you take to implement the QMS in Your Company?
4. What was the mandatory procedure for QMS implementation?
5. What are the main benefits of implementing QMS?
6. What was your role in the implement of quality management systems in your organization?
7. Do you have Quality Manual? And if so what items it contains?
8. How do you conduct the required gap analysis of your Organization?
9. Can a Company actually become efficient using QMS Certification?