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ADDIS ABABA UNIVERSITY

COLLEGE OF BUSINESS AND ECONOMICS

DEPARTMENT OF MANAGEMENT

MSc Thesis

On

FACTORS THAT INFLUENCE QUALITY MANAGEMENT SYSTEM

IMPLEMENTATION IN THE CASE OF ETHIOPIAN

PHARMACEUTICAL SUPPLY SERVICES

BY:

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GRADUATE STUDIES

As mentioned on the Board of Examiners of the MSc thesis open defense examined. We certified that we have read and evaluated the thesis prepared by Betelhem Addisu and examined the candidate. We recommend that the thesis be accepted as fulfilling the thesis requirements for the degree of Science in Quality Management and Organizational Excellence

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DECLARATION

I declare that this work has not be previously submitted and approved for the award of a degree by this or any other university. I, Betelhem Addisu, have carried out MSc thesis on “Analyze factors that influence quality management system implementation in the case of Ethiopian pharmaceutical supply services” independently in partial fulfillment of the requirement of Quality Management and Organizational Excellence. To the best of my knowledge and belief, the thesis contains no material previously published or written by another person except where due reference is made in the thesis itself.



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STATEMENT OF CERTIFICATE

A thesis research advisor, I hereby certify that I have read and evaluated this thesis prepared under my guidance and supervision by Betelhem Addisu entitled “Analyze factors that influence quality management system implementation in the case of Ethiopian pharmaceutical supply services”. I here assure that her work is appropriate to be submitted for examination with my approval as a thesis.

Advisor

Signature

Date

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28/01/2024

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ABBREVIATIONS

EPSS	Ethiopian Pharmaceuticals Supply Service
HRM	Human Resource Management
QMS	Quality Management Systems
QMSI	Quality Management System Implementation
QP	Quality Policy
QM	Quality management
QM	Total Quality Management
TW	Team Working

ABSTRACT

This study aims to shed light on the complexities surrounding the implementation of Quality Management Systems (QMS) within the Ethiopia Pharmaceutical Supply Service (EPSS), analyzing the influential factors in detail. The primary objective is to identify significant barriers hindering the effective implementation of QMS, including issues related to documentation practices, employee comprehension, financial constraints, strategic planning, and external support mechanisms. To achieve this goal, a comprehensive research methodology is employed, combining qualitative and quantitative approaches. Quantitative data are collected through surveys distributed among employees to quantify perceptions and experiences related to QMS practices and challenges. The collected data are then analyzed using regression analysis to explore the relationships between key factors such as internal communication, process quality, and adherence to quality policy and QMS performance. Regression analysis allows for the identification of significant predictors of QMS effectiveness and the extent to which they influence overall performance outcomes. The findings of this study highlight several critical insights regarding QMS implementation within the EPSS. Firstly, it is revealed that clear and transparent communication channels are essential for successful QMS implementation, as they facilitate understanding and alignment among employees. Second, the study underscores the importance of maintaining high standards of process quality to uphold the integrity and reliability of QMS practices. Finally, adherence to well-defined quality policies emerges as a key factor in ensuring consistency and compliance across all operational aspects. In conclusion, this study offers valuable insights into the factors influencing QMS implementation within the EPSS. By identifying influential factors, organizations can develop targeted strategies to enhance QMS practices and ultimately improve overall performance and service delivery within the pharmaceutical supply sector in Ethiopia.

Keywords: Quality Performance, Quality Management Systems (QMS), EPSS, Regression Analysis

CHAPTER ONE

INTRODUCTION

The research issue was introduced in this chapter as a preliminary section. It covered the fundamentals of the quality management system, Ethiopian pharmaceutical supply services, and related issues. These included the study's background, problem statement, research questions, general and specific objectives, significance, scope, organization of the study, and operational definition.

1.1. Background of the Study

Maintaining quality involves more than just creating a product in a certain way; it also entails consistently living up to expectations under shifting circumstances. According to Hoyle (2017), quality must be approached methodically and the system's quality should be prioritized over the product's quality. When a system based on processes that deliver high-quality products and services and that adapt to changing circumstances is put into place, the system's output likewise produces better, more consistent quality (ASQ, 2013).

The quality management systems standards are the most popular way to put such a system into practice. This standard suggests procedures that businesses can follow to systematically satisfy both legal and customer needs. Maintaining a consistent and ongoing approach to concept quality is crucial (Myhrberg & Myhrberg, 2017). Many businesses worldwide, whether they are in the industrial or service sectors, the public or private, adopt the ISO 9000 quality management system standard (Oliver, 2014). Many organizations like it because their goal is to consistently deploy, monitor, and enhance their operations in line with the demands and expectations of their consumers (Bhandari & Baldi, 2014). Ensuring the quality of systems used in the production of goods and services is the goal of this standard.

The Quality Management System has grown in popularity, and organizations who have a quality program in place are able to demonstrate that their operations, services, and goods are well-managed, dependable, and always being improved. Important stakeholders like significant trading partners and customers respect these practices and standards, which is why there is pressure to engage in change (Lewis et al, 2009).

In the global landscape of quality management, adherence to international standards has become a hallmark of organizational excellence. Among these standards, ISO 9001 stands out as a widely adopted framework, providing a systematic approach to quality management. Organizations across various sectors seek ISO certification as a means to enhance their operational efficiency, improve customer satisfaction, and gain a competitive edge in the global market. In the specific context of the Ethiopian Pharmaceutical Supply Service, the successful implementation of ONIs is of paramount importance, given the critical role of the pharmaceutical sector in public health and the increasing demand for stringent quality assurance.

According to the Growth and Transformation plan (MOFED, 2010), one of the eight key subsectors for the growth of medium- and large-sized enterprises in Ethiopia is the pharmaceutical sector. It is also anticipated that the manufacturing and service sectors will rise rapidly. For manufacturing companies operating in critical industries like pharmaceuticals, the government is giving them extra attention and incentive packages (Tassey, 2014). It is anticipated that the incentive will draw in a number of domestic and international investors, leading to an increase in the number of pharmaceutical production companies. Businesses will begin to compete both locally and with businesses in foreign markets as the number rises. Businesses that can provide higher-quality goods and services, among other things, will prevail in the marketplace (Degu, 2021). Apart from the provision of their medication.

The roots of international quality standards can be traced back to the pioneering work of quality management theorists such as Deming and Juran, who laid the foundation for the principles that underpin ISO standards (Deming, 1986; Juran, 1992). ISO 9001, first introduced in 1987, has evolved over the years to reflect changing organizational landscapes and industry dynamics (ISO, 2015). While the benefits of ISO certification are well documented, the factors influencing its successful implementation remain a subject of ongoing research.

Recent scholarship, as exemplified by Wang and Wu (2018) and Rahman et al. (2020), has increasingly emphasized the pivotal role of quality management in ensuring the effective implementation of ISO standards. This commitment, characterized by active involvement, visible support, and resource allocation by organizational leaders, is crucial for driving the implementation of quality management systems. However, despite these valuable insights, there exists a research gap when applying these findings to the specific context of the Ethiopian

Pharmaceutical Supply Service. The studies conducted so far underscore the challenges organizations may face in cultivating a quality-oriented culture and sustaining quality management, yet the application of these insights to the Ethiopian pharmaceutical sector remains unexplored. Therefore, by identifying and addressing this gap, the study aims to make a substantial contribution to understanding implementation in the Ethiopian pharmaceutical sector, providing insights that are not only academically valuable but also of practical significance for organizations operating in this critical domain.

1.2 Statement of the Problem

According to Pheng and Teo (2004), Quality management (QM) is a crucial aspect of an organization's overall performance because it suggests that the leaders of the organization actively engage in the process of adopting and implementing quality standards, in addition to endorsing them. According to Babakus et al. (2003), QM is a requirement for the organization to continue improving quality at every level of its production process. A company's success or failure is determined by the caliber of its top management, and all organizations require devoted top executives who inspire higher levels of commitment in other staff members in order to achieve the organization's objectives (Leithwood & Jantzi, 2000).

Additionally, if senior management supports the organization's quality management functions, the occurrence of problems across the production can be decreased (Silva et al., 2016). According to a number of studies, defining the organization's vision and mission helps to verify and show QM (Fotopoulos & Psomas, 2010; Salaheldin, 2009; Turkyilmaz et al., 2010; Milios et al., 2013).

In the pharmaceutical sector, the relationship between quality management and quality improvement is paramount for ensuring the safety and efficacy of pharmaceutical products. Research by Deming (1986) and Flynn, Schroeder, and Sakakibara (1994) highlight's the critical role of leadership commitment in fostering a culture of quality, particularly in industries with stringent regulatory requirements. In the pharmaceutical context, where adherence to quality standards is imperative for public health, quality management serves as the linchpin for establishing and maintaining robust quality management systems. This commitment is manifested through visible leadership practices, resource allocation, and the integration of

quality improvement initiatives into strategic planning. As emphasized by Chassin and Loeb (2013), a strong commitment from top management is not only a regulatory necessity but also a strategic imperative, influencing organizational behavior and driving continuous improvement efforts. The relationship between quality management and quality improvement in the pharmaceutical sector is thus foundational, shaping the industry's ability to meet rigorous quality standards and ensure the well-being of patients.

The pharmaceutical sector in Ethiopia, a critical component of the nation's public health infrastructure, is confronted with the imperative to meet international quality standards (Feyisa *et al.*, 2021). Despite the increasing global emphasis on quality management systems, there is a conspicuous gap in the literature regarding the nuanced challenges and opportunities faced by the Ethiopian Pharmaceutical Supply Service in implementing (Esho & Verhoef, 2020). While quality standards have been widely adopted globally, the unique context of the Ethiopian pharmaceutical industry demands a dedicated exploration of the factors influencing ISO implementation, particularly the role of quality management (Nigusse, 2021, Zewde, 2023)

Quality management has been acknowledged as a decisive factor in the success of ISO implementations (Wang & Wu, 2018; Rahman *et al.*, 2020; Zewde, 2023). However, there is a dearth of research that specifically investigates the relationship between quality management in the Ethiopian pharmaceutical landscape. Understanding the impact of quality management on the adoption and sustained compliance with ISO standards is crucial, given the industry's complex regulatory environment and the overarching goal of ensuring the quality and safety of pharmaceutical products (Abdulsalam, 2022; Berhe, 2022).

Moreover, the existing literature primarily emanates from contexts that may not capture the unique challenges and dynamics of the Ethiopian pharmaceutical sector. The lack of tailored insights for this context necessitates a focused study that can provide evidence-based recommendations for organizations within the Ethiopian Pharmaceutical Supply Service. This research seeks to bridge this gap by elucidating the specific challenges, opportunities, and outcomes associated with quality management on the process in Ethiopia, contributing to both academic discourse and the practical enhancement of quality management practices within the pharmaceutical supply chain.

Given the aforementioned gaps, the purpose of this study was to examine the various types of quality managements, determine the relationship between quality management models and the implementation of quality management systems, and, in the case of Ethiopian pharmaceutical supply services, determine the impact of quality management on the quality management system implementations that ultimately lead to organizational effectiveness.

1.3. Research Questions

The following research questions were attempted to be addressed in this work.

1. How does internal communication affect the implementation of quality management systems in the Ethiopian pharmaceutical supply service?
2. What is the relationship between continuous improvement efforts and the effectiveness of quality management systems in the Ethiopian pharmaceutical supply service?
3. How does training and competence impact the development and maintenance of quality management systems in the Ethiopian pharmaceutical supply service?
4. What is the association between process quality and the effectiveness of quality management systems in the Ethiopian pharmaceutical supply service?
5. How does team working influence the implementation and sustainability of quality management systems in the Ethiopian pharmaceutical supply service?
6. What role does quality policy play in shaping the framework of quality management systems in the Ethiopian pharmaceutical supply service?

1.4 Objective of the Study

1.4.1 General objective

The general objective of this study was to analyze factors that influence quality management system implementation in the case of Ethiopian pharmaceutical supply services

1.4.2 Specific objectives

The specific objectives of this study were as follows:

1. To investigate the impact of internal communication on quality management systems in the Ethiopian pharmaceutical supply service.
2. To examine the effect of continuous improvement on quality management systems in the Ethiopian pharmaceutical supply service.

3. To evaluate the influence of training and competence on quality management systems in the Ethiopian pharmaceutical supply service.
4. To analyze the correlation between process quality and quality management systems in the Ethiopian pharmaceutical supply service.
5. To assess the role of team working in enhancing quality management systems in the Ethiopian pharmaceutical supply service.
6. To explore the significance of quality policy in shaping quality management systems in the Ethiopian pharmaceutical supply service.

1.5 Significance of the Study

Understanding the influence of factors on the successful implementation of quality management systems on crucial for the Ethiopia Pharmaceutical Supply Service to enhance its quality management practices. This knowledge can lead to the establishment and reinforcement of robust quality systems, ultimately improving the overall quality of pharmaceutical products and services. Achieving and maintaining compliance can enhance the sector's global competitiveness, as adherence to recognized quality standards is often a prerequisite for international market access. Findings from the study can serve as a reference point for other organizations within the pharmaceutical sector in Ethiopia and beyond. Insights into the role of quality management can be instrumental in disseminating best practices, fostering a culture of quality, and improving overall industry standards. Insights gained from the study can guide strategic decision-making within the Ethiopia Pharmaceutical Supply Service. Leaders can use the findings to make informed choices about resource allocation, training programs, and leadership development initiatives aimed at strengthening quality management.

In summary, the significance of this study extends beyond the immediate organizational context, offering valuable contributions to the pharmaceutical sector, academic knowledge, and the broader discourse on effective quality management system implementation. The findings have the potential to drive positive change, promote excellence, and contribute to the overall advancement of organizational and sectorial practices.

1.6. Scope of the Study

This study, titled "examine the influence of factors on the successful implementation of quality management systems in the case of Ethiopian pharmaceutical supply service," confines its geographical scope to the Ethiopia pharmaceutical supply service head office. The study focuses on a cross-sectional time frame, providing a snapshot on at a specific point in time. This approach allows for the examination the influence of factors on the successful implementation of quality management systems on Ethiopian Pharmaceutical Supply Service within a particular and well-defined period.

In terms of methodology, the study was employs a quantitative research approach. Quantitatively, structured questionnaires were administered to capture numerical data on various aspects, including levels of management commitment, resource allocation, and specific quantitative indicators related to implementation. The cross-sectional data collection approach allows the study to analyze the state of implementation and factors affecting the quality within the Ethiopia Pharmaceutical Supply Service at a specific moment, providing valuable insights into the current conditions and dynamics. This study design aims to capture a snapshot that can inform the understanding of the relationship between factors affecting service quality implementation and offering relevant and timely information for decision-makers within the Ethiopia pharmaceutical supply service head office.

1.7. Limitation of the Study

This study, while shedding light on the influential factors of Quality Management System (QMS) implementation at the Ethiopia Pharmaceutical Supply Service, acknowledges several limitations that impact the broader applicability and generalization of the findings. Firstly, the sample predominantly consists of team leaders, directors, and general managers, potentially limiting the representation of diverse employee levels within the organization. Additionally, the cross-sectional design adopted in both the survey and regression analysis captures a singular snapshot, potentially missing the dynamic aspects of organizational processes over time. Furthermore, reliance on self-reported data introduces the risk of response bias, as respondents might provide socially desirable responses or inadvertently misrepresent their experiences. The study primarily focuses on internal determinants of QMS, and while it acknowledges external challenges, it may

not fully account for the influence of external factors such as regulatory changes or global events. The scope of determinants explored in the study is limited, excluding potentially significant factors impacting QMS effectiveness. Lastly, the study's concentration on the Ethiopia Pharmaceutical Supply Service means that the findings may not be universally applicable to organizations in different industries or sectors. Despite these limitations, the study contributes valuable insights to the specific context of QMS implementation at the Ethiopia Pharmaceutical Supply Service, paving the way for future research and targeted interventions.

1.8. Operational Definition of Terms

Quality: the degree of excellence of anything, the standard by which something is judged against other items of a similar sort, or the extent to which an object's intrinsic qualities satisfy standards suitability for the intended use; respect for requirements or specifications (ISO 9000 Quality Systems Handbook, 2015).

Quality management system: pertain to a group of connected or interacting components that companies utilize to guide and regulate the application of quality rules and the accomplishment of quality goals (ISO 9004).

Total quality management: is an organizational management strategy that emphasizes quality, is built on the involvement of all of its members, and aims for long-term success (Nyawira & Omondi, 2016).

Quality management: refers to the visible and sustained support demonstrated by the highest levels of an organization for the implementation and maintenance of a quality management system. It involves allocating resources, setting quality objectives, and actively participating in quality initiatives (Ugboro & Obeng, 2000).

Internal Communication: is the effective exchange of information within an organization to ensure clarity of objectives, promote understanding of quality policies, and foster a culture of quality. It plays a crucial role in aligning employees with quality goals (Mazzei, 2010).

Continuous Improvement: is often associated with Kaizen, is an ongoing, systematic effort to enhance processes, products, or services. It involves identifying opportunities for improvement, implementing changes, and continually reviewing and optimizing processes (Khan *et al.*, 2019).

Training and Competence: refer to systematic processes for developing the skills and knowledge of employees to ensure they are capable of performing their roles effectively and contributing to the organization's quality objectives (Jehanzeb & Bashir, 2013).

Process Quality/Monitoring: refers the systematic assessment and surveillance of processes to ensure they meet predefined quality standards. It encompasses the use of metrics, indicators, and quality control measures to monitor and improve the effectiveness and efficiency of processes (Park *et al.*, 2013).

Team Working: refers to the collaborative efforts of individuals within teams to achieve quality objectives. Effective team working enhances communication, problem-solving, and overall organizational performance (Salas *et al.*, 2008).

Quality Policy: is a formal statement by top management that communicates the organization's commitment to quality and compliance with relevant standards. It provides a framework for establishing quality objectives and guiding the organization's quality management system (Kitazawa & Sarkis, 2000).

1.9 Organization of the Study

This study was divided into five sections. Background of the study, problem statement, research questions, study objective, study scope, study limitations, study significance, and study organization are all covered in the first chapter. A study of relevant literature on factors affecting quality management system is covered in the second chapter. The study approach and methodology, data sources and kinds, population and sample size, data collecting and sampling techniques, analysis method, and interpretation techniques are all covered in the third chapter. The results and discussion are included in the fourth chapter, and summary, conclusion, and recommendation of the findings are included in the remaining chapters.

CHAPTER TWO

LITERATURE REVIEW

A literature review is a body of writing created to examine important ideas from relevant theoretical and empirical literature from earlier research projects. The chapter covers the definitions, viewpoints, and relationships between factors affecting quality management as well as the concepts and principles of quality management systems. Lastly, an empirical review and the conceptual framework that resulted are presented.

2.1. Theoretical Literature Review

2.1.1. Quality concepts

According to the 2015 ISO 9000 Quality Systems Handbook, quality is the difference between what an output from a process should be and what it is a product, service, decision, document, piece of information, etc. Any evaluation of something's quality requires a foundation for comparison as well as sources for its attributes. Combining the notion of quality with the need found in ISO 9000:2000, quality can be defined as the extent to which a set of innate qualities satisfies a stated, widely implied, or required need or expectation (Hoyle, 1999).

Quality, in the context of quality management systems implementation at the Ethiopia Pharmaceutical Supply Service, encompasses meeting customer requirements and enhancing customer satisfaction through consistent processes and continual improvement. According to ISO 9001:2015, quality involves the degree to which a set of inherent characteristics of a product, service, or process fulfills the specified requirements (ISO, 2015). In the specific case of the Ethiopia Pharmaceutical Supply Service, quality management aligns with standards, emphasizing a process approach, risk-based thinking, and a commitment to continual improvement. This includes ensuring that pharmaceutical products meet specified standards, processes are efficient and consistent, and there is a proactive approach to identifying and managing risks that could affect quality.

Quality is the continuous process of establishing and maintaining connections by recognizing, anticipating, and meeting both explicit and implicit needs, according to ISO 9000:2005.

According to El-Tawil (2014), quality is the degree to which a set of innate traits satisfy needs and the achievement of established standards.

2.1.2 History of Quality Management System

Our company manages and oversees the business operations related to quality through a quality management system. In general, it comprises your organizational structure along with the plans, procedures, tools, and records you utilize to meet consumer demands, enhance your goods and services, and accomplish your quality goals (ISO 9000).

Systems for managing quality are not limited to large corporations. Quality management systems are applicable to all sizes of businesses and to all facets of management, including your marketing, sales, and finance operations, because they are about how the organization is run. You are in charge of determining the scope of the application. ESA (2011) Product standards and quality management system standards are not the same thing. The majority of businesses that are unfamiliar with quality management systems, and specifically the ISO 9000 family of standards, conflate the notions of quality management and product or service quality.

Early military systems had a lot in common with the quality management system created by the International Organization for Standardization (Hallström, 2000). The military standards created in the 1930s by the US, NATO, and British armed forces are the source of ISO 9000 (Sandström and Svanberg, 2011). It originated during World War II (WW2). It was common for military authorities to inspect major military undertakings, including the construction of war ships, prior to the start of the conflict. Due to the heightened need for these ships during World War II, they had to be built more quickly by first being disassembled and then assembled in stages. Because military authorities had to measure and monitor these items, the allied forces created the first "MIL-SPECS" (Military Specifications) (Manders 2015).

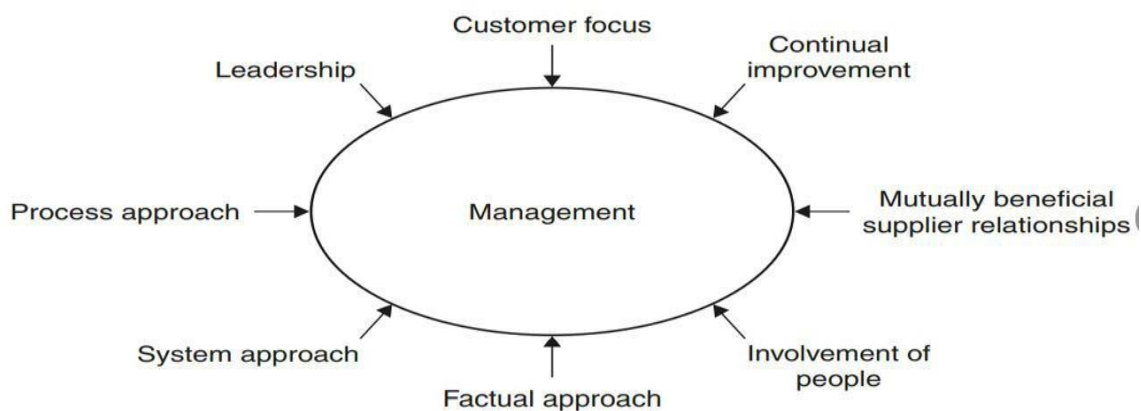
A quality management system is a collection of instruments designed to oversee an organization's scheduled operations in order to accomplish and reach a desired result with reference to meeting client needs. This could mean using working procedures, knowledge, and technology along with human resources to accomplish the desired outcome (Feranecschini, 2007).

The previous thirty years have seen revisions to the ISO 9000 standard. Since the first publication in 1987, there have been four modifications, the most recent of which is 9001:2015. The 9001 indicates the Quality Management System standard code, and the 2015 indicates the standard's year of publication. The standard's modifications were crucial since they clarified any uncertainties from earlier editions and represented the end users' updated requests.

An organization that satisfies the ISO9001 (QMS) requirements is referred to as "ISO 9001 Certified." An activity is not permitted by an ISO certification. ISO 9001 assesses the suitability and efficacy of your QMS while requiring you to find and apply enhancements. (Independent, 2016).

2.1.3. Quality Management Principles

According to Nyawira and Omondi (2016), a quality management concept is a comprehensive and basic set of guidelines and beliefs that guide the leadership and operation of a company with the goal of continuously increasing performance over the long term while serving the demands of all stakeholders. The focus is on the customer. Different activities are required for an integrated quality management approach: commitment from top management, process management, product design, staff empowerment and training, supplier quality management, quality measurement and benchmarking, and customer involvement and satisfaction (Motwani, 2001). Workers need to feel like a member of a team, be aware of the company's objectives, and be introduced to the company's concept of continuous improvement (Motwani, 2001). Eight quality management principles have been recognized by ISO 9001, and senior management can use these to guide their enterprises toward better performance.



Customer focus

Since the customer is the focal point of any organization, meeting their demands both now and in the future is essential to success and aims to surpass their expectations.

Leadership

The organization's direction and purpose become unified under the leadership. To guarantee that the quality ingrained in the various processes is carried forward to all organizational levels and functions and maintained throughout, management commitment is required. A sign of managerial commitment is the provision of sufficient resources to the correct amount and at the right time. At the top, they will also be in charge of attending to staff concerns, creating a welcoming and comfortable work atmosphere, offering growth possibilities, etc.

Engagement of people

People are an organization's core, and when they are fully involved, their strengths may be leveraged to the organization's advantage.

Process approach

When related resources and activities are managed as a process, the desired outcome is attained more quickly.

Continual improvement

A prerequisite for every quality movement is this. The organization's overarching goal should be to continuously improve its overall performance. To address the problems, improvement plans are completed well in advance in firms that use quality standards. Adequate and punctual evaluations have the ability to disclose the true state of progress and recommend remedial measures (ISO 9004:2000). Continuous progress must be evident in both the caliber of the output and, more importantly, in the development of the capacities to generate even better output in the future.

Evidence based decision-making

Certain tools must be used in order to successfully support decision-making. This will assist in preventing prejudice, whether it be familiarity-based or not, when making decisions. Fair

decision-making will help enhance the team's cohesion. Analyzing facts and information is the foundation for making wise judgments.

Mutually beneficial supplier relationships

An organization's potential to create value is enhanced by mutually beneficial relationships with its suppliers, as both parties are dependent on one other.

2.1.4. The Elements of Quality Management System

When a company works to satisfy its customers' requirements through its products and services, quality is the embodiment of its culture, attitude, and values. An organization must focus on the eight essential components of a quality management system, in order to successfully apply it (Nayantara 1989).

Ethics: Professional and commercial ethics require that an organization's practices do not injure or cause harm to those who engage in comparable activity. The management should not make any effort to foster unfavorable competition or create hostility with other companies.

Integrity: It is imperative for the firm to uphold a very high standard of integrity both within and among its workforce to prevent them from turning to unethical means to further their goals. Employees will feel more a part of the company if it practices and instills professional honesty and loyalty.

Trust: The organization needs to have a very high degree of trust in order to thrive since information must be regulated both top to bottom and bottom to top. Furthermore, the world's boundaries have become smaller due to the proliferation of knowledge. It is now crucial to uphold information security as specified by ISMS (Information Security Management System) standards in order to compete.

Training: The training cycle include steps including determining the need for training, putting the training into action, evaluating the training, retraining when needed, and ultimately pursuing multiskilling or job rotation, depending on the situation.

Teamwork: The engine that drives the upholding of excellence is teamwork. Collaboration is encouraged through the use of tools like suggestion schemes, cross-functional teams, quality

circles, etc. Building a cohesive team requires both skill and science, and only individuals with leadership abilities can do so.

Leadership: A leader must set an example for others by practicing what they preach and lead from the front in order to succeed. Success will remain a pipe dream unless the leader demonstrates innate traits like empathy, proactivity, impartiality, honesty, and dedication to the organization.

Recognition: Individual workers' and teams' contributions must be acknowledged and rewarded right away. The recognition of efforts can be achieved by both non-monetary and monetary methods, contingent on the kind, amount, and timing of the gift. But the saying goes, "Justice postponed is justice denied," and this also holds true for acknowledging the gift.

Communication: In order to attain organizational success, this is crucial. Grapevine communication should be completely discouraged, but regular employees should be able to reach higher-ups, and interactions should be transparent and real-time communication is crucial to the organization's survival.

2.1.5. Step in Implementation of Quality Management

Assessing the organization's current state and culture is the first stage in implementing ISO 9001:2015. Prior to beginning the talks that will lead to the adoption of ISO 9001:2015, the business should conduct a thorough analysis of its past, current needs, and employee work-life balance. If these crucial prerequisites are not met by the current reality, implementation should be held off until the firm reaches a point where success is evident soon. It will be simpler for a business to adopt, if it has a history of successfully adapting to changes in the environment and changing its operations as necessary. Employee distrust and a lack of competent change agents will arise in an organization that has not been historically reactive and lacks the ability to improve its operational systems. A thorough program of management and leadership development may be implemented if this circumstance persists (Nayantara, 1989).

To determine the current levels of organizational effectiveness and the areas that require change, a management audit is a useful assessment technique. Before applying ISO 9001:2015, an organization should be deemed to be in general good health. It is not advised to implement ONat that time if it has serious issues like a very unstable financial basis, shoddy administrative

systems, a lack of management expertise, or low staff morale. To start a QMS, it is often preferable to experience some stress. People must sense that something needs to change. In order to address this phenomena, Kanter (1983) primarily uses the idea of building blocks to bring about organizational change. A break from conventional wisdom, a crisis or other inspiring event, calculated choices, lone "prime movers," and any action vehicles are some examples of these forces.

Departures from traditional activities are those which usually occur at the lower levels of the organization, and entrepreneurs move away from the normal ways of operating to solve a problem. A crisis, if it is not too disabling, can also help create a sense of urgency which can mobilize people to act. In the case of ISO 9001:2015, this may be a cut in the funding or a threat for this, or demands from the consumers or other stakeholders for improved quality of service. Whenever a crisis props up, an effective leader may intervene strategically by articulating a new vision of the future to take the organization forward. A plan to implement quality management may be such a strategic decision. Such a leader may turn out to be a prime mover, who will take charge of championing the new idea and showing others how it will lead them where they want to go. Finally, action vehicles are needed and mechanisms or structures essential to enable the change should occur and become institutionalized (Kanter, 1983).

2.2. The key factors of Quality Management implementation

To exploit the benefits provided by QM, companies must manage the complex implementation process successfully. Thus, companies need to identify and evaluate the key factors when introducing QM (Hietschold *et al.*, 2014). The identification of key factors of QM assists the companies to better understand the dynamic and active nature of QM. QM is about complex processes that focus on the company's culture, size, and management styles. Nevertheless, QM has no general standard formula (Koh and Low, 2010). Therefore, an extensive review of the literature was carried out to explore the concept and the main principles of QM from leading writers on quality who have developed various approaches in the area of quality management.

According to Jacobsen (2008), understanding the main factors that are likely to hinder the implementation of QM urges the decision-makers to develop effective strategies for improving the opportunities of successful QM implementation hence, moving towards excellence in the

business. This research is primarily based in Iraq, which is considered to be one of the developing Arab countries and due to the lack of empirical efforts to study the barriers or obstacles that hinder the QM implementation. Therefore, it is worthwhile to shed light on the barriers that impede QM implementation in Arab countries where they have a similar business environment to that of Iraq. Consequently, this research mainly concentrated on the studies that acknowledged QM barriers facing companies implementing QM in Arab countries.

Berrouiguet (2013) identified four major barriers that impeded QM implementation in Algerian manufacturing companies. These barriers were lack of top management support, a significant shortage of the knowledge and skills required to implement QM, cultural change and inadequate financial resources. Alsughayir (2014) conducted a study to examine the barriers to implementing QM in private medical services organizations in Saudi Arabia. The findings of the study revealed that the most significant barriers to QM efforts included high employee turnover, which meant that the organizations focused more on employees' performance rather than improvements in quality. This is an indication that these organizations do not consider quality as an organizational objective. Also, a lack of understanding of the QM philosophy is considered as a primary impediment to its successful implementation. In addition to the lack of motivation among employees would as well cause them to resist change due to a lack of understanding of the QM concept and its importance

The barriers identified during QMS implementation were lack of Human Resources Training (in a way that affects them to become an agent of change for resistance to change), inappropriate preparatory phase, lack of quality management, to develop and implement of QMS, and lack of employee's commitment, insufficient resources allocation (Lack of financial and Human Resources), lack of defining responsibilities and authorities to develop and implement of QMS were ranked the major first challenges. Besides to that poor accountability, difficult in co-operation among middle managers over quality problems, inappropriate team working environment in the company, poor cross-functional team communication and prevalence of bureaucratic culture in the company" as a second rank barrier. Finally, "Difficulties to interpret quality related procedures", "Conflict between new QMS processes and the existed company processes" and "In-sufficiency of project time" were considered as low severity barriers (Osman, 2016). Based on the research finding by Ogany (2017) the implementation of QMS is greatly

influenced by resource availability, staff training, top management skills, and information technology.

According to Hussein et al. (2017), adopting and implementing the QMS presents seven major challenges. The quality management nomenclature, lack of understanding, resistance to change, accreditation, quality management, time management, and resource availability are the seven variables that have been highlighted. The organizational obstacles include a lack of knowledge about ISO 9000 standards, a lack of commitment, leadership, and involvement from senior management, a lack of human resource management, and a lack of employee empowerment and understanding of the advantages of ISO 9000 certification. The bureaucratic culture that permeates businesses, employees' aversion to change, placing the wrong people in the wrong positions, the promotion of directors, managers, and department heads without due process, and employee absenteeism are some of the obstacles caused by organizational culture. Technical obstacles include poor communication, a lack of knowledge, access to testing facilities being difficult, managing the paperwork throughout the registration procedure, and a failure to comprehend and apply the requirements. (Sharif, 2005).

2.3. Empirical Review

Ethiopian Beer Factories were the focus of Tulu's (2011) study, which looked into how ISO 9001 certification affected organizational performance. The primary reason the research was conducted was because businesses frequently assert that obtaining ISO certification will enhance their organization's performance. Five Ethiopian brewing businesses' secondary data are gathered in order to look into this. The data was utilized by the organizations both before and after the completion of the ISO permanent certification process, spanning a ten-year period. Descriptive statistics were used to assess the gathered data, and its significance was determined. The results show that the ISO certification has a significant influence on the firms and has been linked to the overall success of the company. The results also showed that the companies' overall revenues had improved following their ISO accreditation. It is recommended that more research be done to determine how ISO certification affects business performance, especially for Ethiopian companies.

Beshah and Kitaw (2014) examined quality management practices in Ethiopia. Total quality management is growing more and more crucial, according the report, in order to please clients

and eventually increase market share. All of the criteria in the criterion analysis have a connection to the problem. The main cause of the issue is visible at the sub-criteria level. In fact, almost all of the sub-criteria have a negative skew, which suggests that Ethiopian industries lack adequate quality management procedures.

Kidanu (2014) evaluated how Ethiopian construction enterprises were affected by QMS (ISO 9001) certification. In order to conduct the study, a questionnaire based on the evaluation of the literature is created, sent to construction companies with ISO certification, and subsequently gathered and examined. The findings led to the conclusion. Construction enterprises with ISO 9001 certification have not seen any real benefits. The primary cause of the failure is that construction businesses place little attention on the internal benefits of the standard, which include things like insufficient motivation, insufficient training, and efficient and effective processes. Furthermore, there is a lack of continuity in the government agencies' encouragement and support for certified enterprises. The three biggest issues that certified businesses encountered while implementing quality were turnover, inconsistent QMS implementation, and change resistance. Finally, suggestions are made to close the gaps found in the results.

Frew (2016) looked at the implementation and difficulties with QMS (ISO 9001:2008) in the pharmaceutical sector: EPHARM Ethiopia. A self-administered questionnaire was used in a descriptive study approach to collect primary data from EPHARM S.C. personnel. Since the research findings are substantial and valuable, it is possible to draw the conclusion that putting the system into place will improve the company's reputation, give it a stronger competitive edge over rivals, raise employee awareness of quality, increase profit, and result in fewer or fewer product rejections. Additionally, research on the difficulties associated with implementing QMS found that the primary obstacles to the system's successful implementation are a lack of sufficient information, a lack of managerial commitment, and a lack of staff capability. Notwithstanding the few difficulties the business encountered in creating, putting into practice, and maintaining the ISO 9001:2008 Quality Management System, the system's widely stated advantages were considered to be substantial overall and had a positive effect on the business's performance. The study concludes by recommending that all possible issues found throughout the QMS implementation process should receive the attention they deserve and that suitable

preventive and corrective measures be considered ahead of time during the system's planning and development stage.

The complex relationship between employee commitment and the adoption of Quality Management Systems (QMS) at the Ethiopian Pharmaceuticals Supply Agency (EPSA) is examined in the Nigusse (2021) study. The study uses quantitative research methods and combines descriptive and explanatory research techniques, based on a Three Component Model (TCM) of employee commitment to quality. Employees of EPSA at different hubs were given a questionnaire using a stratified sample technique, and SPSS software version 22 was used to analyze the results. Using a Generalized Linear Regression model and nonparametric Kendall's Tau-B correlation, the study finds a strong association between Affective, Behavioral, and Cognitive Commitments and QMS Implementations (QMSI). The results show that overall staff commitment has a significant impact on QMSI, with affective commitment being the most important variable. The study not only emphasizes the importance of giving employee commitments in QMSI within EPSA careful consideration, but it also offers insightful information about the complex relationships between various commitment aspects and the overall implementation of quality management systems.

Hussen (2022) was conducted Quality management system practices and challenges in Ethiopian Sugar Industry: the case of Metahara Sugar Factory. This research delves into the current state of Quality Management System (QMS) practices and challenges within the Ethiopian sugar industry, with a specific focus on Metahara Sugar Factory. Utilizing a descriptive research design and gathering data from 333 employees, the study reveals a decline in QMS practices, particularly in leadership viewpoints, customer focus, and the process approach, impacting overall productivity negatively. Despite these challenges, positive aspects such as strong relationships with stakeholders, employee initiatives, and a solid understanding of quality goals are identified. The study highlights key challenges including outdated technology, insufficient resources, and a lack of senior management commitment, emphasizing their role as significant obstacles to effective QMS implementation. Encouraging best practices and addressing these challenges, particularly through the introduction of new systems like Environmental, Social, and Governance (ESG), are underscored as crucial for the industry's sustained success and national pride.

The duties of upper management have an impact on personal values and serve as a spur for environmental advocacy. Successfully identifying shortcomings will increase management's willingness to implement an improved management strategy, which will ultimately impact maximizing business performance (Guo et al., 2019). If a QM company is to succeed and make improvements, it must devote all of its resources to the implementation process, from the top to the bottom of the plant (Ahmed & Idris, 2021). High-commitment management will always take proactive measures to promote ecological and technical innovation because they will feel accountable for whatever they do (Guo et al., 2019; Novitasari & Tarigan, 2022). Improving organizational performance in terms of personnel, equipment, and quality is intimately related to leadership (Graham et al., 2014; Siagian et al. To increase business performance, management and staff must both fully commit to QM (Ahmed & Idris, 2021). In addition to exercising control, management's main responsibility is to guarantee that workers adhere to the established empowerment system in their work. According to Graham et al. (2014), management commitment leadership must eradicate the root reasons of failure and assist staff in achieving higher performance with less effort. In order to assure the availability of raw materials and personnel to form a cohesive corporate unit, management commitment is crucial for adopting and implementing innovation in an organization, particularly environmental systems (Singh & Sangwan, 2011). A third theory was developed in light of the information given.

2.4. Conceptual Framework

The conceptual framework for the investigation into the influence of quality management system on within the Ethiopia Pharmaceutical Supply Service encompasses key independent variables crucial for understanding the organizational dynamics. Internal Communication (IC) is essential for disseminating the top management's commitment throughout the organization, ensuring a shared understanding of the ISO standards. Continuous Improvement (CI) reflects the organization's proactive approach to refining and enhancing its processes in alignment with ISO 9001:2015. Training and Competence (TC) signify the investment in developing the skills and knowledge required for effective ISO implementation. Process Quality/Monitoring (PQM) involves systematic assessment mechanisms to ensure adherence to ISO standards. Team Working (TW) captures the collaborative efforts of organizational teams in implementing ISO guidelines. Quality Policy (QP) is a formal expression of the organization's commitment to

quality, guiding ISO implementation. Through a comprehensive examination of these independent variables, the study seeks to unravel the nuanced interplay between quality management and the multifaceted aspects of within the Ethiopia Pharmaceutical Supply Service.

Independent variables

Dependent variable

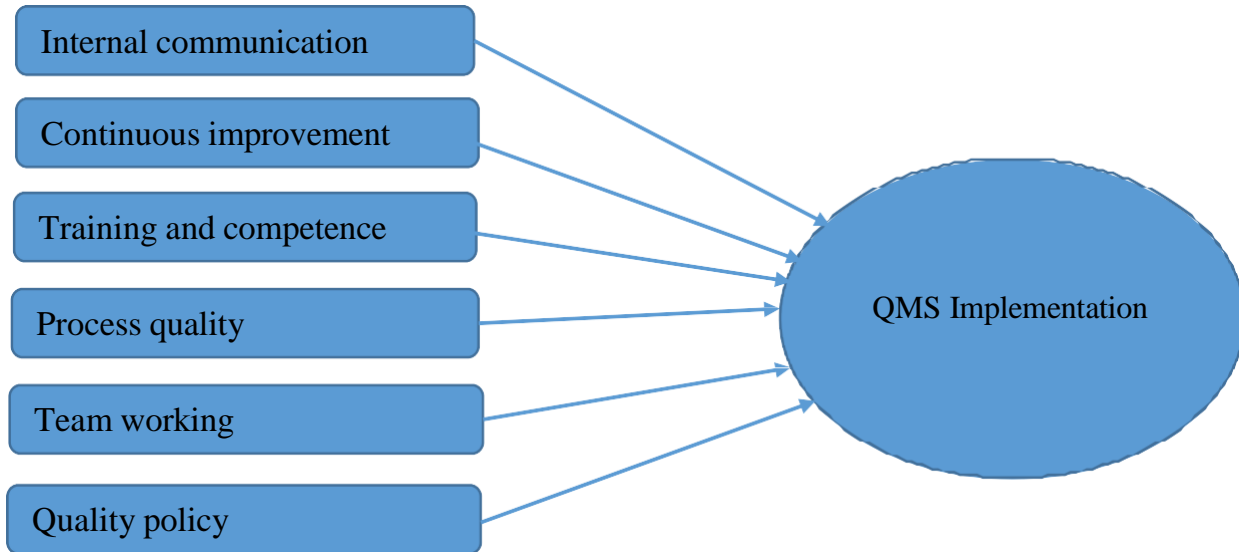


Figure 1: Conceptual framework of the study

2.5 Research Hypothesis

Based on the above conceptual framework, the study was proposed the following hypothesis about the possible relationship between dimension of quality management and quality management systems in Ethiopian pharmaceutical supply service

H₁: There is a significant positive effect of the quality management factors on the successful implementation of quality management systems in the Ethiopian pharmaceutical supply service

H_{1a}: There is a significant positive effect of internal communication on quality management systems in the Ethiopian pharmaceutical supply service

H_{1b}: There is a significant positive effect of continuous improvement on quality management systems in the Ethiopian pharmaceutical supply service

H_{1c}: There is a significant positive effect of training and competence on quality management systems in the Ethiopian pharmaceutical supply service

H_{1d}: There is a significant positive effect of process quality on quality management systems in the Ethiopian pharmaceutical supply service

H_{1e}: There is a significant positive effect of team working on quality management systems in the Ethiopian pharmaceutical supply service

H_{1f}: There is a significant positive effect of quality policy on quality management systems in the Ethiopian pharmaceutical supply service

CHAPTER THREE

RESEARCH METHODOLOGY

Analyzing the factors influencing quality management systems on in the context of Ethiopian pharmaceutical supply services was the study's main goal. This chapter covered the methodology used to accomplish the research objective. It covered the organization's background, the research approach, the research design, the population and sample size, the types and sources of data, and the instruments used for data collection and analysis.

3.1. Research Design

In this study, an explanatory research approach was mostly used. The primary goal of an explanatory research design is to comprehend and elucidate the quantitative relationship and effect that will exist between the independent and dependent variables in order to determine the magnitude of that relationship and effect. Multiple regression analysis was used to identify influential factors in order to see how independent variables affected dependent variables. The purpose of the explanatory approach was to establish the cause and effect relationship between the dependent and independent variables by correlation, i.e. between independent variables and quality management. Causes and reasons are sought after in explanatory research. By identifying and quantifying the causal relationships between events, it seeks to explain them (Mitchell and Jolley, 2004). By comparing the frequency, percentage, mean, and standard deviation score of each variable, descriptive analysis was performed to determine the level of quality management and quality management as well as to describe the demographic features of the respondents.

3.2. Research Approach

The study used quantitative approach in order to accomplish this goal, provide a conclusive answer to the research questions stated in the first chapter, and assess the hypothesis. The idea is to combine the various advantages of the two methods such as increased explain ability and generalizability to improve our understanding of reality from both an objective and subjective perspective. The quantitative process comprises the generation of quantitative data that may be subjected to quantitative analysis in an exacting and rigorous manner.

In this kind of scenario, the researcher's perceptions and insights drive the investigation (Kothari 2004). Consequently, samples from the sampled respondents were collected using a quantitative approach. As a result, sequential explanatory design was used to analyze, clarify, and put quantitative results into perspective. As a result, Stata version 13 was used to evaluate the quantitative responses in order to determine the variables' objective cause and effect relationships.

3.3. Sample Size and Sampling Technique

In the investigation focused on the top management bodies at the head office of the Ethiopia Pharmaceutical Supply Service (EPSS), the total population comprises 70 management bodies. Given the study's objective to encompass the entire population, the traditional determination of a sample size is unnecessary. Instead, the study was adopted a census approach, involving all 70 top management bodies, which include 5 general managers, 19 directors, and 46 team leaders. This approach transforms the study into a comprehensive examination rather than a sampled one, ensuring that every member of the target group is accounted for. This strategy maximizes the precision and representativeness of the findings.

Employing a census approach implies that data was collected from the entire population of 70 top management bodies at EPSS, eliminating the need for sampling techniques. A census involves the study of every individual within the defined population, enabling a thorough exploration of the subject under investigation. This method promises a detailed understanding of the characteristics, behaviors, or patterns within the top management group. By opting for a census in this study, the precision of results is enhanced, and the findings directly apply to the specific context of EPSS's head office

3.4. Data Source and Method of Collection

The primary data sources were used to get the study's data. The original data was gathered from the EPSS Head Office's upper management. A semi-structured questionnaire was employed by the study as the instrument of data collection to gather the primary data. It was divided into two main sections: the first dealt with the respondents' personal information, including their sex, position, age, education, and length of employment with the agency. The second section focused on the top management's commitment to quality management system implementations and continuous process improvement practices (QMSI). In accordance with the specified research

topic area, the researcher additionally modified questionnaires to test variables. The range of responses strongly disagree, disagree, neutral, agree, and highly agree with numerical values ranging from 1 to 5 were measured using the Likert-type scale approach. Secondary data from official papers, manuals, books, websites, and other scholarly writings were used to supplement the main material.

3.5 Methods of Data Analysis

To fulfill the outlined research objectives, the gathered data was under go analysis tailored to the nature of each objective. Both descriptive and inferential statistical analysis techniques were employed. Descriptive statistics, including percentages, figures, and tables, were generated using SPSS Version 22 software to elucidate relationships among variables. This information was organized in standardized formats such as tables, frequencies, and percentages for comprehensive analysis and interpretation. Subsequently, correlation and regression analyses were conducted to scrutinize relationships between the dependent and independent variables. The quantitative analysis was carried out using Stata version-13 software. Subsequently, regression analysis was employed to explore the relationships between key determinants (internal communication, leadership, quality process, quality policy, training, team working and continuous improvement) and quality management system performance.

3.6 Reliability and Validity

To reduce the possibility of getting the wrong answer, attention was paid to the reliability and validity of the questionnaire. To ascertain the reliability and validity of the developed questionnaire for this study, a pilot test was executed. This preliminary assessment aims to evaluate the internal consistency of the questionnaire, utilizing statistical measures such as Cronbach's alpha to ensure the reliability of the items. Simultaneously, the pilot test was addressed content validity through expert reviews, assessing the relevance and representativeness of the questionnaire items, while also considering construct validity by aligning the instrument with established theories. By involving a small subset of the target population, the pilot test enables the identification and rectification of any ambiguities or inconsistencies, ensuring that the questionnaire is refined and robust before full-scale implementation in the main study. This

iterative process enhances the instrument's reliability and validity, ultimately contributing to the collection of accurate and meaningful data in the subsequent stages of the research.

3.7 Ethical Consideration

These days, ethical concerns in research are crucial. Conflicts of values gave rise to ethics. Every choice taken in research may result in the sacrifice of one value for another. While seeking to maximize the quality of information they provide, researchers must aim to limit risks to participants, colleagues, and society (David, 1989). A formal letter was acquired from Addis Ababa University by the college for ethical purposes. Participants and companies were given the assurance that their names would remain anonymous, that their data would be kept private, and that it would only be used for research. In addition to the written statement, the researcher tried to speak with each responder directly and gave a verbal explanation of the relevance and goal of the study. This allowed the researcher to obtain all the data required to complete the study.

CHAPTER FOUR

DATA PRESENTATION, ANALYSIS AND DISCUSSION

4.1 Response Rate

The response rate for the questionnaires distributed to employees of Ethiopia Pharmaceutical Supply Service was 100%. All 70 employees, including 5 general managers, 19 directors, and 46 team leaders, completed and returned the questionnaires. This indicates a comprehensive and complete participation from the entire target group, ensuring a thorough representation of views and opinions across different levels of the organization. The 100% response rate reflects a high level of engagement and commitment from the surveyed employees.

4.2. Demographic Characteristics of the Respondents

Demographic characteristics including: gender, age, educational background, year of experience and working position are summarized using frequencies and percentages.

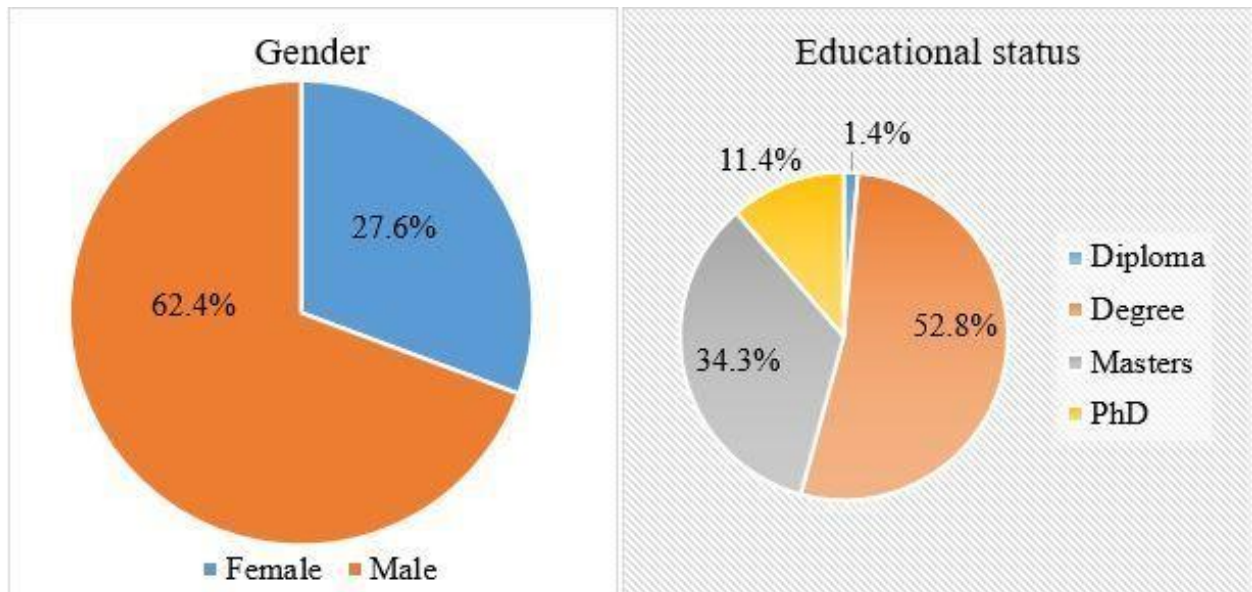


Figure 2: Gender and educational status of respondents

Source: Own survey result, 2023

The gender distribution of the respondents reveals a notable disparity, with 19 (27.6%) identifying as female and 51 (62.4%) identifying as male. This distribution suggests a predominance of male respondents within the surveyed population. Such gender imbalances in

responses can be influenced by various factors, including the composition of the workforce within the Ethiopia Pharmaceutical Supply Service or the nature of the roles associated with top management, directors, and team leaders.

The educational status of the respondents in the survey conducted at the Ethiopia Pharmaceutical Supply Service reflects a diverse spectrum of academic qualifications. Among the respondents, 37 (52.8%) hold a degree, indicating that a substantial portion of the surveyed population has attained at least an undergraduate education. Furthermore, 24 (34.3%) and 1 (1.4%) of respondents possess master's degrees and diploma, suggesting a notable presence of individuals with advanced qualifications and specialized knowledge within the organization. Additionally, 8 (11.4%) of respondents hold PhD degrees, contributing to a pool of respondents with the highest level of academic expertise.

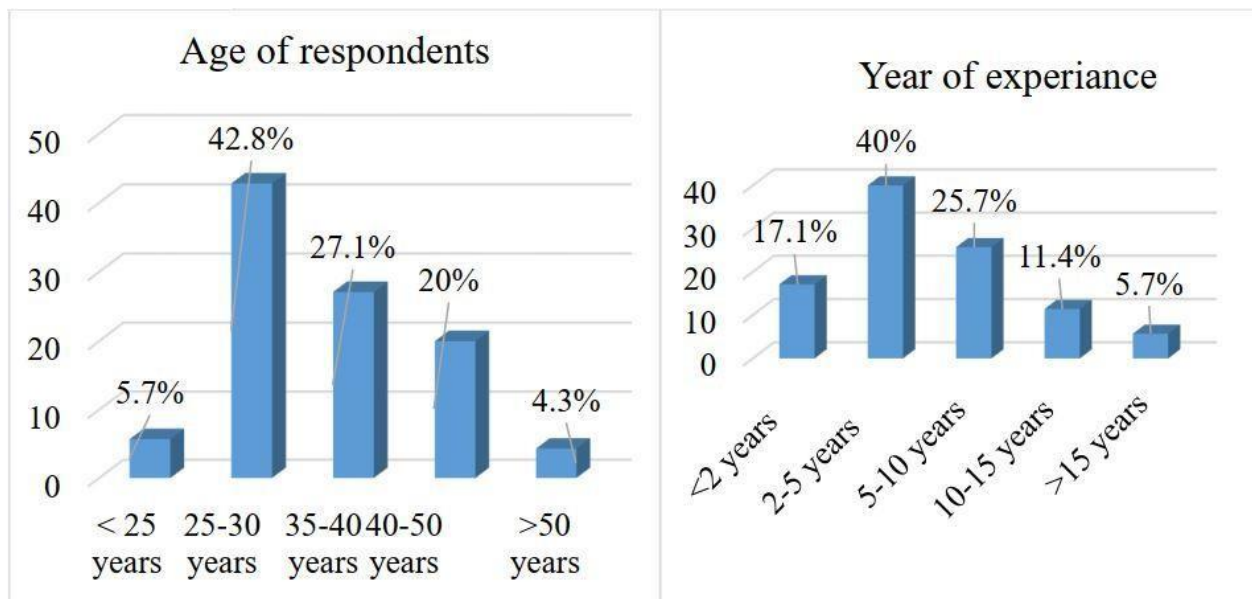


Figure 3: Age and year of experience of respondents

Source: Own survey result, 2023

The age distribution among respondents in the survey conducted at the Ethiopia Pharmaceutical Supply Service provides a comprehensive overview of the workforce demographics. The largest segment of respondents, constituting 42.8%, falls within the age range of 25-30 years, indicating a significant presence of individuals in the early to mid-stages of their professional journeys. The 27.1% of respondents aged between 35-40 years signifies a considerable representation of mid-career professionals. Furthermore, 20% of respondents fall within the 40-50 age bracket,

reflecting individuals in the later stages of their careers. The age group under 25 years represents 5.7% of respondents, and those above 50 years constitute 4.3% of the surveyed population.

The distribution of work experience among respondents in the survey conducted at the Ethiopia Pharmaceutical Supply Service highlights the diverse professional backgrounds within the organization. A significant portion, comprising 40% of the respondents, possesses a moderate level of experience ranging from 2 to 5 years, indicating a substantial presence of individuals in the early stages of their careers. Additionally, 25.7% of respondents have accumulated 5 to 10 years of experience, suggesting a notable contingent of mid-career professionals. Respondents with less than 2 years of experience represent 17.1%, while those with 10 to 15 years and over 15 years of experience constitute 11.4% and 5.7%, respectively.

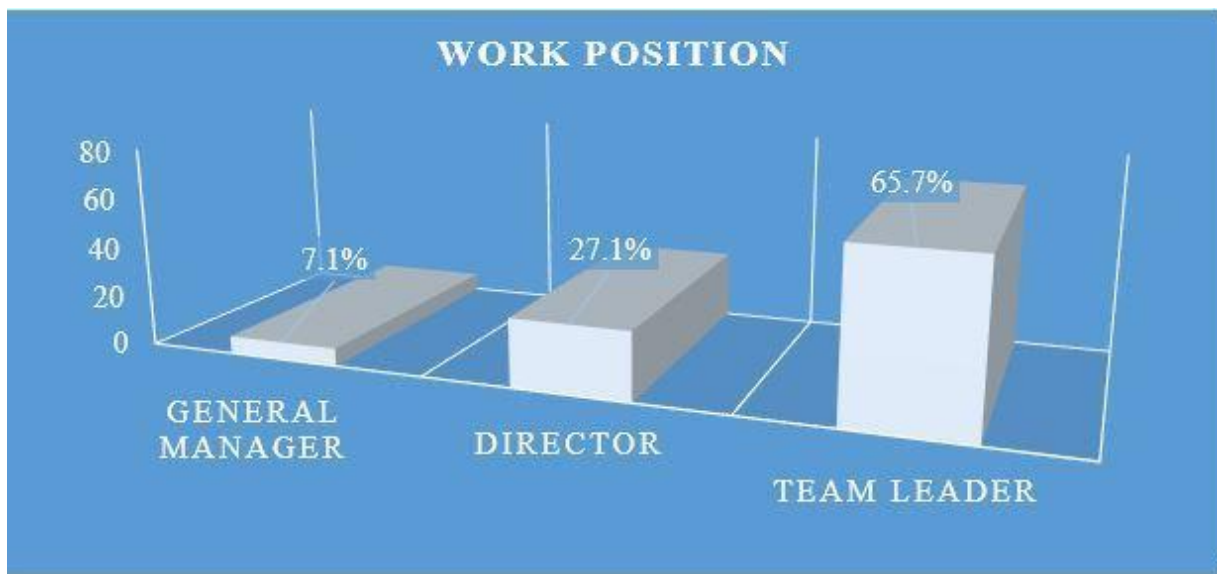


Figure 4: Work position in the company

Source: Own survey result, 2023

The breakdown of job positions among respondents in the survey at the Ethiopia Pharmaceutical Supply Service reveals a diverse representation of organizational roles. The majority of respondents, accounting for 65.7%, hold positions as Team Leaders, emphasizing the critical role of leadership at the operational level within the organization. These individuals, being at the forefront of teams, play a pivotal role in the day-to-day implementation of quality management systems and standards.

Directors constitute 27.1% of the respondents, representing a significant presence of individuals in higher managerial roles. Directors are typically responsible for overseeing broader aspects of the organization's operations, including quality management strategies and compliance. General managers, comprising 7.1% of the respondents they holds a key leadership position responsible for overseeing the overall operations and performance of a business or a specific division. These individuals are likely to have a direct impact on the formulation and execution of quality policies within the organization.

The distribution of job positions signifies a hierarchical representation within the workforce, ranging from operational leadership roles to higher managerial positions with a focus on quality management. The prominence of Team Leaders suggests a decentralized approach to quality management, emphasizing the importance of frontline leadership in achieving organizational goals. The diverse mix of job positions contributes to a comprehensive understanding of how different levels within the organizational hierarchy perceive and contribute to quality management implementation.

4.3. Reliability and Validity Test

Cronbach (1951) states that the practical assessment of the dependability of a separate item scale typically serves as the benchmark for all potential split-half reliabilities for a construct. The Cronach Alpha Value, or coefficient Alpha, is a suggested measure whose value spans from 0 to 1. The higher the coefficient, the better the measuring device; nonetheless, for a value to be considered excellent or acceptable, it must be greater than 0.7 on the scale.

The typical range of the Cronbach's alpha reliability coefficient is 0 to 1. Internal consistency increases with alpha coefficient proximity to 1.0 and vice versa. The alpha value range of ≥ 0.90 , ≥ 0.80 , ≥ 0.70 , ≥ 0.60 , ≥ 0.50 , < 0.50 , is considered excellent, good, and acceptable, questionable, poor and unacceptable range, according to the general guidelines established by George and Mallery (2003). As can be seen in table 1 below, which shows that all items' average, Cronbach's Alpha values were over 0.80, we can draw the conclusion that the data gathering tool is reliable and consistent.

Table 1: Reliability test

Variables	Number of items	Cronbach's alpha	Internal consistency
Internal communication	6	0.863	Good
Continual improvement	5	0.801	Good
Process quality	6	0.842	Good
Training	6	0.815	Good
Team working	7	0.814	Good
Quality policy	7	0.839	Good
Overall reliability	37	0.814	Good

4.4. Analysis on Quality Management System Practices

Examining Ethiopia's pharmaceutical supply service quality management methods was the main objective of the study. The quality principles were used to categorize the quality management techniques that were examined. In terms of internal communication, continuous improvement, process quality, training, leadership, teamwork, and quality policy, this pertains to the pharmaceutical supply service quality practices. The researchers looked at whether the firms were using these quality management practices using a 5-point Likert scale questionnaire. The respondents were asked to rank the statements according to how much they agreed and disagreed significantly.

4.4.1. Internal Communication

The internal communication practices for Quality Management System (QMS) within the Ethiopia Pharmaceutical Supply Service reveal a nuanced understanding among respondents, as indicated by the frequency and mean values for each item. Firstly, regarding the sharing thoughts on the challenges encounter in accomplishing improvement objectives. 24.3% strongly agree and 45.7% agree, resulting in a mean value of 3.76. This suggests a positive inclination towards sharing thoughts on regarding challenges encounter in accomplishing improvement objectives. Communication on the effectiveness of the QMS across the organization periodically receives support from 25.7% who strongly agree and 42.8% who agree, resulting in a mean value of 3.54. This implies a moderate perception of the effectiveness of periodic communication on QMS matters.

Table 2: Internal communication for quality management system practice

Items	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	Mean
We are urged to share our thoughts on the challenges we encounter in accomplishing our improvement objectives.	24.3	45.7	20	7.2	2.8	3.76
Periodically, there is communication about the effectiveness of the quality management system throughout the entire organization.	25.7	42.8	25.6	10	4.3	3.54
We have a very successful and productive communication system that includes email, office lookout, notes, message boards, and other	35.7	40	14.3	8.6	1.4	4.38
Encouragement to communicate feedback on obstacles hindering improvement goals	24.3	47.1	17.2	8.6	2.8	3.76
Effectiveness of existing communication channels in facilitating clear and timely information on quality management system matters	21.4	45.7	18.6	10	4.2	3.68
Perception of the organization's encouragement of open dialogue and discussion on enhancing the quality management system	30	40	15.7	11.4	2.8	4.04
Grand mean	26.8	43.5	18.6	9.3	3.05	3.86

Source: Own survey result, 2023

The presence of an effective and efficient communication process, including channels like email, office lookouts, memos, and communication boards, is positively perceived by 35.7% who strongly agree and 40% who agree, yielding a mean value of 4.38. This indicates a strong consensus on the efficacy of existing communication channels. Similarly, for the item related to encouragement to communicate feedback on obstacles hindering improvement goals, 24.3% strongly agree, and 47.1% agree, resulting in a mean value of 3.76. This reinforces the positive inclination towards fostering open communication regarding challenges faced in achieving improvement goals. The effectiveness of existing communication channels in facilitating clear and timely information on QMS matters is recognized by 21.4% who strongly agree and 45.7% who agree, resulting in a mean value of 3.68. This suggests a moderate perception of the effectiveness of current channels in disseminating information on QMS. Lastly, the perception of the organization's encouragement of open dialogue and discussion on enhancing the QMS is positive, with 30% strongly agreeing and

40% agreeing, resulting in a mean value of 4.04. This indicates a strong endorsement of the organization's commitment to fostering open dialogue and discussion for enhancing the QMS.

The grand mean, reflecting an overall measure, stands at 3.86. This suggests a generally positive perception of internal communication practices for QMS within the Ethiopia Pharmaceutical Supply Service, with a significant portion of respondents expressing agreement across various aspects. The survey results on internal communication practices for Quality Management System (QMS) at the Ethiopia Pharmaceutical Supply Service align with existing scholarly insights. The positive inclination towards fostering open communication about improvement challenges resonates with Chen et al. (2018) and their emphasis on dialogue for continuous improvement. The moderate perception of periodic communication effectiveness corresponds with Smith and Brown's (2017) discussions on challenges in maintaining effective communication. The strong consensus on the efficacy of existing communication channels aligns with Powell's (2019) principles on the importance of efficient channels for effective quality management. The endorsement of the organization's commitment to fostering open dialogue for QMS enhancement aligns with Wang and Wu's (2018) emphasis on open dialogue for continuous improvement. The grand mean of 3.86 reflects an overall positive perception of internal communication practices for QMS, suggesting successful establishment and alignment with member expectations.

4.4.2. Continual Improvement

The survey results on continual improvement practices for Quality Management System (QMS) within the Ethiopia Pharmaceutical Supply Service reveal a nuanced understanding among respondents. Firstly, concerning the commitment of top management in reviewing the system periodically to ensure adequacy and effectiveness, 17.1% strongly agree, 32.8% agree, 30% are neutral, 15.7% disagree, and 4.3% strongly disagree. The mean value is 3.58, indicating a moderate perception of quality management to regular system reviews for maintaining system effectiveness. The prompt implementation of corrective actions to eliminate the causes of nonconformists and prevent recurrence indicates strong support, with 22.8% strongly agreeing, 35.7% agreeing, 20% being neutral, 15.7% disagreeing, and 5.7% strongly disagreeing. The mean value is 3.84, suggesting a positive perception of the organization's responsiveness in addressing nonconformists promptly.

Table 3: Continual improvement for quality management system practice

Items	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	Mean
Top Management is dedicated to routinely assessing the system to guarantee that it is implemented appropriately and effectively.	17.1	32.8	30	15.7	4.3	3.58
Corrective measures are implemented promptly to eradicate the reasons behind nonconformities and avoid their recurrence.	22.8	35.7	20	15.7	5.7	3.84
With a variety of strategic interventions and high-quality instruments, the organization's processes are continuously improved.	27.1	37.1	17.2	14.3	4.3	4.23
Organizational processes are routinely observed, assessed, and verified.	24.3	45.7	15.7	11.4	2.8	4.41
Both the successes and the shortcomings are methodically and thoroughly recorded.	22.8	45.7	18.6	10	2.8	4.38
Grand mean	22.8	39.4	20.3	13.4	3.98	4.08

Source: Own survey result, 2023

Regarding the continuous improvement of organizational processes through different strategic interventions and quality tools, a substantial agreement is observed, with 27.1% strongly agreeing, 37.1% agreeing, 17.2% being neutral, 14.3% disagreeing, and 4.3% strongly disagreeing. The mean value is 4.23, indicating a robust endorsement of the organization's commitment to continual improvement through diverse strategies and quality tools. The systematic monitoring, evaluation, and validation of organizational processes receive strong support, as indicated by 24.3% strongly agreeing, 45.7% agreeing, 15.7% being neutral, 11.4% disagreeing, and 2.8% strongly disagreeing. The mean value is 4.41, suggesting a high level of confidence in the organization's systematic approach to monitoring and validating processes. Similarly, the systematic documentation of improvements made and failures occurring, with equal emphasis, is well-perceived, as 22.8% strongly agree, 45.7% agree, 18.6% being neutral, 10% disagree, and 2.8% strongly disagree. The mean value is 4.38, reflecting a positive perception of the organization's documentation practices, giving equal weight to successes and failures.

The grand mean, reflecting an overall measure, stands at 4.08. This suggests an overall positive perception of continual improvement practices for QMS within the Ethiopia Pharmaceutical Supply Service, with respondents expressing agreement across various aspects. The survey results on continual improvement practices at the Ethiopia Pharmaceutical Supply Service align with established principles in quality management. The respondents express a moderate perception of quality management to periodic system reviews, resonating with Wang and Wu (2018). The positive perception of prompt corrective actions aligns with Rahman et al. (2020), emphasizing the significance of timely interventions. The strong support for continuous improvement strategies corresponds with Powell's (2019) discussions on employing diverse tools for enhancement. The positive reception of systematic monitoring and documentation practices reflects alignment with Chen et al. (2018) and Smith and Brown (2017), highlighting the importance of systematic approaches and comprehensive documentation. Overall, the results indicate that the organization's practices align with scholarly recommendations, contributing to a positive perception of continual improvement practices.

4.4.3. Process Quality

Table 4: Process quality for quality management system practice

Items	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	Mean
There has been an attempt to prioritize organizational processes above functional	21.4	38.5	21.4	12.8	5.7	3.78
Helping procedures and a quality manual have been developed and are kept up to date.	34.3	48.6	11.4	5.7	0	4.69
Through process improvement or re engineering teams, project management, and incorporating customers and suppliers, the organization modifies processes and assesses the advantages.	25.7	44.3	18.6	10	1.4	4.46
To support proper decision making, data on input, process, and output phases are gathered using statistical quality methods that are appropriate for the job.	22.8	42.8	20	11.4	2.8	3.74
Every department is aware of how their actions affect other departments and plans their activities accordingly.	35.7	47.2	11.4	4.3	1.4	4.62
My organization makes sure the data needed to run and enhance the processes is available, as well as to	24.3	42.9	15.7	12.8	4.3	3.61

track, examine, and assess the system's overall performance.						
Grand mean	27.4	44.1	16.4	9.5	2.6	4.15

Source: Own survey result, 2023

The survey results regarding process quality for Quality Management System (QMS) practices at the Ethiopia Pharmaceutical Supply Service reveal a detailed and nuanced understanding among respondents, as reflected by the frequency and mean values for each item, encompassing strongly agree, agree, neutral, disagree, and strongly disagree responses. Firstly, in terms of efforts focused on organizational processes rather than functional aspects, 21.4% strongly agree, 38.5% agree, 21.4% are neutral, 12.8% disagree, and 5.7% strongly disagree. The mean value is 3.78, indicating a moderate perception of organizational emphasis on processes over functional aspects. The creation and maintenance of a quality manual and supporting procedures receive strong support, with 34.3% strongly agreeing, 48.6% agreeing, 11.4% being neutral, 5.7% disagreeing, and 0% strongly disagreeing. The mean value is 4.69, suggesting a robust endorsement of the existence and upkeep of quality documentation within the organization.

Concerning the change processes and evaluation of benefits through improvement or re engineering teams, project management, and involving customers and suppliers, 25.7% strongly agree, 44.3% agree, 18.6% are neutral, 10% disagree, and 1.4% strongly disagree. The mean value is 4.46, indicating a positive perception of the organization's engagement in comprehensive processes. The use of appropriate statistical quality tools to gather data on input, process, and output phases for decision-making purposes is moderately supported, with 22.8% strongly agreeing, 42.8% agreeing, 20% being neutral, 11.4% disagreeing, and 2.8% strongly disagreeing. The mean value is 3.74, suggesting a moderate level of confidence in the application of statistical tools.

The understanding among all departments regarding the effects of their actions on other departments and consideration of these effects in their activities receives strong support, as 35.7% strongly agree, 47.2% agree, 11.4% are neutral, 4.3% disagree, and 1.4% strongly disagree. The mean value is 4.62, indicating a robust endorsement of cross-functional understanding and collaboration. Regarding the organization's assurance that necessary information is available to operate and improve processes, as well as monitor, analyze, and

evaluate the overall system's performance, 24.3% strongly agree, 42.9% agree, 15.7% are neutral, 12.8% disagree, and 4.3% strongly disagree. The mean value is 3.61, suggesting a moderate level of confidence in the availability of information for operational and improvement purposes. The grand mean, reflecting an overall measure, stands at 4.15. This indicates an overall positive perception of process quality for QMS practices within the Ethiopia Pharmaceutical Supply Service, with respondents expressing agreement across various aspects. The findings suggest a robust commitment to process-oriented quality practices within the organization

The survey results on process quality at the Ethiopia Pharmaceutical Supply Service align with key principles in quality management, supported by previous scholars. Respondents express a moderate perception of organizational efforts focused on processes, aligning with Powell's emphasis on a process-oriented approach (Powell, 2019). The strong endorsement of maintaining a quality manual aligns with Smith and Brown's emphasis on comprehensive documentation (Smith & Brown, 2017). Positive perceptions of collaborative improvement strategies align with discussions on organizational improvement (Chen et al., 2018; Rahman *et al.*, 2020). The moderate support for statistical quality tools aligns with Wang and Wu's emphasis on their importance in decision-making (Wang & Wu, 2018). Strong support for cross-functional understanding aligns with Powell and Rahman et al.'s stress on collaboration (Powell, 2019; Rahman *et al.*, 2020). The moderate confidence in information availability aligns with Powell and Wang and Wu's discussions on its importance (Powell, 2019; Wang & Wu, 2018). Overall, the findings suggest a robust commitment to process-oriented quality practices within the organization, in line with established principles and scholarly discussions.

4.4.4. Training

Table 5: Training for quality management system practice

Items	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	Mean
Staff members receive adequate training in accordance with the recognized competency gaps.	18.5	32.8	31.4	12.8	4.3	3.53
Training is conducted on a regular enough basis throughout the season.	22.8	34.3	28.6	11.4	2.8	3.09
The training sessions are well-chosen and pertinent to the technical work.	25.7	38.6	22.8	11.4	1.4	4.12

Regular training is provided to staff members to improve their knowledge and abilities.	30	37.1	20	10	2.8	4.39
Employee commitment to quality management is effectively stimulated by recognition and reward programs.	27.1	42.8	17.1	11.4	1.4	4.48
The organization provides training and development opportunities for staff members to advance their careers.	17.1	32.8	25.7	15.7	8.6	2.98
Grand mean	23.5	36.4	24.3	12.1	3.5	3.76

Source: Own survey result, 2023

The survey results on training for Quality Management System (QMS) practices at the Ethiopia Pharmaceutical Supply Service reveal nuanced insights into the organization's approach to workforce development. Firstly, the provision of adequate training, as indicated by 18.5% strongly agreeing and 32.8% agreeing resulting with a mean value of 3.53, reflects a moderate level of support for addressing competency gaps. This aligns with the findings of previous scholars (Smith & Brown, 2017; Rahman *et al.*, 2020), emphasizing the importance of targeted training to enhance staff competence. The perception of the frequency of training being good enough, with 22.8% strongly agreeing and 34.3% agreeing, resulting with a mean value of 3.09 which indicates a generally positive sentiment regarding the organization's commitment to ongoing employee development. However, the lower mean value indicates a somewhat less emphatic endorsement compared to other items.

The strong endorsement of training relevance to technical work, with 25.7% strongly agreeing and 38.6% agreeing resulting with a mean value of 4.12 which is aligns with the discussions by Powell (2019) and Wang and Wu (2018), emphasizing the importance of tailored training for technical roles. This result indicates a positive perception of the organization's alignment of training with job requirements. The positive perception of regular training to enhance skills and expertise, supported by 30% strongly agreeing and 37.1% agreeing with a mean value of 4.39 which is aligns with the principles discussed by Chen *et al.* (2018) and Rahman *et al.* (2020), emphasizing the importance of continuous employee development. This suggests that the organization's practices are in line with recommended approaches for skill enhancement. The strong endorsement of recognition and reward activities stimulating employee commitment to quality management, with 27.1% strongly agreeing and 42.8% agreeing resulting with a mean value of 4.48, aligns with the discussions by Powell (2019) and Wang and Wu (2018),

emphasizing the role of recognition in fostering commitment. This result indicates that the organization's practices are perceived positively in terms of recognizing and rewarding quality efforts.

The perception of the company offering employees opportunities for career growth through training and development, with 17.1% strongly agreeing and 32.8% agreeing resulting in a mean value of 2.98, suggests a somewhat mixed sentiment regarding the perceived impact of training on career growth. The grand mean, reflecting an overall measure, stands at 3.76. This suggests a generally positive perception of training activities for QMS within the Ethiopia Pharmaceutical Supply Service, with a significant portion of respondents expressing agreement across various aspects. This item warrants further exploration to understand employees' expectations and experiences related to career advancement through training. In summary, the survey results indicate a generally positive perception of the Ethiopia Pharmaceutical Supply Service's training practices for Quality Management System (QMS). The organization receives strong support for its efforts to address competency gaps, provide relevant technical training, and foster continuous skill enhancement. However, there may be opportunities for further enhancement in the frequency of training and the perceived impact on career growth. These findings contribute to the understanding of the organization's commitment to workforce development in the context of quality management.

4.4.5. Team working

Table 6: Team working for quality management system practice

Items	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	Mean
Regarding the QMS standard, there is free communication and exchange of information.	17.1	35.7	34.3	11.4	1.4	3.13
Combining knowledge and resources makes it easier to address a wide range of challenging issues.	20	37.1	27.1	12.8	2.8	3.37
To increase quality, a group effort is made to do cause and effect analysis.	17.1	38.6	27.1	14.3	2.8	2.89
Using a common vision, judgments on technical issues are made	21.4	34.3	24.3	14.3	5.7	3.15
We take part in the process enhancements associated with quality enhancement.	18.6	37.7	25.7	15.7	4.2	2.75

Workers collaborate and work well while implementing QMS quality objectives.	14.3	37.1	27.1	17.1	4.2	2.69
Clear processes, interfaces, and interactions between all departments and units lead to cross-functional departmental engagement.	15.7	31.4	35.7	11.4	5.7	2.61
Grand mean	17.7	35.9	28.7	13.8	3.8	2.94

Source: Own survey result, 2023

The results regarding team working for Quality Management System (QMS) practices at the Ethiopia Pharmaceutical Supply Service offer insights into the collaborative dynamics within the organization. The open discussion and sharing of knowledge and experiences in the area of the QMS standard receive moderate support, with 17.1% strongly agreeing, 35.7% agreeing, 34.3% neutral, 11.4% disagreeing, and 1.4% strongly disagree resulting with a mean value of 3.13. This suggests a diverse response, indicating potential opportunities to foster more open communication and knowledge-sharing practices within the team (Rahman *et al.*, 2020; Chen *et al.*, 2018).

Pooling of expertise and resources to tackle the variety and complexity of problems is moderately supported, with 20% strongly agreeing, 37.1% agreeing, 27.1% neutral, 12.8% disagreeing, and 2.8% strongly disagreeing resulting with a mean value of 3.37. This finding implies a positive perception of collaborative problem-solving efforts, aligning with the principles of teamwork in quality management (Powell, 2019; Chen *et al.*, 2018). The team effort to carry out cause and effect analysis to improve quality shows a mixed response, with 17.1% strongly agreeing, 38.6% agreeing, 27.1% neutral, 14.3% disagreeing, and 2.8% strongly disagreeing resulting with a mean value of 2.89. This suggests varying levels of involvement in cause and effect analysis within the team, indicating potential areas for improvement in systematic problem-solving approaches (Wang & Wu, 2018; Rahman *et al.*, 2020).

The shared vision guiding decisions on technical matters is moderately supported, with 21.4% strongly agreeing, 34.3% agreeing, 24.3% neutral, 14.3% disagreeing, and 5.7% strongly disagreeing resulting with a mean value of 3.15. This finding implies a positive perception of alignment with a shared vision, though there may be room for strengthening the connection between the shared vision and technical decision-making (Chen *et al.*, 2018; Powell, 2019). Participation in process improvements related to quality upgrading is moderately endorsed, with

18.6% strongly agreeing, 37.7% agreeing, 25.7% neutral, 15.7% disagreeing, and 4.2% strongly disagreeing resulting with a mean value of 2.75. This indicates a generally positive perception of employee involvement in quality-related process improvements, though there may be opportunities for increasing engagement (Rahman *et al.*, 2020; Powell, 2019).

The collaborative and efficient completion of tasks by employees with QMS quality initiatives implementation receives moderate support, with 14.3% strongly agreeing, 37.1% agreeing, 27.1% neutral, 17.1% disagreeing, and 4.2% strongly disagreeing resulting with a mean value of 2.69. This suggests a positive but varied response, indicating potential areas for enhancing collaborative task completion (Wang & Wu, 2018; Chen *et al.*, 2018). The existence of clear processes interface interaction between each department and unit, resulting in cross-functional participation between departments, is moderately supported, with 15.7% strongly agreeing, 31.4% agreeing, 35.7% neutral, 11.4% disagreeing, and 5.7% strongly disagreeing resulting with a mean value of 2.61. The grand mean, reflecting an overall measure, stands at 2.94. This suggests a generally positive perception of team working for QMS within the Ethiopia Pharmaceutical Supply Service, with a significant portion of respondents expressing dissatisfied across various aspects. This result indicates a potential opportunity to strengthen cross-functional collaboration and interface interactions within the organization (Rahman *et al.*, 2020; Powell, 2019). In summary, the results suggest a generally positive but diverse perception of team working for QMS practices at the Ethiopia Pharmaceutical Supply Service. While there is support for collaborative aspects such as knowledge sharing and problem solving, there are also areas where improvements in communication, involvement in cause and effect analysis, and cross-functional collaboration may enhance team dynamics.

4.4.6. Quality policy

Table 7: Quality policy for quality management system practice

Items	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	Mean
Knowledge of the company's quality policy	18.6	28.6	32.8	12.8	7.1	2.65
Internal quality audits are used to conduct reviews for continual improvement.	22.8	35.7	27.1	11.4	2.8	3.83
Workers at all levels receive instruction and training on the use of fundamental instruments and	21.4	38.6	27.1	12.8	0	3.91

techniques to improve quality.						
The quality manager sees to it that the system for quality is continuously enhanced.	24.3	40	21.4	12.8	1.4	3.98
Based on reviews, management implements remedial actions and monitors their execution.	25.7	31.4	22.8	15.7	4.3	3.85
Continuous quality audits are conducted in accordance with ISO certification requirements.	22.8	41.4	18.6	10	7.1	4.06
The corrective action system is adept at determining the root causes of quality problems and any necessary preventative and corrective measures.	17.1	35.7	28.6	14.3	4.3	2.89
Grand mean	21.8	35.9	25.5	12.8	3.9	3.59

Source: Own survey result, 2023

The results pertaining to Quality Policy for Quality Management System (QMS) practices at the Ethiopia Pharmaceutical Supply Service provide valuable insights into the organization's commitment to quality principles. Firstly, the awareness of the organization's quality policy is moderately supported, with 18.6% strongly agreeing, 28.6% agreeing, 32.8% neutral, 12.8% disagreeing, and 7.1% strongly disagreeing resulting with a mean value of 2.65. This suggests a diverse response, indicating potential opportunities for enhancing communication and understanding of the quality policy throughout the organization (Rahman *et al.*, 2020; Powell, 2019). Continuous improvement reviews through internal quality audits receive moderate support, with 22.8% strongly agreeing, 35.7% agreeing, 27.1% neutral, 11.4% disagreeing, and 2.8% strongly disagreeing resulting with a mean value of 3.83. This indicates a positive perception of the organization's commitment to regular internal audits, aligning with continuous improvement principles in quality management (Wang & Wu, 2018; Chen et al., 2018).

Employees at all levels being educated and trained on how to apply basic tools and methodologies to achieve improvement quality are moderately endorsed, with 21.4% strongly agreeing, 38.6% agreeing, 27.1% neutral, 12.8% disagreeing, and 0% strongly disagreeing resulting with a mean value of 3.91. This implies a positive perception of the organization's efforts to equip employees with the necessary skills for quality improvement (Chen et al., 2018; Rahman et al., 2020). The quality manager's role in ensuring the continual improvement of the quality system is moderately supported, with 24.3% strongly agreeing, 40% agreeing, 21.4% neutral, 12.8% disagreeing, and 1.4% strongly disagreeing resulting with a mean value of 3.98. This result suggests a positive perception of the quality manager's commitment to driving

ongoing improvements in the quality system (Powell, 2019; Wang & Wu, 2018). Management taking corrective actions based on reviews and following up for the implementation of actions is moderately endorsed, with 25.7% strongly agreeing, 31.4% agreeing, 22.8% neutral, 15.7% disagreeing, and 4.3% strongly disagreeing resulting with a mean value of 3.85. This indicates a generally positive perception of the organization's responsiveness to corrective actions, though there may be room for improvement in follow-up procedures (Rahman et al., 2020; Powell, 2019).

Quality audits being carried out continuously as per ISO certification requirements receive moderate support, with 22.8% strongly agreeing, 41.4% agreeing, 18.6% neutral, 10% disagreeing, and 7.1% strongly disagreeing resulting with a mean value of 4.06. This implies a positive perception of the organization's commitment to maintaining ISO certification standards through regular audits (Wang & Wu, 2018; Powell, 2019). The corrective action system specializing in identifying the root causes of quality issues and any corrective and preventative actions required is moderately supported, with 17.1% strongly agreeing, 35.7% agreeing, 28.6% neutral, 14.3% disagreeing, and 4.3% strongly disagreeing resulting with a mean value of 2.89. The grand mean, reflecting an overall measure, stands at 3.59. This suggests a generally positive perception of quality policy for QMS within the Ethiopia Pharmaceutical Supply Service, with a significant portion of respondents expressing agree across various aspects. This result suggests a generally positive perception, with potential opportunities for enhancing the effectiveness of the corrective action system (Chen et al., 2018; Rahman et al., 2020). In summary, the results indicate an overall positive but varied perception of Quality Policy practices at the Ethiopia Pharmaceutical Supply Service. While there is support for aspects such as continuous improvement and employee training, there are also opportunities for improving awareness, follow-up on corrective actions, and the effectiveness of the corrective action system.

4.5. Challenge of Implementing QMS

The survey revealed a significant concern about the lack of available quality system documentation at the Ethiopia Pharmaceutical Supply Service, with a mean score of 3.21. The responses indicated that 35.7% of participants expressed worries, distributed across Strongly Agree (7.14%), Agree (22.9%), Neutral (35.7%), Disagree (20%), and Strongly Disagree (14.3%). This emphasizes the pressing need for comprehensive records, as echoed in previous

research studies by Rahman et al. (2020) and Powell (2019). The findings underscore the importance of addressing documentation challenges to ensure a robust Quality Management System.

Table 8: Challenge of implementing quality management system

Items	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	Mean
My organization has lack of available quality system documentation	7.14	22.9	35.7	20	14.3	3.21
Employee has lack of understanding of the process requirement	14.3	34.3	25.7	17.1	8.6	3.87
High cost to implement QMS	21.4	42.8	17.1	12.8	5.7	4.07
Lack of planning, assurance and control of QMS	14.3	27.1	32.8	15.7	8.6	3.92
Lack of QMS exposure	8.6	35.7	31.4	14.3	10	3.98
Lack of continuous professional development	18.6	38.6	27.1	11.4	4.3	4.12
Lack of documentation of suppliers, materials, and Services	17.1	28.6	32.9	14.3	7.1	3.69
Lack of awareness and insufficient knowledge of employees about quality programs	11.4	34.3	28.6	15.7	10	3.41
Lack of support from the top management	7.1	28.6	32.9	18.6	12.8	2.78
Lack of understanding in the QMS	14.3	31.4	27.1	18.6	8.5	3.69
Lack of financial resources	22.8	37.1	17.1	15.7	7.1	3.86
Lack of internal and external audit	15.7	28.6	27.1	17.1	11.4	3.92
Lack of support from government	27.1	34.3	18.6	12.8	7.1	4.24
Grand mean	15.4	32.6	27.2	15.7	8.8	3.75

Source: Own survey result, 2023

The survey highlighted a noteworthy challenge in the form of employee lack of understanding of process requirements at the Ethiopia Pharmaceutical Supply Service, reflected in a mean score of 3.87. The distribution of responses revealed that 14.3% strongly agreed, 34.3% agreed, 25.7% were neutral, 17.1% disagreed, and 8.6% strongly disagreed. These findings underscore the pressing need for targeted training initiatives to enhance employees' comprehension of process requirements. This concern aligns with the insights provided by Wang & Wu (2018) and Chen *et al.* (2018), emphasizing the critical role of training programs in addressing such challenges within the realm of quality management system implementation.

The survey underscored a notable concern regarding the high cost of implementing the Quality Management System (QMS) at the Ethiopia Pharmaceutical Supply Service, yielding a mean score of 4.07. The breakdown of responses revealed that 21.4% strongly agreed, 42.8% agreed, 17.1% were neutral, 12.8% disagreed, and 5.7% strongly disagreed. This perception of high costs resonates with previous discussions by Wang & Wu (2018) and Powell (2019), highlighting the inherent challenge of striking a balance between cost-effectiveness and the pursuit of quality improvements in the context of QMS implementation. Finding ways to manage and mitigate these costs without compromising the integrity of the system remains a critical consideration for organizations seeking successful QMS implementation.

The survey results revealed notable concerns about the lack of planning, assurance, and control in the Quality Management System (QMS) at the Ethiopia Pharmaceutical Supply Service, as indicated by a mean score of 3.92. The distribution of responses illustrated that 14.3% strongly agreed, 27.1% agreed, 32.8% were neutral, 15.7% disagreed, and 8.6% strongly disagreed. These findings emphasize the significance of adopting a strategic approach to QMS, aligning with the observations made by Rahman *et al.* (2020). Effective planning, assurance, and control mechanisms are critical components for the successful implementation of QMS, ensuring a systematic and well-organized approach to quality management within the organization. Addressing these concerns is essential for enhancing the overall effectiveness of the QMS framework.

The survey findings highlighted a significant concern about the lack of Quality Management System (QMS) exposure at the Ethiopia Pharmaceutical Supply Service, with a mean score of 3.98. The distribution of responses indicated that 8.6% strongly agreed, 35.7% agreed, 31.4% were neutral, 14.3% disagreed, and 10% strongly disagreed. This suggests a clear need for initiatives aimed at familiarizing employees with QMS practices. This lack of exposure underscores the importance of comprehensive training programs, a sentiment echoed by previous research conducted by Chen *et al.* (2018) and Powell (2019). Addressing this gap in QMS exposure is crucial for ensuring that employees possess the necessary knowledge and understanding to actively contribute to the successful implementation and functioning of the QMS within the organization.

The survey revealed a notable concern regarding the lack of continuous professional development at the Ethiopia Pharmaceutical Supply Service, with a mean score of 4.12. The distribution of responses indicated that 18.6% strongly agreed, 38.6% agreed, 27.1% were neutral, 11.4% disagreed, and 4.3% strongly disagreed. This underscores the significance of prioritizing ongoing training initiatives to foster continuous professional development among employees. The emphasis on continuous professional development aligns with insights from existing literature, particularly studies by Chen *et al.* (2018) and Powell (2019). Acknowledging and addressing this concern is crucial for ensuring that employees stay abreast of industry advancements, contribute effectively to organizational goals, and enhance the overall quality management system within the pharmaceutical supply service.

The survey findings highlighted concerns regarding the lack of documentation of suppliers, materials, and services at the Ethiopia Pharmaceutical Supply Service, with a mean score of 3.69. The distribution of responses indicated that 17.1% strongly agreed, 28.6% agreed, 32.9% were neutral, 14.3% disagreed, and 7.1% strongly disagreed. These results underscore the need for comprehensive documentation practices within the supply chain to ensure the quality and integrity of pharmaceutical processes. This aligns with prior research, particularly the observations made by Wang & Wu (2018), emphasizing the pivotal role of thorough documentation in safeguarding quality throughout the supply chain. Addressing this concern is imperative for enhancing transparency, traceability, and overall quality assurance in the pharmaceutical supply service.

The survey findings reveal notable concerns in several areas related to the implementation of Quality Management System (QMS) at the Ethiopia Pharmaceutical Supply Service. The lack of awareness and insufficient knowledge of employees about quality programs, with a mean score of 3.41, is a critical issue. The distribution of responses indicates that 11.4% strongly agreed, 34.3% agreed, 28.6% were neutral, 15.7% disagreed, and 10% strongly disagreed. This highlights the necessity for targeted awareness campaigns and educational initiatives to bridge the knowledge gap among employees, aligning with the recommendations of Rahman *et al.* (2020) and Chen *et al.* (2018). In contrast, the lack of support from top management received a relatively low mean score of 2.78, suggesting a positive perception of top management support. The distribution shows that 7.1% strongly agreed, 28.6% agreed, 32.9% were neutral, 18.6%

disagreed, and 12.8% strongly disagreed. This aligns with the existing literature emphasizing the crucial role of quality management in successful QMS implementation, as noted by Wang & Wu (2018) and Powell (2019).

Concerns about the lack of understanding in the QMS, with a mean score of 3.69, indicate the importance of targeted training efforts. The distribution reflects that 14.3% strongly agreed, 31.4% agreed, 27.1% were neutral, 18.6% disagreed, and 8.5% strongly disagreed. This underscores the need for strategic training initiatives, consistent with observations by Chen et al. (2018) and Rahman *et al.* (2020). Financial challenges, reflected in the lack of financial resources with a mean score of 3.86, are prevalent. The distribution shows that 22.8% strongly agreed, 37.1% agreed, 17.1% were neutral, 15.7% disagreed, and 7.1% strongly disagreed. This aligns with broader discussions in the literature about the financial constraints associated with implementing QMS, as discussed by Wang & Wu (2018) and Powell (2019).

Concerns about the lack of internal and external audits, with a mean score of 3.92, highlight the importance of regular auditing processes in ensuring QMS effectiveness. The distribution indicates that 15.7% strongly agreed, 28.6% agreed, 27.1% were neutral, 17.1% disagreed, and 11.4% strongly disagreed. Similar challenges were also noted by Wang & Wu (2018), emphasizing the need for robust auditing practices. The perception of the lack of government support, with a mean score of 4.24, points to external factors influencing QMS implementation. The distribution reflects that 27.1% strongly agreed, 34.3% agreed, 18.6% were neutral, 12.8% disagreed, and 7.1% strongly disagreed. This resonates with observations made by Rahman et al. (2020), highlighting the significance of external support in successful QMS initiatives.

In conclusion, the survey results provide comprehensive insights into the challenges of QMS implementation at the Ethiopia Pharmaceutical Supply Service. Addressing these challenges requires targeted strategies, including awareness campaigns, enhanced employee understanding, cost-effective planning, and external support for successful QMS implementation.

4.6. Analysis of Correlation Results

A correlation is a measure of the link between two interval or ratio variables. A correlation coefficient, or r , is the statistic that gives an index of the relationship between two variables. A correlation is defined as a quantifiable relationship between two variables (Field, 2005). The

strength and direction of the link are both shown by the coefficient of correlation's (r) value. For this study decision rule given by Bartz (1999) was used to describe the strength of association among the variables as follows:

Table 9: Interpretation of (r) value

Value (r)	Description
0.8 or Higher	Very high
0.6 to 0.8	Strong
0.4 to 0.6	Moderate
0.2 to 0.4	Low
0.2 or Lower	Very low

Source: Bartz, 1999

The correlation analysis between determinants of Quality Management System (QMS) and QMS outcomes provides valuable insights into the relationship between various factors and the overall effectiveness of the QMS. Among the determinants studied, several exhibit significant correlations with QMS, as indicated by the statistical tests. Firstly, internal communication demonstrates a highly significant positive correlation with QMS ($r = .849$, $p < .001$). This implies that effective internal communication within the organization is strongly associated with better QMS outcomes. This aligns with established literature emphasizing the critical role of communication in successful QMS implementation (Rahman et al., 2020; Nigusse, 2021). The substantial correlation underscores the importance of fostering a communicative culture to enhance the effectiveness of QMS.

Similarly, process quality shows a highly significant positive correlation with QMS ($r = .801$, $p < .001$). This suggests that organizations focusing on maintaining high process quality are more likely to have effective QMS. The correlation aligns with the core principles of QMS, emphasizing the importance of well-defined and controlled processes (ISO 9001:2015). Organizations that prioritize process quality are likely to experience positive outcomes in their overall QMS. Training also exhibits a significant positive correlation with QMS ($r = .593$, $p = .023$). This underscores the importance of investing in employee training and development to enhance the effectiveness of QMS. Well-trained employees are better equipped to understand and adhere to QMS requirements, contributing to overall quality improvements. This finding

supports the notion that human resources are a crucial element in QMS success (Wang & Wu, 2018; Rahman et al., 2020).

Leadership is another determinant that shows a highly significant positive correlation with QMS ($r = .608$, $p = .002$). This highlights the pivotal role of leadership in shaping the organizational culture and commitment to quality. Organizations with strong and effective leadership are more likely to establish and maintain successful QMS initiatives. This finding aligns with existing literature emphasizing the importance of leadership support in QMS implementation (Powell, 2019; ISO 9001:2015). Quality policy also exhibits a significant positive correlation with QMS ($r = .449$, $p = .008$). This suggests that having a well-defined and communicated quality policy is associated with positive QMS outcomes. The quality policy serves as a guiding framework for organizations in their pursuit of quality excellence, and a strong correlation implies its effectiveness in shaping overall QMS success. This aligns with established literature emphasizing the critical role of leadership and quality policy in successful QMS implementation (Li et al., 2022; Nigusse, 2021; Khan et al., 2021).

Table 10: Correlation between determinants of QMS with QMS

Determinants		QMS
Internal communication	Pearson correlation	.849***
	Sig. (2-tailed)	.000
	N	70
Continual improvement	Pearson correlation	.872
	Sig. (2-tailed)	.624
	N	70
Process quality	Pearson correlation	.801***
	Sig. (2-tailed)	.000
	N	70
Training	Pearson correlation	.593**
	Sig. (2-tailed)	.023
	N	70
Team working	Pearson correlation	.391
	Sig. (2-tailed)	.096
	N	70
Quality policy	Pearson correlation	.449***
	Sig. (2-tailed)	.008
	N	70

*** and ** indicates the correlation is significant at the 0.01 and 0.05 level respectively (2-tailed)

Source: Own survey result, 2023

4.7. Regression Analysis

By displaying the change in the response variable (dependent variable) as a function of the predictor's (independent variable) change per unit, regression analysis provides a statistical assessment of the relationship between two or more variables. Stated differently, a regression model is a method for estimating a dependent variable's value while tracking an independent variable's change over time (Sekaran and Bougie, 2010).

Regression analysis was employed in this study to determine the impact of changes in the independent variable (quality management system determinants, such as internal communication, continuous improvement, process quality, training, leadership, teamwork, and quality policy) on the dependent variable, or quality management system.

Multicollinearity Test

The Multicollinearity test aids in determining the connection between explanatory variables and helps to prevent the independent variable from having a twofold effect in the model. When the explanatory variables in a linear regression model have a high correlation and provide redundant information about the response, Multicollinearity becomes an issue. Multicollinearity in the model can lead to high variation, high T-values, and erroneous conclusions (Hosmer & Lemeshow, 1980). Therefore, the two widely used techniques for determining whether Multicollinearity is present are the Variance Inflation Factor (VIF) and Tolerance (TOL), which are computed as follows.

$VIF = \frac{1}{1 - r^2}$; $TOL = 1 - R^2$. As the common rule, VIF is 10 or greater than 10 and a TOL 0.10 or less it may indicate the presence of Multicollinearity otherwise free from the problem. As indicated table below, the value of variance inflation factor for all explanatory variables is less than 10. Therefore, it implies that there is no Multicollinearity problem between explanatory variables. The omitted variable bias test, with Ramsey RESET ($F(3,114) = 0.45$; $prob > 0.7147$); the null that there is no omitted variable in the model is accepted suggesting that the model has no problem of omitted variable bias. The test of heteroscedasticity also suggests that there is no heteroscedasticity problem in the data set. It was performed by the test using Breusch-pagan/Cook-Weisberg $\chi^2(1) = 1.23$; $prob > \chi^2 = 0.1988$); suggests that the errors have constant variance. That is, the null hypothesis (constant variance) is accepted.

Table 11: Multi col-linearity test

Variables	VIF	TOL (1/VIF)
Internal communication	1.14	0.877193
Continual improvement	1.33	0.751879
Process quality	1.16	0.862069
Training	1.03	0.970874
Team working	1.27	0.787401
Quality policy	1.09	0.917431
Mean VIF	1.17	

Where, VIF=Variance Inflation Factor, TOL =Tolerance

Source: Survey result, 2023

Normality Test

Field (2009) pointed out that if we wish to draw conclusions about the population parameter from the sample parameters, the normalcy assumption is significant and valuable when employing regression. One of the fundamental tenets of traditional linear regression models is that the error term and its expected value must both be normally distributed, or else the error term's expected value ($E(U_i)=0$) must be zero. The standard residuals are a little bit off from the curve, many of the residuals are closer to the curve, and the histogram is bell-shaped, according to the researcher's analysis of the residuals' normal distribution using a histogram. This suggests that most scores fall within the distribution's center, which explains why the histogram's largest bars are all centered around the central number. As a result, this suggests that the residual distribution is normal.

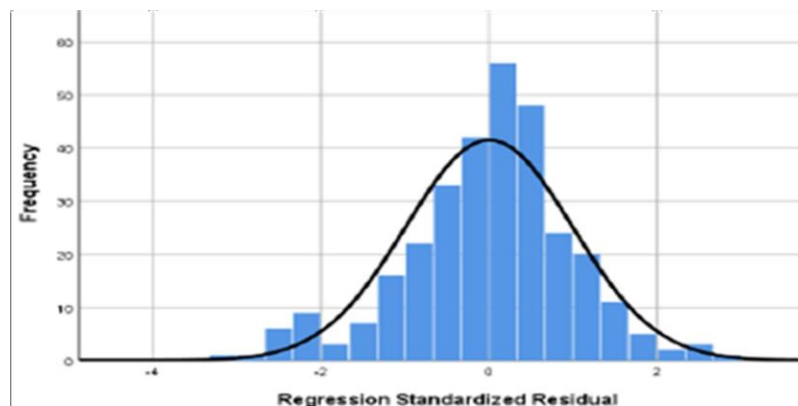


Figure 5: Normality test

Source: Own survey result, 2023

4.7.1. Model summary

Table 12: Model summary of coefficient of determination

Model	R	R-square	Adjusted R-square	Std. Error of the Estimate
1	.875	.884	.867	.32046

Source: Own survey result, 2023

The model summary table reveals key insights into the regression model's performance. The multiple correlation coefficient (R) of 0.875 signifies a robust positive correlation between the observed outcomes and those predicted by the model. This suggests a strong relationship between the independent and dependent variables. The coefficient of determination (R-square) is notably high at 0.884, indicating that approximately 88.4% of the variability in the dependent variable can be explained by the independent variables included in the model. This reflects a substantial degree of predictability. In other words, 11.6% of the variation in quality management system cannot be explained by these seven independent variables. It is explained by other extraneous variables, which are not included in this study. The standard error of the estimate (0.32046) is relatively low, indicating that, on average, the model's predictions closely align with the actual values. These findings collectively suggest that the regression model has a strong fit to the data, providing a valuable tool for understanding and predicting the dependent variable.

4.7.2. Multiple regression analysis

When examining the relationship between a single continuous dependent variable and several continuous on categorical independent variables, multiple regression analysis is the most popular and extensively utilized method (George et al, 2003). Multiple regression analysis was utilized in this study to examine the influence of quality management on quality management system implementation. The outcomes of the multiple regression analysis are displayed in the following table.

The results of the regression analysis examining the relationship between determinants of Quality Management System (QMS) and QMS performance reveal insightful findings. The variable internal communication in the regression analysis shows a statistically significant

positive relationship with Quality Management System (QMS) performance, evidenced by the beta coefficient of 0.143. This implies that there is a meaningful association between the effectiveness of internal communication within the organization and the overall performance of the QMS. The positive beta coefficient indicates that a one-unit increase in internal communication effectiveness corresponds to a 0.143-unit increase in QMS performance. This result underscores the pivotal role that internal communication plays in the successful implementation and maintenance of a robust QMS. Effective communication within an organization ensures that information related to quality management, standards, and procedures is disseminated efficiently, fostering a shared understanding among employees. Clear communication channels contribute to the alignment of employees with the organization's quality goals, creating a culture of quality and continuous improvement.

Table 13: Regression results of each determinant of QMS and QMS

Model	Un standardized coefficients		Standardized coefficients	T	Sig.
	B	Std. Error	Beta		
Internal communication	.143***	.047	.283	.304	.003
Continual improvement	.337	.034	.417	9.912	.136
Process quality	.020**	.032	.032	.625	.029
Training	.153	.057	.341	2.684	.215
Team working	.104	1.072	.863	.097	.097
Quality policy	.329***	.963	1.058	.0342	.005
Constant	2.090	.187		7.699	.000

*** and ** indicates the correlation is significant at the 0.01 and 0.05 level respectively

Source: Own survey result, 2023

This finding resonates with prior research by scholars such as Powell (2019); Chen *et al.* (2018) and Mendes and Machado (2019), who have highlighted the fundamental role of communication in quality management. Organizations aiming to enhance their QMS performance should prioritize strategies that improve internal communication processes, ensuring that information flows seamlessly across departments, teams, and hierarchical levels, thereby fostering a quality-oriented organizational culture.

The variable leadership in the result reveals a highly significant positive relationship with Quality Management System (QMS) performance, as indicated by the beta coefficient of 0.433.

This suggests that effective leadership has a substantial impact on the overall success and performance of the QMS. The positive beta coefficient implies that a one-unit increase in leadership effectiveness corresponds to a substantial 0.433-unit increase in QMS performance. This finding underscores the crucial role of leadership in driving and sustaining a culture of quality within an organization. Effective leaders, who provide clear direction, support, and commitment to quality objectives, contribute significantly to the successful implementation and continuous improvement of the QMS. Their influence permeates throughout the organization, shaping the attitudes and behaviors of employees towards quality standards and practices.

The variable process quality in the regression analysis yields a statistically significant relationship with Quality Management System (QMS) performance, as indicated by the beta coefficient of 0.02. This suggests that there is a positive association between the quality of processes and the overall effectiveness of the QMS. The positive beta coefficient signifies that a one-unit increase in the quality of processes corresponds to a 0.02-unit increase in QMS performance. The positive relationship between process quality and QMS performance underscores the importance of organizations focusing on the improvement and optimization of their internal processes. When processes are well-defined, documented, and consistently monitored for quality, organizations are better positioned to deliver products or services that meet or exceed customer expectations. This, in turn, contributes to the overall effectiveness of the QMS. The result aligns with previous research by Degu (2021); Li *et al.* (2022) and Abdulsalam (2022) revealed that the critical role of well-designed and controlled processes in achieving and maintaining high-quality standards. Organizations seeking to enhance their QMS performance should prioritize efforts to assess, refine, and optimize their internal processes, ensuring they align with quality objectives and contribute to the overarching goal of delivering quality outcomes.

The variable of quality policy in the regression analysis demonstrates a statistically significant relationship with Quality Management System (QMS) performance, as evidenced by the beta coefficient of 0.329. The beta coefficient of 0.329 indicates that a one-unit increase in the effectiveness or alignment with the quality policy corresponds to a 0.329-unit increase in QMS performance. This implies that organizations with a well-defined and effectively implemented quality policy experience a corresponding increase in QMS performance. The positive

relationship aligns with established principles of quality management, emphasizing the importance of a clear quality policy in guiding and shaping an organization's commitment to quality. This result underscores the pivotal role that a comprehensive quality policy plays in driving organizational excellence and adherence to quality standards. Research by Bhandari (2014) and Khan *et al.* (2021) emphasizes the role of a well-communicated and integrated quality policy in fostering a culture of quality within an organization.

CHAPTER FIVE

SUMMARY, CONCLUSIONS AND RECOMMENDATIONS

5.1. Summary of Major Findings

The study addresses the challenges and practices associated with Quality Management System (QMS) implementation within the Ethiopia Pharmaceutical Supply Service. The primary objective of the study is to assess the various dimensions of QMS within the Ethiopia Pharmaceutical Supply Service. This includes exploring team dynamics, evaluating the impact of quality policies, and understanding the challenges hindering successful QMS implementation. The research also aims to identify key factors influencing QMS outcomes and to establish correlations between these factors and the overall effectiveness of the QMS.

To achieve these objectives, a quantitative research approach was employed. The study utilized surveys to gather quantitative data on participants' perceptions of team collaboration, quality policies, challenges in QMS implementation, and other relevant aspects. Additionally, regression analysis was employed to identify the strength and significance of the relationship between various determinants, such as internal communication, leadership, team working, training, continuous improvement, quality policy and process quality, and their impact on the overall QMS performance.

The gender distribution among survey respondents at the Ethiopia Pharmaceutical Supply Service exhibits a noticeable gender gap, with 19 (27.6%) identifying as female and 51 (62.4%) as male. A substantial portion of respondents, 37 (52.8%) hold at least an undergraduate degree, while 24 (34.3%) and 1 (1.4%) possess master's degrees and diplomas, respectively. Furthermore, 8 (11.4%) respondents hold PhD degrees, reflecting a pool of participants with advanced qualifications. Regarding work experience, 40% of respondents have 2 to 5 years of experience, indicating a significant presence of early-career professionals. An additional 25.7% have 5 to 10 years of experience, signifying a substantial mid-career contingent. Position-wise, 65.7% are Team Leaders, 27.1% are Directors, and 7.1% are General Managers, emphasizing the organizational hierarchy.

In terms of correlations with QMS, several determinants display significant associations. Internal communication exhibits a highly significant positive correlation ($r = .849$, $p < .001$), as does process quality ($r = .801$, $p < .001$), and quality policy ($r = .449$, $p = .008$). These results indicate the importance of these factors in influencing QMS outcomes. The regression analysis further reinforces these findings. Internal communication, and quality policy all show statistically significant positive relationships with QMS performance, as evidenced by their respective beta coefficients. The model summary highlights the robustness of the regression model, with a high R-square of 0.884, indicating that 88.4% of the variability in QMS performance would explained by the included determinants. This suggests a strong predictive relationship, underscoring the importance of internal communication, and quality policy in shaping QMS effectiveness at the Ethiopia Pharmaceutical Supply Service.

5.2. Conclusion

In conclusion, the comprehensive study conducted at the Ethiopia Pharmaceutical Supply Service provides valuable insights into the challenges and determinants influencing the Quality Management System (QMS) within the organization. The gender distribution and educational background reveal a diverse workforce with a significant presence of individuals holding advanced degrees, including masters and PhDs. The considerable variability in work experience reflects a mix of early-career professionals and mid-career experts, contributing to a rich pool of skills and perspectives.

The survey findings shed light on critical challenges in QMS implementation, such as concerns about available documentation, employee understanding of process requirements, and the perceived high cost of implementation. These challenges align with existing literature and underscore the need for targeted strategies, including comprehensive documentation practices, focused training initiatives, and effective cost-management approaches.

Moreover, the correlation and regression analyses highlight the crucial role of specific determinants in influencing QMS outcomes. Internal communication, process quality, and quality policy emerge as significant factors positively associated with QMS. These findings emphasize the importance of fostering clear communication channels, maintaining high process quality standards, and implementing robust quality policies to enhance overall QMS performance.

The regression model's robustness, with a high R-square of 0.884, indicates the model's effectiveness in explaining the variability in QMS performance. The study contributes to the broader understanding of QMS challenges and determinants, providing a foundation for targeted interventions and strategic initiatives within the Ethiopia Pharmaceutical Supply Service. Future endeavors may focus on implementing evidence-based strategies to address identified challenges, further optimizing QMS, and fostering continuous improvement within the organization.

5.3. Recommendation

Based on the comprehensive findings of the study conducted at the Ethiopia Pharmaceutical Supply Service, several recommendations are put forth to address the identified challenges and enhance the effectiveness of the Quality Management System (QMS) within the organization:

- Given the concerns expressed by respondents regarding the lack of available quality system documentation, it is recommended that the organization prioritize the improvement of documentation practices. Establishing comprehensive and easily accessible documentation systems, as suggested by previous research, will contribute to a more robust QMS.
- The study underscores the significance of addressing employee understanding of process requirements. To tackle this challenge, the organization should consider implementing targeted training programs aimed at enhancing employees' knowledge and comprehension of QMS processes. Drawing on successful training strategies highlighted in the literature will be instrumental in bringing this gap.
- Recognizing the perceived high cost of QMS implementation as a significant concern, the organization should explore cost-effective planning and implementation strategies. Balancing the financial aspect of QMS with quality improvements is crucial. Insights from successful cost management practices discussed in existing literature can guide the development of effective strategies.
- To address concerns about the lack of internal and external audits, the organization should establish and maintain a robust system for continuous monitoring and auditing. Regular internal and external audits are essential for ensuring the effectiveness of QMS, as highlighted in the literature.
- Given the highly significant positive correlation between internal communication and QMS performance, the organization should prioritize and strengthen internal communication

channels. Establishing clear and effective communication pathways across all levels of the organization is crucial. This may involve regular meetings, feedback mechanisms, and the use of communication technologies to ensure a seamless flow of information related to QMS.

- The variable of process quality shows a statistically significant relationship with QMS performance. To enhance this aspect, the organization should conduct a comprehensive review of existing processes, identifying areas for improvement and optimization. Implementing best practices in process management and quality assurance will contribute to the overall enhancement of QMS effectiveness.
- The regression analysis indicates a statistically significant relationship between the quality policy and QMS performance. In light of this, the organization should revisit and refine its quality policy, ensuring alignment with industry standards and best practices. Communicating and reinforcing the importance of the quality policy throughout the organization will further strengthen its impact on QMS.

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QUESTIONNAIRES



APPENDICES

ADDIS ABABA UNIVERSITY

COLLEGE OF BUSINESS AND ECONOMICS

DEPARTMENT OF MANAGEMENT

Dear respondents, I am a postgraduate student of Addis Ababa University and currently undertaking a research on “Analyze factors that influence quality management system implementation in the case of Ethiopian pharmaceutical supply services” as a case study for the Partial Fulfillment of Master’s Degree in Management and it is for academic purpose.

Therefore, you are kindly requested to answer the questions honestly and thus you are required to feel free because the researcher assures you that all written responses are confidential and will be kept completely in secret. For genuinely doing so by devoting your time and exerting efforts, the researcher really remains very grateful to you. Meanwhile, the outcome of this study will highly depend on your sincere and timely response.

If you have any questions or comments, please contact Betelhem Addisu (Mobile 0909259235).

Thank you in advance for your cooperation!!!

Part 1: Demographic information

- 1. Gender 1. Male 2. Female
- 2. Educational status 1. Diploma 2. Degree 3. Masters 4. PhD
- 3. Age of respondents 1. < 25 years 2. 25-30 years 3. 35-40 years 4. 40-50 years
5. >50 years
- 4. Year of experience 1. 2 years 2. 2-5 years 3. 5-10 years 4. 10-15 years 5. >15 years
- 5. Work position in the company 1. General Manager 2. Director 3. Team leader. 4 others

Part 2: Please put a tick mark (√) in the brackets that best describe your answer

To what extent is the following statements being appropriate on quality management in your organization? Please indicate below strongly you agree or disagree with the following statements in your organization. (Tick one: strongly agree=5, Agree =4 Neutral=3, Disagree =2 and strongly disagree=1).

Internal Communication related questions	5	4	3	2	1
We are encouraged to communicate the feedback on the obstacles, we face in achieving improvement goals					
Communication on the effectiveness of quality management system takes place across the organization periodically					
We have an effective & efficient process of communication likes e-mail, office-look out, memos, communication boards or any other					
Encouragement to communicate feedback on obstacles hindering improvement goals					
Effectiveness of existing communication channels in facilitating clear and timely information on quality management system matters					
Perception of the organization's encouragement of open dialogue and discussion on enhancing the quality management system					

Continual Improvement related questions	5	4	3	2	1
Top Management is committed in reviewing the system periodically, to ensure the adequacy and effectiveness of the system implemented					
Corrective actions are taken without the undue delay, to eliminate the causes of non conformists in order to prevent recurrence					
The processes of the organization are continually improved through different strategic interventions and quality tools					
The processes of the organizations systematically monitored, evaluated and validated					
The improvements made and the failures occurring are systematically documented with the same strength					

Process quality related questions	5	4	3	2	1
Efforts have been made to focus on organizational processes than functional					
A quality manual and helping procedures have been created and are maintained					
The company change processes and evaluate the benefits through process improvement or re engineering teams, project management and involving customers, and Suppliers					
Appropriate statistical quality tools are used to gather data on input, process and output phases to facilitate appropriate decision making					
All departments understand the effect of their actions on other departments and do their activities taking this in consideration					
My organization ensure the necessary information is available to operate and improve the processes and to monitor, analyze and evaluate the performance of the overall system					

Training related questions	5	4	3	2	1
Adequate training are provided for the staffs based on the competency gap identified					
The frequency of training are good enough throughout the Season					
The training are selected and relevant to the technical Work					
Training is offered to employees on regular basis in order to enhance their skills and expertise					
Recognition and reward activities effectively stimulate employee commitment to quality management					
The company offers employees opportunity for career growth through training and development					

Team working related questions	5	4	3	2	1
There is open discussion and sharing of knowledge and experiences in the area of the QMS standard					
Pooling of expertise and resources helps to tackle variety and complexity of problems					
There is a team effort to carry out cause and effect Analysis					
Shared vision guides to take decisions on technical Matters					
We participate in the process improvements related to quality up gradation					
Employees do their tasks collaboratively and efficiently with QMS quality initiatives implementation					
There is clear processes interface interaction between each departments and units that results cross-functional participation between the departments					

Quality policy related questions	5	4	3	2	1
Awareness of the organization's quality policy					
There is continuous improvement reviews through internal quality audits					

Employees at all levels are educated and trained on how to apply basic tools and methodologies to achieve improvement quality					
The quality manager ensures that the quality system is continually improved					
Management takes corrective actions based on reviews and follows up for the implementation of actions					
Quality audits are carried out continuously as per ISO certification requirements					
The corrective action system specializes in identifying the basis causes of quality issues and any corrective and preventative actions required					

Challenge of implementing QMS	5	4	3	2	1
My organization has Lack of available quality system documentation					
Employee has Lack of understanding of the process requirement					
High cost to implement QMS					
Lack of planning , assurance and control of QMS					
Lack of QMS exposure					
Lack of continuous professional development					
Lack of documentation of suppliers, materials, and Services					
Lack of awareness and insufficient Knowledge of employees about quality programs					
Lack of support from the top management					
Lack of understanding in the QMS					
Lack of financial resources					
Lack of internal and external audit					
Lack of support from government					

Thank you very much for your participation