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INSTITUTE OF QUALITY AND PRODUCTIVITY MANAGEMENT

ASSESSMENT OF QUALITY MANAGEMENT SYSTEM PRACTICES IN ETHIOPIA PHARMACEUTICALS MANUFACTURING S.C (EPHARM)

BY:

BERHANU DEGU (BSc)

June, 2021

Addis Ababa, Ethiopia

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A THESIS SUBMITTED TO ST. MARY'S UNIVERSITY, SCHOOL OF THE GRADUATE STUDIES, INSTITUTE OF QUALITY AND PRODUCTIVITY MANAGEMENT, IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTERS OF SCIENCE IN QUALITY AND PRODUCTIVITY MANAGEMENT.

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DECLARATION

I, the undersigned, declare that this thesis is my original work, prepared under the guidance of Melaku Girma (PhD). All sources of material used for the thesis have been duly acknowledged. I further confirm that the thesis has not been submitted either in part or in full to any other higher learning institutions for the purpose of earning any degree.

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Name: BERHANU DEGU

Date: June, 2021

Endorsement

This thesis has been submitted to St. Mary's University, School of Graduate studies for examination with my approval as a university advisor.

_____ _____

Advisor Signature

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Acronyms

EPHARM ---------- Ethiopian Pharmaceuticals Manufacturing

GMP ---------- Good Manufacturing Practices

ISO ---------- International Organization for Standardization

QMS ---------- Quality Management System

SPSS---------- Statistical Package for Social Science

TQM---------- Total Quality Management System

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ABSTRACT

This research has been conducted to assess the practices and implementation of Quality Management System in the case company Ethiopian Pharmaceuticals Manufacturing S.C. (EPHARM) which is certified ISO-9001-2015 Quality management System. A descriptive research approach was employed using a questionnaire and interview to get primary data from employees of EPHARM S.C. The data were collected with a response rate of 100% from the distributed sixty seven (67) questionnaires and analyzed using descriptive statistics focusing on the mean, standard deviation and percentages, which is calculated using statistical package for the social sciences (SPSS) version 26. The validity of the instrument was checked and internal consistency of the instrument was measured using Cronbach's Alpha and the result was greater than 0.7, which signifies that reliability of data was good. The results of this study shows that majority of the employees agreed that EPHARM is practicing all the seven QMS principles. The research work has identified lack of employee's commitment, difficulty of performing internal auditing, lack of financial resources, in sufficient training about QMS implementation, organizational structure limitation and documentation problem as a challenge to implementation of Quality Management System in the Organization. The benefits of the EPHARM from implementation of QMS practices also listed in this study such as, improvement in productivity, improvement in efficiency, reduction in cost and waste, competitive advantage, increase in sale and market share, good customer relations, increase customer satisfaction. This study finally recommended that all potential problems identified in the implementation of QMS to be given a due attention and appropriate preventive and corrective actions planned ahead during the planning and development stage of the system.

Key words: Quality Management System, assessment, ISO-9001-2015

CHAPTER ONE

1. INTRODUCTION

This chapter consists of background of the study, statement of the problem, research questions, general and specific objective of the study, significance of the study, limitation of the study, scope of the study, organization of the study and operational definition.

1.1Back ground of the Study

Quality is a widely used concept that has become one of the important agendas in most organizations. This specifically for them to compete and face with the challenging forces of globalization. Global competition demands organizations across borders to initiate efforts in order to ensure their products and services achieve the highest standard of quality. Furthermore to establish, implement, and maintain a system that allows the delivery of products with the quality attributes appropriate to meet the needs of patients, health care professionals, regulatory authorities(including compliance with approved regulatory filing) and other internal and external customers (Samrinah,2011).

Pharmaceutical industry is a very vital segment of the our health care system, which deals with manufacturing and marketing of pharmaceuticals and biological products and medicinal devices, used for the diagnosis and treatment of diseases as well as conducts research for development of new products for human welfare. So maintenance of quality is very necessary to prevent health hazard as many pharmaceutical products are lifesaving products, so if products are not of appropriate quality then they may result in severe adverse effects or even death of the consumer or patient (Ashish and others, 2014).

The term quality is used very commonly, this term looks to be very easy but it is difficult to define quality precisely. As per ISO, it is defined as “Degree to which a set of inherent characteristics fulfills requirements”. Degree refers to a level to which a product or service satisfies. So, depending upon the level of satisfaction, a product may be termed as excellent, good or poor quality product. Inherent characteristic are those features that are a part of the product and are responsible to achieve satisfaction. Requirements refer to the needs of customer, needs of organization & those of other interested parties (Ashish and others, 2014).

Many quality management philosophies, methodologies, concepts and practices were created by quality gurus to manage quality of product and service in an organization. These practices have evolved over time to create sustainable sources of competitive advantage. New challenges faced by managers are addressed to improve organization's performance and future competition. In the total quality management form, it is a structured management system adopted at every management levels that focused on ongoing effort to provide product or service. Its integration with the business plan of the organization can exact positive influence on customer satisfaction and organizational performance (Ng Kim-Soon, 2012).

In today's highly competitive business environment, forward-thinking organizations are more committed than ever to continue refining their processes and procedures to improve their products and services. The development and implementation of a quality management system (QMS) is perhaps the best way to demonstrate this commitment (Rivera, 2017).

A quality management system provides organizations with the opportunity to raise their competitive position by focusing on improvement efforts on those operational areas in the most in need of change. This in turn streamlines operations, increases efficiency and enables organizations to provide quality products and more effective services to their customers (Rivera, 2017).

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

The ISO 9000 family addresses various issues of quality management and holds some of ISO's best known standards. The standards provide guidance and tools for companies and organizations who want to ensure that their products and services to consistently meet customer's requirements, and that quality is consistently improved (ISO, 2017).

Effective Quality Management System focuses on systematically developing and communicating a customer-focused mission, strategies and action plans; listening and responding to the customer' needs and expectations; empowering employees to

continuously improve and increase their satisfaction with their work processes and environment; and gathering and analyzing key performance indicators to improve organizational and process results (Daniel Amare, 2010).

The Ethiopian pharmaceutical industries are identified as one of the eight priority subsector for medium and large industries development in the Growth and Transformation plan (MOFED, 2010). The growth in the manufacturing and service industry are also expected to be high. The government is providing special emphasis and packages of incentives for manufacturing firms engaged in strategic sectors like pharmaceuticals. It is assumed that several national and foreign investors will be attracted by the incentive and the number of pharmaceutical manufacturing firms will grow. As the number increases companies will start to compete locally and with companies in the international market. Companies with better quality products and services, among others, will survive the competition. In addition to the supply of their pharmaceutical products to the local public, these industries will need to gear their orientation to the external market in view of increasing market share and revenue (Pharmanet, 2014).

This move often faces stiff competition both locally and with generic and brand manufactures exporting to, and selling their products in Ethiopia. In light of the stiff competition and as rule of survival pharmaceutical companies should focus delivering quality products which can satisfy the needs and expectation of users, prescribers and middle stake holders like distributors and retailers. Both doctors and mid-to-high-income patients prefer to use brand-name drugs because they are thought to offer the guarantee of better quality and higher efficiency than those of similar locally manufactured or imported generic options. However as the price of branded products usually tends to be high shifting to the generic ones will be inevitable. To capture this opportunity of shift towards them, generic manufacturers have to ensure to the concerned stakeholders that their products are to the required quality standards and this would entail the adoption of a certain quality management system (FMHACA, 2014).

This study demonstrate principles of Quality Management Systems and techniques which are considered practical in Ethiopian Pharmaceuticals Manufacturing S.C. The study examines the effectiveness of current quality management activities and identifies quality management implementation challenges.

1.2 Statement of the problem

One of major wrong practice made by organizations is letting only the production department to take the responsibility for producing quality products. However, many scholars believe that quality should not be the obligation of the production process only. All members of the organization should be involved to bring quality. Okland (2004) for instance, stated that traditionally, quality has been regarded as the responsibility of quality assurance and quality control departments and still it has not yet been recognized in some organizations that many quality problems originate in the commercial, service or administrative areas. Good quality management is the act of overseeing all activities and tasks that must be accomplished to maintain a desired level of excellence. This includes the determination of a quality policy, creating and implementing quality planning and assurance, and quality control and quality improvement (Barone, 2019).

QMS is a continuing process of improvement involving all aspects of the business. The wider aim of QMS is to prevent mistakes before they happen. These three phases of QMS are as Quality Planning, Quality Control and Quality Assurance. It is a process to follow in reducing errors in work. The keys to continuous improvement are commitment and teamwork. This commitment must start with the chief executive officer and filter throughout the entire organization. Quality Management System will not work without a total commitment and involvement from top management. Manager, in all areas of the company, must provide employees with the proper training, tools, equipment, and work place environment to accomplish the assigned task (Kaziliunas and others. 2010).

According to Osman (2016) the most important barriers facing QMS in an organization are insufficient resources allocation, lack of management commitment, lack employee's commitment and factors related to organization's internal systems such as inherited deficiencies in planning and preparatory phase, the nature and complexity of the project, lack of a total change in organizational focus and also lack of new strategies that produced improving in operational processes at all levels. Husseinet and others (2017) identified seven main challenging factors in the implementation of QMS. The seven identified factors are lack of awareness, resistance to change, the existence of accreditation, commitment of top management, time management, and resource

availability. 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.

There are many pharmaceutical manufacturing companies found in Ethiopia. Although all those pharmaceuticals manufacturing companies has to operate as per the Good Manufacturing Practice (GMP) to ensure the quality of products, little or no information is available as to why the pharmaceutical industry is not opting to implement the ISO QMS and what benefits were obtained and challenges faced by those companies which have undergone the implementation and certifications processes. This research basically tries to answer the above mentioned questions.

Daniel (2010) identified major problems that challenged the implementation of Quality Management System to be lack of top management commitment to support the system, lack of employee experience on implementation of such system in the country due to its recent introduction, size of firms and the old mentality of doing things and the belief that this system by itself is a change initiative. Similar studies in the pharmaceutical industry are lacking in Ethiopia.

Regardless of its broadly asserted importance in improving product quality and organizational performance, the status of QMS in the pharmaceutical sector in Ethiopia is very low. Little or no information is available on and what were the practices, benefits obtained and challenges faced by those companies which have undergone the implementation and certifications processes of ISO QMS.

This study focuses on pharmaceuticals industry, EPARM which have implemented QMS but still a number of customers complain on quality and delivery time. The company has a primary concern to satisfy the pressing demands for high quality drugs or medicines on a timely basis. But the company experiences a number of complaints from its customer's in terms of Quality. However, with limited scope, the practice of QMS in EPHARM will be assessed with internal customers in focus.

1.3 Basic Research Questions

- What is the current status of QMS practice in EPHARM?
- What are the good practices of QMS in EPHARM
- What are the major challenges of implementing the quality management system at EPHARM?
- What are the benefits of QMS practices in EPHARM?

1.4 Objectives of the Study

1.4.1 General Objective

The general objective of this study was to assess the practices of QMS and to identify challenges faces to implement QMS (ISO 9001-2015) in EPHARM.

1.4.2 Specific Objectives

- To explore the practice of quality management system in EPHARM?
- To identify the good practices of QMS in EPHARM
- To identify the major challenges of implementing the quality management system in EPHARM?
- To identify the benefits of QMS practices in EPHARM

1.5 Significance of the study

The study establishes some valued information that determined the current situation of case company in their overall understanding of quality management practices and organizational performance. From the managerial perspective, the findings of the study can benefit in developing written strategies, policies and standard procedures based on the requirements of international standards that can help the firm to increase its competitive advantage. This study is important to EPHARM as well as similar manufacturing companies in Ethiopia because elements of quality management will discussed and evaluate their potential benefits. Thus, the study is of value to managers in the firm since they will get insights on how to implement the practice of quality management for strengthening competitive position.

1.6 Scope of the Study

This study has delimited itself to exploring and describing the implementation of the Quality Management System in the selected Pharmaceutical industry Ethiopian

Pharmaceutical manufacturing S.C., which works in Addis Ababa. It tried to assess the practices and challenges of implementing Quality Management System within the organization and assesses the practice with internal customers in focus. This study has not included the external customer and supplier of this company.

1.7 Limitations of the Study

The limitation for the current research is the exclusion of other pharmaceutical factories which could have a negative impact in inferring conclusion on the level of QMS throughout the pharmaceutical industry in the country. The rationale behind the selection of participants is due to constraints of time as well as convenience and limited budget of the researcher. There are also resource constraints, in terms of time and logistics as well as the difficulties in accessing data. Besides there was also limitations as to which type of methodology to use that would briefly help in analyzing the data.

1.8 Operational definition

Assessment: is the process of gathering and discussing information from multiple and diverse sources in order to develop a deep understanding and Knowledge (Huba and Freed 2000).

Quality: Quality is the ongoing process of building and sustaining relationships by assessing, anticipating, and fulfilling stated and implied need. (Gibson and Hamilton, 1994)

Quality management: according to (ISO 9000:2005) defines quality management as the coordinated activities to direct and control an organization with respect to quality

Quality Management System: is the interaction between people, processes and documentations to meet the requirements and satisfaction of customers (Abdul Hakim, 2006)

1.9 Organization of the study

This paper enclosed five chapters. The first chapter covered the introduction of the study, and it explains the background of the study, the statement of the problem, study objectives, significance of the study, scope of the study, and limitation of the study. The second chapter discussed the related literature review about the subject matter. In chapter three the research methodologies was presented. Chapter Four covered the

research findings and discussion, presenting the background information on descriptive statistics. Finally, Chapter Five provided the summary, conclusion, recommendations and suggestions for further studies.

CHAPTER TWO

2 Review of Related Literature

This chapter aimed at giving insight to the researcher regarding the study. It included literature works from the books, articles, journals and previous studies which are relevant to quality management practices. The literature review is divided into two major parts; theoretical review and review some related studies. This chapter also provided a conceptual framework to show the link between principles of ISO 9001, 2015 QMS and its practices and implementation.

2.1 The Concept of Quality

Quality has become a strategic weapon, which is nowadays being widely used by companies. A company with better quality has the tendency to have better market share than its competitors (Awoku, 2012). According to Awoku (2012), several manufacturing companies have realized the importance of quality. This time, quality is a competitive dimension for companies by which they can excel their competitors and achieve wider market share.

There are different ways of defining quality. Today there is no single universal definition of quality. Quality is perceived differently by different people. Yet, everyone understands what is meant by "quality." (Cambridge University, 2017). In a manufactured product, the customer as a user recognizes the quality of fit, finish, appearance, function, and performance. The quality of service may be rated based on the degree of satisfaction by the customer receiving the service.

Some people view quality as performance to standards; others view it as meeting the customer's needs or satisfying the customers' (Awoku, 2012). In order to ensure total quality in manufacturing, the definition of quality needs to be defined from customers' perspectives.

ISO 9001 defines quality as "The degree to which a set of inherent characteristics fulfills requirements." To fulfill requirements is to meet customers' needs and regulatory requirements. The difference between one organization and another or between one product and another is generally perceived in relation to the product or service of the company.

In manufacturing, quality is best defined in terms of conformance, performance, reliability, features, durability and serviceability of a product (Awoku, 2012). Conformance is the degree at which a product's characteristics meet set standards, while performance shows how the product functions efficiently. Reliability is the probability that a device will perform its required functions under stated conditions for a specific period of time. It is also vital that the products produced have features that would enable their efficient usage and to have durability and be easily repaired. Different scholars define quality differently i.e. according to Joseph Juran, quality means "fitness for use". According to Philip Crosby, it means "conformance to requirements" (Diaz, 2014). Quality planning involves developing the products, systems, and processes needed to meet or exceed customer expectations (Nanda, 2005).

2.2 Quality Management System and ISO Standards

2.2.1 Quality Management System

The concept of quality management systems has existed for many decades. In the 1930s, Walter Shewhart at Bell Laboratories inspired the use of statistics to identify 'best practice' in the USA. This discovery has evolved over many years into control charts and in the US was adopted by manufacturing industries before 1950. During World War II in the 1940s, quality control charts and statistical techniques were deployed to monitor production process and evaluate quality respectively (Goeff, 2001). In the 1950s and 1960s, W. Edwards Deming and Joseph Juran saw the importance of pursuing perfection by applying quality principles and techniques to processes and management of organizations. With the U.S dominating world manufacturing, there was no practical interest in quality practices. Deming and Juran were invited to Japan to lecture on statistical quality control (Goeff, 2001). In the 1970s and 1980s, many U.S companies lost market share to foreign competition. Foreign manufacturing companies were producing lower priced products and better quality. As the West continued to add luxury to products in order to sell at higher prices and increased profits, the East was busy adding quality to products in order to produce items better and cheaper (Goeff, 2001). In order to increase quality awareness, the ISO family standards and Malcolm Baldrige National Quality Award were established in 1987.

Implementing a QMS for Pharmaceuticals industry does not guarantee perfect projects, but provides a framework for consistently maximizing the quality of the overall

company activities. This framework should include provisions for training and qualification of specific Pharmaceutical procedures, audits and corrective actions. Incorporating these elements at an early stage of these processes will help to ensure company's quality objectives are consistently met.

According to (ISO 9001, 2015) the implementation of a QMS implies planning, defining, verifying, and updating processes and procedures. This is defined in the (ISO 9001, 2015) norm as the "*plan-do-check-act*." It encourages a change of attitude from a reactive to a proactive attitude. Planning and prevention gain ground to replace the daily solving of unexpected urgent problems. (Griffith & Watson, 2004), described that, there are different QMS that Pharmaceuticals company use including Investors in People (IIP), ISO 9000, EFQM, custom designed systems and or third party certifications. According to Hakim and others (2006) QMS is defined as "all activities of the overall management function that determine the quality policy, objectives and responsibilities, and implement them by means such as quality planning, quality control, quality assurance and quality improvement within the quality system". To ensure the continually improvement of QMS, it is essential that the top management to give their full support and commitment especially to the development and implementation. This indicates that quality should be managed in ways that which are clearly identified, well documented and efficiently planned, implemented and controlled. A Pharmaceutical quality plan is prepared to establish Pharmaceutical level quality procedures bringing together the information and the companies' policies, procedures and inspection routines' (Griffith & Watson, 2004). This concept is practically and theoretically related to all the appropriate parts of the participants in the project activities to quality systems together around the needs of the pharmaceutical activities.

ISO 9001:2015 is the standard that provides a set of standardized requirements for a quality management system, regardless of what the user organization does, its size, or whether it is in the private, or public sector. It is the only standard in the family against which organizations can be certified, although certification is not a compulsory requirement of the standard. Without satisfied customers, an organization is in threat. To keep customers satisfied, the organization needs to meet their requirements. The ISO 9001:2015 standard provides a tried and tested framework for taking a systematic approach to managing the organization's processes so that they consistently turn out

product that satisfies customers' expectations. The international standard for quality management (ISO 9001, 2015) adopts a number of management principles that can be used by top management to guide their organizations towards improved performance such as: customer focus, leadership, engagement of people, process approach, improvement, evidence-based decision making and relationship management(ISO 9001, 2015). Since any Pharmaceutical industry and its suppliers are mutually supporting, therefore a mutually beneficial relationship between them increases the ability of both to add value and these seven principles form the basis for the quality management system standard.

The internal and external customer to the pharmaceuticals industry can be both the employees and the society at large, which can represent important stakeholders for the Pharmaceutical industry. Therefore, the project achievement depends on the knowledge, skills, creativity, and motivation of its employees and partners. Thus, Pharmaceutical industries should demonstrate commitment to the employees; provide opportunities for development and growth. Pharmaceuticals quality depends on the availability of skilled personnel, material including raw material, finished products, semi-finished products, components' and parts. Moreover the technology and innovation in the machinery and equipment are essential for the modern Pharmaceuticals, reflecting the capabilities of the firm, which have a direct and a significant impact on the quality. The concept of continuous improvement can be achieved through enhancing values to the customer by the deployment of modern, new and innovative products and services, through minimizing wastes and their related costs, through effective utilization of resources for boosting productivities and finally through improving responsiveness and minimizing customer complaints and poor quality of inputs to the pharmaceutical activities. According to Crawford (2002), the overall aim of quality management is to satisfy the customer, conform to requirements, ensure fitness for purpose, and to ensure the product for use. Project model looks at quality management as set of activities or tasks that are required to ensure the project satisfies all the needs for which it was undertaken based on documented in the state of work and includes a focus on quality management from the perspective of product, processes, and the people needed to make quality an effective and efficient aspect of successful project completion.

2.2.2 ISO Quality Management Standards

ISO is a worldwide federation of national standards bodies (ISO member bodies) which develop and publish International Standards. ISO is a non-governmental organization that forms a bridge between the public and private sectors. On the one hand, many of its member institutes are part of the governmental structure of their countries, or are mandated by their government. On the other hand, other members have their roots uniquely in the private sector, having been set up by national partnerships of industry associations (Selamawit, 2019).

Company registered as complying with ISO standards has demonstrated to an accredited third party. Processes have been documented and the company is systematically audited that they are following the policies and procedures necessary to produce high quality products (Behaman, 2016).

The entire series of **ISO 9000** consists of the following standards, which represent an international consensus on good quality management practices :(Behaman, 2016)

(a**) ISO 9000:2015**, Quality management systems – Fundamentals and vocabulary. This Standard describes the fundamentals of quality management systems and specifies the terminology used in ISO (WHM2013).

(b) **ISO 9001:2015**, Quality Management Systems –is the new standard, it determines the requirements an organization must provide in their quality system for ISO 9001:2015 certification. It is the only standard in the ISO family against which organizations can be certified (or registered) through a third-party audit process.

(c**) ISO 9004:2009**

It is a quality management approach for the sustained success of an organization. This Standard focuses on achieving sustainable success in today's complex, demanding and ever-changing environment by meeting the needs and expectations of customers and other stakeholders (WHM2013).

An interesting facet of this Standard is that it promotes self-assessment as an important tool, which enables ongoing review of the level of maturity attained by the QMS. However, it should be noted that the self-assessment tool is not a substitute for a third-party audit process, which is fundamental to ISO 9001(WHM2013).

(D) ISO 19011:2018

This is the third edition and the first and the second were ISO 19011:2002 and ISO 19011:2011 respectively. This international standard provides guidance for internal and external audits of management systems. Effective audits ensure that an implemented QMS meets the requirement specified in ISO 9001(Behaman, 2016).

2.3 Quality Management System Principles

There are seven Quality Management Principles upon which the ISO 9001 requirements for Quality Management Systems are based. These are not presented in any order, as they are all seen as equally important to running a good quality management system. They are equally applicable to product- or service-based organizations, and they are important organizational ideas behind any system for quality management (Mark Hammar, 2020).

Customer Focus

Since the whole goal of a company is to provide products or services to customers, it makes sense that there is a focus on customers as a main element. This starts with knowing your customer and their requirements, ensuring there is communication with customers throughout the process, and measuring the satisfaction of your customer as a way of measuring if the requirements, spoken or unspoken, have been met.

Leadership

It has been said many times that if the top levels of management are not behind the implementation of any QMS, it is bound to fail. While this may not always be a fact, it is true that the more involved the top levels of management are in the QMS, the better the chance of success, and the better implemented the end result. If top management – who is responsible for controlling the cash flow of the organization – can see the benefit of the system, it is much more likely to be used to its fullest advantage.

Engagement of People

It is important that people throughout the organization create value, especially in our ever-growing competitive world. To ensure this, the QMS must focus on the competence of people to help them become engaged in the processes to build value in them. By having empowered and engaged people in the organization, this can become a driving force behind meeting the objectives of the organization.

The Process Approach

Trying to understand, control and improve an overall system can often be complicated, which can make any efforts doomed to failure. However, by looking at the overall system as smaller interrelated processes you can focus your efforts toward more consistent and predictable results on the individual processes of the system. Controlling and improving the individual processes can be a much easier and more effective way to control and improve the entire system.

Improvement

Companies that stay stagnant in an ever-more-competitive market will quickly be overtaken by their competition, and in order to counteract this pressure the company must improve in order to drive down cost and maintain market share. This allows the company to react to changes in internal or external conditions to create new opportunities. The whole idea of having a quality policy, with objectives that are consistent with this policy, works toward improvement. Objectives need to be planned and SMART (Specific, Measurable, Attainable, Realistic, Time-based), and will not work without commitment to change.

Evidence-based decision making

It is said that you are more likely to get the desired results by basing decisions on analysis and evaluation of data rather than a gut instinct of the situation. This is why there is a focus on monitoring & measurement in the ISO 9001 requirements (in fact, 4 of 6 mandatory documented procedures are from this section). In order to know that a process is functioning properly we need adequate data, and in order to plan and assess improvements this data is even more important. Because of this, maintaining good records becomes crucial to facilitate many of the other Quality Management Principles.

Relationship Management

Because the interaction with interested parties such as customers, employees and suppliers can influence the performance of an organization, it is critical to manage these relationships. The focus is often on managing the relationships with the supplier network, but maintaining the relationships of all parties is important to optimize their impact on the organization and make sustained success more likely. Successful companies see these relationships as partnerships rather than strictly customer/supplier interactions.

2.4 Quality Management System Implementation and its Benefits

The design and implementation of quality management system will vary depending on the type, size and products of the organization and should be used in conjunction with the ISO 9001:2015 standards. In implementing a QMS, the key is planning and commitment.

How complex or simple the QMS is depends entirely on the organization and what the objectives are. It can be a simple guide to the organization policy and procedures, or it can document every task and procedure. It really depends on how much risk is involved and how much control is required (Forgaciu & Rahau, 2008). The documentation of QMS involves (ISO, 9001:2000):

- The policy to refer to quality, the objectives of quality and the book of quality (Quality Management System)
- Management Responsibility
- Resource Management
- Product Realization
- Measurements, Analysis and Improvement

The implementation of a quality management system, and its subsequent certification, is a voluntary process, supported by an organization's own strategy, motivations, policies and goals. To benefit more from ISO 9001 quality management systems, organizations may take into consideration that the design and implementation of an organization's quality management system is influenced by the organization's strategy, its size and organizational structure, its organizational environment, changes in that environment

and the risks associated with it (ENISO 9001:2008). In this connection it can be stated that organizations can implement quality management systems in very different ways. In the present world of intense competition, one of the primary factors for sustainable competitive advantage lies in delivering the highest quality service that leads to satisfied customers (Shemwell and others, 1998).

According to the 2011 report of the ISO, many users decide to have their management systems independently audited and certified as conforming to the standards. Certification is not a requirement of the standards themselves, which can be implemented without certification for the benefits that they help user organizations to achieve for themselves and for their customers. Nevertheless, many thousands of organizations have chosen certification because of the perception that an independent confirmation of conformity adds value (ISO, 2011). ISO itself does not perform certification to its standards, does not issue certificates and does not control Certification performed independently of ISO by other organizations.

2.5 Barriers of Quality Management System Implementations

According to Fasika (2003) lack of strong quality sense, superficial of quality management activities instead of fundamentality, the focus of quality management is not for customer satisfaction are identified as a limitation of quality management initiatives in Ethiopia. In addition, as the result of poor management commitment in quality, most enterprises don't have their own business culture to support total employees involvement in quality improvement. When quality conflicts with quantity, quantity is above quality and short-term interest will override long term interest. Some managers have a misconception about ISO 9000. In many manufacturing companies in Ethiopia, because they don't have a systematic quality training program, people in quality and other departments are not familiar with quality tools and thus quality improvement cannot be achieved in a systematic way, and quality efforts in Ethiopia were initiated by the top-down approach.

Barriers to implementation of QMS are classified into external, organizational, organizational culture and technical barriers. The external barriers include the impact of government on the implementation of ISO 9000 standards in the country's organizations. The impact of the government represented in issues such as legislation, financial support. The external barriers include also the effect of the certification

process fees such as consultancies and certification body fees and cost of training programs. Finally, it contains the role of the national standards body, consultants and the certification body. The organizational barriers, which include the lack of understanding the benefits of ISO 9000 certification, awareness of ISO 9000 standards, lack of top management commitment, leadership and involvement, lack of human resource management and lack of employees' involvement and empowerment. The organizational culture barriers include employee's resistance to change, the bureaucratic culture that is prevalent in organizations, wrong people in wrong positions, promotion of directors, managers and head of departments not based on qualifications and employee absenteeism. The technical barriers include ineffective communication, lack of information, the difficulty of access to test laboratories, controlling the documentation during the registration process, lack of understanding the requirements and implementing them (Sharif, 2005).

Hussein, Abou-Nassif and others (2017) identified seven main challenging factors to adopt and implementation of QMS ISO 9001. The seven identified factors are lack of awareness, the terminology used in ISO 9001, resistance to change, the existence of accreditation, and commitment of top management, time management, and resource availability.

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 top management commitment, 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.

2.6 Review of some related studies

The research done by Yu-chung, H. and others (2005) in pharmaceutical industry shows that benchmarking strategy and Knowledge structure, the organizational culture, information technology, employee involvement and training, the leadership and commitment of senior management, a learning environment and resource control and evaluation of professional training and teamwork as critical factor in adopting a quality management system (Yu-chung, H. and others 2005).

The result of study done by Rana and others in 2009 on the role of Quality management in Pharmaceutical industry in Islamabad and Lahore shows the application of QMS principles, culture of continuous improvement, overcoming a lack of trust and understanding of QMS Process itself are some of the Key challenges facing in the organization to implement QMS (Rana and others, 2009).

Neetu, D. and others in 2011 says on their research paper, Pharmaceutical industry is amongst most astringently regulated manufacturing units. Quality Management System affairs the ultimate quality of the finished product. They also shows in their result of the study, understanding and implementation of appropriate QMS model enables a Pharmaceutical organization to fulfill ethical as well as regulatory responsibility of including management of identify, quality, safety, purity and efficacy of finished medical product(Neetu, D. and others, 2011).

The research done by Forgaciu and others in 2008 on the title of Advantage achieved by the implement of QMS in Romanian pharmaceutical organization presents the benefits of QMS implementation, such as increase of domestic sales and exports, competitive advantages, flexibility and ability to respond to market opportunities and challenges faces in the organization to implement QMS such as profitability on a fluctuating market, competitiveness with foreign companies, globalization, speed of change, adaptability, growth and technologies (Forgaciu and others, 2008).

An empirical study conducted by Gupta, A. on Quality management practices of ISO Vs non-ISO organization in Indian suggest that ISO and non-ISO organizations do differ in their quality management practices. ISO 9000 registered manufacturing

organizations in this study had formal commitment to quality management (Gupta, A. 2000).

Jose and others, provides a useful methodology for the implementation of document management systems to support the requirements of the Quality Management System ISO 9001: 2008 proposed in this document. This methodology consists of six stages that are executed in a cycle to obtain the ideal Document System. The proposal begins with the definition of the requirements of the document ISO 9001: 2008; followed by the evaluation of the Document Management System existing in the organization; the identification of document strategies; the design of the document management system; its application and, finally, the definition of the continuous improvement plan to guarantee compliance with the initially detected requirements (Jose and others, 2013).

2.7 Profile of the study company

The company started production on June, 1964 as Ethiopian drug manufacturing shack after a memorandum of agreement was signed by the British company Smith and Nephew associated company limited and the Imperial Ethiopian government (IEG). After two years of operations the company reported significant lose and had even been closed for nine months. After many ups and downs the company was re-established in Aril 1970 as Ethiopian pharmaceutical manufacturing (EPHARM). From 1970 to 1974, with the improved motto "Quality is our most important product" the factory was producing about 130 pharmaceutical products which included tablets, syrups, ointments, inject able and capsules. It started making profits. EPHARM was nationalized on 2nd Feb. 1975 following the popular revolution that resulted in the demise of the imperial regime. The factory was then merged with the state owned pharmaceuticals and medical supplies import and distribution corporation. After down fall of the socialist regime, the factory was re-established as an independent public enterprise under the directory of public enterprises supervising authority on 13th Feb. 1994. In line with the government's program to privatize public enterprises, MEDTECH Ethiopia, the major customer of EPHARM by then, bought the factory in Sep.2014. Since then it has been working aggressively to transform the factory to a greater level and make it competent than it was ever before.

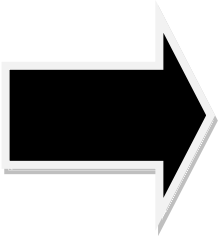
2.8 Conceptual Framework

This section showed the distinct dimensions related to QMS as presented in literature dealing with the topic. This has formed the basis for a comprehensive framework that encompasses the different features of QMS. The key dimensions of QMS as per (ISO 9001, 2015) have been identified with emphasis on their critical value in the framework. The dimensions of QMS described in this section have all been thoroughly documented by many authors and experts on the subject. This is also captured in the conceptual framework, which shows list of management responsibilities in the company and assess the practice and implementation of QMS.

The scope have further divided into factor describing them such as customer focus, leadership capabilities, factual based decision, improvement, process approach, peoples engagement and relationship management which potentially explain the implementation and practice of QMS as per (ISO 9001, 2015). These elements in conceptual model show the relationship among the variables to describe the practice and the extent of implementation of QMS in the Pharmaceutical industry. The study was guided by the formulated conceptual framework as shown bellow

Management responsibilities

- Leadership
- Customer Focus
- Process Approach
- Continuous improvement
- Engagement of people
- Relationship Management
- Evidence based Decision



Practices and implementation

CHAPTER THREE

3 Research Methodology

This chapter explained the research methodology that was used in carrying out the study. Research methodology present brief explanation on how the study conducted basically it includes; the study design and approach, sample size, sampling techniques, data collection methods, data analysis,

3.1 Research Design and Approach

This study applied mixed methods design which is a procedure for collecting, analyzing and producing of results by mixing both quantitative and qualitative data at some stage of the research process within a single study. This approach comprised two complimentary methods: questionnaire survey and interview. The questionnaire generated quantitative data, while the second provided richer qualitative details, while at the same time validating the quantitative findings. Hurmerinta-Peltomaki and Nummela (2006) have found there is value-adding to results based on the adoption of mixed methods, when compared with using a single method.

Since the objective of this study was to assess the practices and challenges involved in the implementation of QMS the study was descriptive type of research. A descriptive survey method was used to measure the characteristics described in the research question. In connection with the application of descriptive survey method, it was stated that this method is a method of investigation which attempts to describe and interpret what exists at present in the form of conditions, practice, process, trends, effects, attitudes, beliefs, etc

3.2 Population and sampling Technique

The target population for this study was EPHARM which is found in Addis Ababa. This Pharmaceutical industry was selected because of its experience in the pharmaceutical sector and company which had implemented QMS in their organizational system. The company is well organized and produces different kinds of drugs or medicines. Sample size of the study was all of the permanent employees of EPHARM out of which managers, supervisors, experts, seniors, pharmacists and all quality assurance and quality control department employs are selected purposively.

The study used a purposive sampling technique from the population of interest. The reason for choosing this technique is that the selected participants are the focal and more responsible persons in the practice and implementation of QMS in their organization and to get the right management body to have a seat and share ideas related to the practice of QMS in the organization. Moreover, these samples helped to understand the problem and the research question since they are assumed to be rich in information in QMS.

3.3 Data Sources and Data Collection tools

Both primary and secondary data sources have been used for the study. According to (Kothari, 1985) questionnaires, interviews and direct observations are the most important means of data collection tools. The questionnaire was designed using five levels Likert Scale (Cooper and Schindler, 2008) to obtain the required information. The Likert scale is preferred because it allows measuring the attitudes of the respondents in a scale of 1 to 5 (from the least to the most) as to how they disagree or agree, disapprove or approve the attributes or factors presented as questions. Therefore, in this study, both questionnaires and interviews has employ as a primary data collection.

3.4 Methods of data Analysis

The data analysis for this research has be descriptive type of data analysis. The researcher had examined the collected data in order to find constructs, themes and patterns that can be used to describe and explain the phenomenon being studied. Descriptive statistics analysis was applied for the presentation, interpretation and discussion parts on various dimensions of the evaluation system. Frequency tables and percentages were used as appropriate to analyses, interpret, tabulate and present the result of the study. The data gathered through questionnaires were checked, filtered, coded and entered for further statistical analysis in the version of SPSS-26 software and also employed ranking, the weighted average methods mean, and standard deviation and presented in the form of tables. The results of the interview questions were integrated to the responses of employees through questionnaires and were analyzed accordingly. Finally, conclusions were made based on the results of the study and recommendations were forwarded on the basis of the data analyzed.

3.5 Reliability and Validity of test

Mainly survey method was the strategy of the research and the reliability of the scale which is how the collected data is free from random error was checked. Collected data is worthwhile only if they are recorded in accurate ways. For any measurement to be valid, it must first demonstrate reliability (Frey et al, 2002). Cronbach's alpha is a statistic. It is generally used as a measure of internal consistency or reliability of a psychometric instrument. In order to be reliable, using SPSS result, the Cronbach's alpha should exceed the threshold of 0.70. This indicates that there was a high degree of internal consistency amongst the test items (Streiner and Norman, 1989).

The result of Cronbach's alpha for this study found by analyze the data using SPSS version 26 was 0.789. This result tells that there was high degree of internal consistency among the items. It also indicates that the items were closely related in terms of idea and do not create confusion or cause of misunderstanding to the respondents.

3.6 Ethical Consideration

In order to keep the confidentiality of the data given by the respondents they will not require writing their name and they are assured that responses will be treated in strict confidentiality. The purpose of the study will be disclosed in the introductory part of the questionnaire.

CHAPTER FOUR

4 Data Analysis and Interpretation

4.1 Introduction

This chapter is present the empirical data collected from the case company through standard questionnaire and by interviewing the members of top management of the case company. The analysis of the data has been done by making use of SPSS 26 data processing software. The findings of the data collected were analyzed and discussed thoroughly so as to meet the research objectives defined and answer research questions posed. 67 respondents from the case company approached through personal contact for data collection as designed in the research methodology of this research. These respondents were requested to complete the designed questionnaire. All of these respondents agreed and responded, resulting in a response rate of 100 percent.

4.2 Demographic Characteristics of the respondent

Table 4.1 Frequency of age, Years of service and Educational Background of respondent

No.	Item		Response	
			Frequency	Percent
I	Age of respondent	25-30	30	44.8%
		31-35	25	37.3%
		36-40	11	16.4%
		Above 40	1	1.5%
II	Educational background of the respondent	Certificate	2	3.0%
		Diploma	3	4.5%
		1st degree	55	82.1%
		Masters and above	7	10.4%
III	Years of experience of the respondent in the organization	Below 5	21	31.3%
		5-10	28	41.8%
		11-15	12	17.9%
		Above 15	6	9.0%

Source: Data collected by the researcher through Questionnaire, 2021

Table 4.1 in item I indicated that, most of the respondents i.e. 30(44.8%) of the respondents are in the age category of 25-30. While the rest 25(37.3%), 11(16.4%) and 1(1.5%) of the respondents fall in the age category of 31-35, 36-40 and above 40 respectively. This indicates that, much of the study respondents are fall under productive age.

Item II of the same table indicated that, large number of the respondents i.e. 55(82.1%) of them replied that they are Bachelor degree holders. While Masters comes after 7(10.4%) and only 3(4.5%) and 2(3%) of them are Diploma and Certificate holders respectively. This shows that, respondents are addressed from different educational background mostly bachelor.

Item III of the same table signifies that, most of the respondents 28(41.8%), of them replied that they are working within the organization5-10 years. While the remaining 21(31.3%) and 12(17.9%) of the respondents have work experience of below 5 and 11-15 years respectively in addition to above 15 years' experience in number 6(9%). Form this one can understand that, respondents have reach experience to judge the fact within the company.

4.3 Basic Information Regarding to (QMS) Implementation

Table 4.2 Basic Information Regarding to (QMS) Implementation

Item	Statement	Response	Frequency	Percent
I	Have you used any form of QMS in your current organization?	Yes	64	95.5%
		No	3	4.5%
		Total	67	100%
II	Have you ever been communicated about QMS from Senior Management in your current organization?	Yes	61	91%
		No	6	9%
		Total	67	100%
III	Do you think the company should have a Quality Manager responsible for implementing Quality Plans and Checklists?	Yes	47	70.1%
		No	20	29.9%
		Total	67	100%
IV	Do you agree QMS help reduce defective work and the number of problem corrections in your current organization?	Yes	67	100%
		No	0	0%
		Total	67	100%
V	Have you ever received training in any form of QMS?	Yes	57	85.1%
		No	10	14.9%
		Total	67	100%

Source: Data collected by the researcher through Questionnaire, 2021

Table 4.2 in item I indicates 95.5% of the respondents confirms that they used QMS forms in the organization and also in regarding to the communication about QMS from senior management in their organization, which is stated in item II showed that 91% of respondents have positive response. This shows that the application and communication of QMS is performed well in their organization.

Table 4.2 in item III shows that 70.1% of respondents understood that quality manager is responsible for implementing quality plans and check shits and also item IV indicates that all of the respondents asserted that QMS could help them to reduce defective works and problem that occurs in their organization.

Regarding to item V in the same table 85.1% of the respondents confirms that they received training about QMS.

4.4 Descriptive Analysis of variables

Table 4.3 Analysis of Customer Focus

Response 1=strongly Disagree 2=Disagree 3=Average 4=Agree 5= strongly agree

Item	Question	N	Frequency of responses/ Percentage					Mean	Std
			1	2	3	4	5		
I	Emphasis on assessing current and future customers' needs and expectations	67	1/ 1.5%	10/ 14.9%	30/ 44.8%	22/32. 8%	4/ 6.0%	3.27	0.845
II	Customer complaints are frequently resolved by your organization	67	---	4/ 6.0%	27/ 40.3%	30/ 44.8%	6/ 9.0%	3.57	0.743
III	The organization adopts formal ways to collect customer complaints	67	---	4/ 6.0%	30/ 44.8%	30/ 44.8%	3/ 4.5%	3.48	0.682
IV	Customers' complaints are studied to identify patterns and prevent the same problems from recurring.	67	---	4/ 6.0%	30/ 44.8%	26/ 38.8%	7/ 10.4%	3.54	0.765
V	incorporation of data on customer expectations and/or satisfaction when designing new products	67	---	5/ 7.5%	23/ 34.3%	37/ 55.2%	2/ 3.0%	3.54	0.682

Source: Data collected by the researcher through Questionnaire, 2021

Table 4.3 item I responses shows that 32.8%(22) respondents agreed that the organization assess current and future customers' needs and expectation, 6.0%(4)

respondents have strongly agreed, 44.8%(30) respondent have average this may be because of the department or the participants did not interact with customer's current and future needs and expectation, 14.9%(10) respondents have disagreed and 1.5%(1) have strongly disagreed. Moreover, the average mean value 3.27 and standard deviation 0.845 shows the organization assess current and future customers need and expectation.

The item II in Table 4.3 Indicates the responses of the participants to the question which asked that customer complaints are frequently resolved by the organization, 9%(6) of the respondents strongly agree, 44.8%(30) agree, 40.3% (27) were average, 6%(4) have disagree and mean and Std. deviation were 3.57 and 0.743 respectively. From the finding around 54% of the respondents were either agreed or strongly agree. This shows that the organization try to resolve the customer complaints frequently.

For the question "The organization adopts formal ways to collect customer complains?" which stated in item III of table 4.3, 44.8%(30) of the respondents agree, 44.8%(30) were average this may be the job type and department of the respondents prevent from knowing the phenomena, only 4.5%(3) and 6%(4) were strongly agree and disagree respectively. The above finding indicates that the organization adopts formal ways to collect customer complaints.

Regarding to item IV in table 4.3, 38.8 % (26) and 10.4% (7) respondents were agreed and strongly agreed respectively on customers' complaints are studied to identify patterns and prevent the same problems from recurring, 44.8% (30) were average and only 6% (4) disagreed and there was no strongly disagree response. The above responses and the mean 3.54 imply the organization study customers' complains to identify the patterns.

The responses shown in the table 4.3 item V indicates 55.2%(37) have agreed,34.3%(23) respondents have average responses, only 3%(2) strongly agreed and 7.5%(5) were disagreed. The above result and the mean 3.54 imply that the organization incorporates data on customer expectations and/or satisfaction when designing new products. When asking some managers to get information about product development procedure the company clearly states that the research should include types of drugs have high demands in terms of dosage form, packaging style, strength and color of the dosage form.

Table 4.4 Analysis about leadership

Response 1=strongly Disagree 2=Disagree 3=Average 4=Agree 5= strongly agree

Item	Question	N	Frequency of responses/ percentage					Mean	Std
			1	2	3	4	5		
I	Senior executive's highly visible leadership in maintaining an environment that supports quality improvement	67	---	10/ 14.9%	40/ 59.7%	14/ 20.9%	3/ 4.5%	3.15	0.723
II	Top management is a primary driving force behind quality improvement efforts	67	---	5/ 7.5%	21/ 31.3%	31/ 46.3%	10/ 14.9%	3.69	0.820
III	The senior executives consistently participate in quality improvement activities	67	---	---	37/ 55.2%	23/ 34.3%	7/ 10.4%	3.55	0.631
IV	Demonstration of an ability to manage the changes needed to improve the quality	67	---	8/ 11.9%	43/ 64.2%	13/ 19.4%	3/ 4.5%	3.16	0.687
V	Senior executives appreciate efforts that improve quality throughout the organization	67	2/ 3%	9/ 13.4%	24/ 35.8%	27/ 40.3%	5/ 7.5%	3.36	0.916
VI	Senior executives involvement on obtaining information on needs and suggestions for quality improvement directly from customers	67	1/ 1.5%	7/ 10.4%	22/ 32.8%	31/ 46.3%	6/ 9.0%	3.51	0.859

Source: Data collected by the researcher through Questionnaire, 2021

Table 4.4 in item I show the responses about the subject which state the senior executives of the organization provide highly visible leadership in maintaining an environment that supports quality improvement. It was found on the table that the number of those respondents with strongly agree, agree, average and disagree response were 4.5 %(3), 20.9% (14), 59.7% (40) and 14.9% (10) respectively and the mean and std. deviation was 3.15 and 0.723. The above result shows only about 25% of respondents were strongly agree and agree on the subject and the mean value was 3.15, this indicates there is gap on the organization on maintaining an environment that supports quality improvement.

Table 4.4 in item II hold responses of the subjects on question whether Top management is a primary driving force behind quality improvement efforts or not. 46.3% (31) and 14.9% (10) of the respondents agree and strongly agree respectively,

31.3% (21) were average and only 7.5% (5) disagree. The responses indicate that top management of the organization is a primary driving force behind quality improvement efforts and it has positive impact on QMS implementation.

The responses of the participants shown in item III of table 4.4 indicates 10.4% (7) and 34.3% (23) have strongly agree and agree respectively, 55.2%(37) have average responses and there was no disagree and strongly disagree responses. The finding indicates that the organization tries to participate senior executives in activities to improve the quality but it needs to give stress on increasing the participation of senior executives in quality improvement activity.

Table 4.4 in item IV shows that 19.4%(13) and 4.5%(3) of respondents are agree and strongly agree respectively that senior executives have demonstrated an ability to manage the changes needed to improve quality, 64.2%(43) were average. This may be their job type may prevent them from knowing about the phenomena, 11.9% (8) have disagreed. The above result and the mean 3.16 indicate that the company (EPHARM) needs more works on these phenomena because it is important to implement QMS effectively and quickly.

For the above table 4.4 in item V that asks if the senior executives appreciates, efforts that improve quality throughout the organization, 7.5% (5), 40.3% (27), 35.8% (24),13.4(9) and 3%(2) have strongly agree, agree, average, disagree and strongly disagree responses. Majority of the responses implies that the senior executives of the company appreciate efforts that improve quality throughout the company.

Table 4.4 in item VI hold responses of the question asking if senior executives involve on activities that enhance customer expectation by obtaining information on needs and suggestions for quality improvement directly from the customers 46.3%(31) and 9.0%(6) agree and strongly agree. 32.8 % (22) have average, 10.4% (7) disagree and only 1.5% (1) strongly disagree responses. The responses and the mean (3.51) indicate that senior executives involve on activities that enhance customer expectation by obtaining information on needs and suggestions for quality improvement directly from the customers.

Table 4.5 Analysis about engagement of People

Response 1=strongly Disagree 2=Disagree 3=Average 4=Agree 5= strongly agree

Item	Question	N	Frequency of responses/ percentage					Mean	Std
			1	2	3	4	5		
I	Employee's thought as an input to make any quality decision	67	---	5/ 7.5%	28/ 41.8%	31/ 46.3%	3/ 4.5%	3.48	0.704
II	Employees' involvement and empowerment to improve quality	67	---	11/ 16.4%	31/ 46.3%	19/ 28.4%	6/ 9.0%	3.30	0.853
III	Employees are interested about their jobs and are prepared to go extra mile to improve quality	67	---	17/ 25.4%	30/ 44.8%	17/ 25.4%	3/ 4.5%	3.09	0.830
IV	Education and training in statistical and other quantitative methods that support quality improvement	67	---	7/ 10.4%	34/ 50.7%	20/ 29.9%	6/ 9.0%	3.37	0.795
V	Effective system for employees to make suggestions to management on how to improve quality	67	---	23/ 34.3%	22/ 32.8%	19/ 28.4%	3/ 4.5%	3.03	0.904

Source: Data collected by the researcher through Questionnaire, 2021

Item I of table 4.5 indicates that 46.3%(31) and 4.5%(3) respondents were agreed and strongly agreed that the company use employee's through as an input to make any quality decision, followed by 41.8%(28) and 7.5%(5) were average and disagreed responses respectively. The result infers that every employee through have been used as an input to make any quality related decisions.

The responses of the participant for item II in table 4.5 showed that 9.0% (6) strongly agreed, 28.4%(19) agreed, 46.3%(31) average and 16.4%(11) disagreed on the question asking if employee's involvement and empowerment encourages them to exert the best of their abilities to improve quality. The above findings and the mean (3.30) shows more of positive responses from the participant for the question but about the majority of the participants responses was average, this infers that there is some gap in the organization on employees involvements and empowerment to improve quality.

Item III in the same table hold responses of participants for the question asking if employees at work are interested in a positive, even excited about their jobs and are

prepared to go extra mile to improve quality. 25.4% (17) and 4.5% (3) have agreed and strongly agree responses, 44.8% (30) were average and 25.4% (17) have disagreed responses and the mean value also 3.09.

Table 4.5 in item IV shows that 29.9% (20) and 9.0% (6) of the respondents were agreed and strongly agreed respectively on the question asking the organization's employees given education and training in statistical and other qualitative methods that support quality improvement, 50.7%(34) have average and 10.4%(7) disagreed responses. The mean and std. deviation of the responses were 3.37 and 0.795 respectively. The result indicates that about 90% of the participants have positive responses for the question but about the majority of the responses were on average because of this the company need some works on this phenomena to improve quality and implement QMS quickly.

Item V in the same table presents responses of the subjects, whether the organization has an effective system for employees to make suggestions to management on how to improve quality or not, 28.4% (19) and only 4.5% (3) were agree and strongly agree respectively. 32.8% (22) average and 34.3% (23) were disagreed. The finding indicates that large number of participants gives disagree responses for the question, this infers that there was a gap in the company on creating effective system for employees to make suggestions to management on how to improve quality.

Table 4.6 Analysis of Process Approach

Response 1=strongly Disagree 2=Disagree 3=Average 4=Agree 5= strongly agree

Item	Question	N	Frequency of responses / Percentage					Mean	Std
			1	2	3	4	5		
I	Identification of the key business processes by prioritizing	67	1/ 1.5 %	5/ 7.5%	22/ 32.8%	32/ 47.8%	7/ 10.4%	3.58	0.838
II	Managing processes systematically by giving process ownership and resolving process interface issues through meetings or ownership models	67	---	7/ 10.4%	21/ 31.3%	31/ 46.3%	8/ 11.0%	3.60	0.836
III	Review processes and set improvement targets	67	---	13/ 19.4%	29/ 43.3%	22/ 32.8%	3/ 4.5%	3.22	0.831

IV	Innovation and creativity to improve processes by adopting self-managed teams, business process improvement and idea schemes	67	3/ 4.5 %	12/ 17.8%	31/ 46.3%	19/ 28.4%	2/ 3.0%	3.02	0.876
V	Change processes and evaluates the benefits through process improvement or re-engineering teams, project management and involving customers, and suppliers.	67	---	5/ 7.5%	28/ 41.8%	26/ 38.8%	8/ 11.9%	3.55	0.803

Source: Data collected by the researcher through Questionnaire, 2021

For item I of table 4.6 which asking the respondents if the organization identifies the key business processes by prioritizing based on the value chain, customer needs and strategic significance and using process models and definitions, 47.8% (32), 10.4% (7), 32.8%(22), 7.5% (5) and only 1.5% (1) of the respondents agreed, strongly agreed, average, disagreed and strongly disagreed respectively. The above result and 3.58 mean implies that the organization identifies the key business processes by prioritizing based on the value chain, customer needs and strategic significance and using process models and definitions.

Regarding to Managing processes systematically by giving process ownership and resolving process interface issues through meetings or ownership models, the response from table 4.6 for item II 46.3%(31), 11.9% (8) and 31.3% (21) of the respondents have agreed, strongly agreed and average respectively. Respondents who are disagreed have the percentage 10.4% (7). These results indicates that, most of the participants of the research believe that the organization manages processes systematically by giving process ownership to the most appropriate individual or group and resolving process interface issues through meetings or ownership models.

For the same tablet holding the responses of the respondents for the item III, 32.8% (22), 4.5% (3), 43.3% (29) and 19.4% (13) have agreed, strongly agreed, average and disagreed respectively. The result shows about 80% responses of the participants have average and above, this implies that the company (EPHARM) reviews processes and sets improvement targets by empowering process-owners to set targets and collect data from internal and external customers.

For Item IV of the same table which asking the respondent whether the organization uses innovation and creativity to improve processes by adopting self-managed teams, business process improvement and idea schemes or not 28.4%(19) and only 3.0%(2) of respondents

have agreed and strongly agreed respectively. The fact that 46.3% (31) about the majority of the respondents are on average, 17.9% (12) disagreed and 4.5% (3) strongly disagreed. These result shows that only about 31% of the respondents were agree and strongly agree and the mean also 3.02, this implies that there is some gap in the company on uses of innovation and creativity to improve processes.

Table 4.6 in item V shows that 38.8% (26) and 11.9% (8) of the respondents have agreed and strongly agreed respectively on the question asking the organization change processes and evaluate the benefits through process improvement or re-engineering teams, project management and involving customers, and suppliers, 41.8%(28) have average and 7.5%(5) disagreed responses. The mean and std. deviation of the responses were 3.55 and 0.805 respectively. From these responses, about 50% of the respondents agree and strongly agree and it indicates that organization change processes and evaluates the benefits through process improvement or reengineering teams, project management and involving customers and suppliers.

Table 4.7 Analysis about Continuous Improvement

Response 1=strongly Disagree 2=Disagree 3=Average 4=Agree 5= strongly agree

Item	Question	N	Frequency of responses/ percentage					Mean	Std
			1	2	3	4	5		
I	Everyone in the organization is aware of the need to improve continuously and show their efforts for improvement	67	1/ 1.5%	4/ 6.0%	27/ 40.3%	30/ 44.8%	5/ 7.5%	3.51	0.780
II	Supporting employees in their personal career developments	67	2/ 3.0%	25/ 37.3%	20/ 29.9%	14/ 20.9%	6/ 9.0%	2.96	1.036
III	Identification of possible faults, training on common types of faults and how to manage problematic situations when happened	67	1/ 1.5%	6/ 9.0%	33/ 49.3%	23/ 34.3%	4/ 6.0%	3.34	0.789
IV	Continuous improvement tools are applied on regular basis	67	---	7/ 10.4%	29/ 43.3%	27/ 40.3%	4/ 6.0%	3.42	0.762
V	Continuously improving by trying to apply the latest knowledge and technologies in the industry	67	1/ 1.5%	9/ 13.4%	28/ 41.8%	23/ 34.3%	6/ 9.0%	3.36	0.883

Source: Data collected by the researcher through Questionnaire, 2021

For item I on table 4.7 which asks the respondents if everyone in the organization is aware of the need to improve continuously and show their efforts for improvement, 44.8%(30) and 7.5%(5) of the respondents have agree and strongly agree respectively.

The respondents who were average, disagree and strongly disagree have the percentage 40.3% (27), 6.0% (4) and 1.5% (1) respectively. By looking the responses of the respondents and mean 3.51, one can infer that everyone in the organization is aware of the need to improve continuously and show their efforts for improvement.

Table 4.7 for item II holding the responses of respondents for the question if the organization supported employees even in their personal career developments like sponsoring for education and providing scholarships which is 37.3%(25) disagreed and 3.0%(2) strongly disagreed it takes large pie than total of agree and strongly agree responses (about 30%). 29.9% (20) of the respondents have average responses. By depending on these result we can fairly say that the organization have a gap on supporting employees in their personal career developments like sponsoring for education and providing scholarships.

For item III in the same table regarding to identifying, informing and managing the causes possible fault which happen in the organization 34.3% (23) and 6.0% (4) respondents have agreed and strongly agreed respectively. 49.3% (33) respondents have average responses and 9.0% (6) and only 1.55(1) were disagreed and strongly disagreed. The above result indicates that about 90% of the respondents have above average responses, this implies that the causes of all the possible faults identified, informed and employees are well trained on common types of faults, and how to manage problematic situations when happened in the organization.

For the item IV of the same table which asking if continuous improvement tools (brainstorming, check sheet and other statistical process control) applied on regular basis in the organization, 40.3% (27) and 6.0% (4) respondents have agreed and strongly agreed respectively. 43.3% (29) have average and 10.4% (7) disagreed responses. Since most of the respondents were agreed and strongly agreed with the subject, we can infer that the organization applies continuous improvement tools on regular basis.

Table 4.7 in item V shows that 34.3% (23) and 9.0% (6) respondents agreed and strongly agreed to that the organization is continuously improving by trying to apply the latest knowledge and technologies in the industry, 41.8%(28) have average responses and 13.4%(9) and only 1.5%(1) disagreed and strongly disagreed respectively on the subject. Based on the above responses of respondents, we can infer that the organization

is continuously improving itself by trying to apply the latest knowledge and technologies in the industry.

Table 4.8 Evidence-based decision making

Response 1=strongly Disagree 2=Disagree 3=Average 4=Agree 5= strongly agree

Item	Question	N	Frequency of responses / percentage					Mean	Std
			1	2	3	4	5		
I	Encouragement of statistical measurements and analysis throughout the organization	67	---	2/ 3.0%	33/ 49.3%	30/ 48.8%	2/ 3.0%	3.43	0.679
II	Every activity in the organization is recorded by employees	67	---	---	11/ 16.4%	45/ 67.2%	11/ 16.4 %	4.00	0.577
III	Summarized reports of the facts recorded on a daily basis to make quality related decisions	67	---	4/ 6.0%	20/ 29.9%	39/ 58.2%	4/ 6.0%	3.64	0.690
IV	Providing planned targets and decisions made based on deviations of actual and targeted outcomes	67	2/ 3.0%	1/ 1.5%	39/ 58.2%	23/ 34.3%	2/ 3.0%	3.33	0.705

Source: Data collected by the researcher through Questionnaire, 2021

For item I in table 4.8 holding the responses of the respondents if organization encourages statistical measurements and analysis throughout the organization 48.8% (30) and 3.0%(2) of the respondents agreed and strongly agreed respectively, 49.3(33) have average and only 3.0%(2) of the respondents chooses disagree. From these result, we can understand that about half of the respondents agree and strongly agree, this implies that the organization encourages statistical measurements and analysis throughout the organization.

Table 4.8 in item II shows that 67.2% (45) and 16.4% (11) of the respondents have agreed and strongly agreed respectively on the question asking if every activity in the organization is recorded by employees. 16.4% (11) the respondents chose average but disagree and strongly disagree have not chosen by the participants. From these results, we can understand that large number of the respondents about 85% have agreed and strongly agreed on the phenomena; this implies that every activity in the organization is recorded by employees in the organization.

For the same table in item III holding responses for question which asked if top management seeks summarized reports of the facts recorded on a daily basis to make quality related

decisions 58.2% of the respondents agree. 29.9% (20) average and also strongly agree and disagree responses were chosen by equal number of respondents 6% (4). The above result implies that top management of the organization seeks summarized reports of the facts recorded on a daily basis to make quality related decisions.

Table 4.8 in item IV presents responses of the subjects, if the organization provides planned targets for every employee and subsequent decisions are made based on deviations of actual and targeted outcomes 34.3% (23) and 3% (2) of the respondents agree and strongly agree respectively. 58.2% (39), 1.5% (1) and 3.0% (2) of the respondents were average, disagree and strong disagree. The result indicates that only 4.5% of respondents were disagree and strongly agree on the subject but about the majority of the respondents were on average responses, this infers that the organization is make a good work on providing a planned targets for every employees and subsequent decisions but it needs some improvement to reduce the number of respondents which select average response and to increase agree and strongly agree response.

Table 4.9 Relationship Management

Response 1=strongly Disagree 2=Disagree 3=Average 4=Agree 5= strongly agree

Item	Question	N	Frequency of responses/ percentage					Mean	Std
			1	2	3	4	5		
I	Plans and manage external partnerships to support the effective operation of its processes	67	1/ 1.5%	4/ 6.0%	40/ 59.7%	21/ 31.3%	1/ 1.5%	3.25	0.659
II	The organization maintains successful partnerships with its suppliers through good communications and exchange of information	67	1/ 1.5%	7/ 10.4 %	24/ 35.8%	28/ 41.8%	7/ 10.4 %	3.49	0.877
III	Recruit and retain suppliers to improve quality	67	---	7/ 10.4 %	24/ 35.8%	33/ 49.3%	3/ 4.5%	3.48	0.749
IV	Closer relationships with suppliers helped to get technical support from its suppliers when needed rather than merely exchange of goods	67	1/ 1.5%	5/ 7.5%	34/ 50.7%	24/ 35.8%	3/ 4.5%	3.33	0.705

Source: Data collected by the researcher through Questionnaire, 2021

For item I of table 4.9 holding the responses of the respondents for the question asking if the organization plans and manages the external partnership that is in line with its overall policies and strategies, being designed and developed to support the effective operation of its processes 31.3%(21) agreed and only 1.5%(1) strongly agreed. 59.7%

(40), 6.0% (4) and only 1.5% (1) have average, disagree and strongly disagreed responses respectively. The result shows about 92% responses of the respondents have average and above, but about 60% of the respondents chose average. The above responses and mean 3.25 implies that the organization need some work on these areas.

Regarding to maintaining successful partnerships with its suppliers through good communications and exchange of information, the response from table 4.9 for item II showed that 41.8% (28) and 10.4% (7) of the respondents have replied agree and strongly agree respectively. Responses of 35.8% (24) respondents were average and the remaining 11.9% chosen by the respondents who disagree and strongly disagree. By looking at these results, one can infer that the organization maintains successful partnerships with its suppliers through good communications and exchange of information.

From the same table in item III we can see that 49.3%(33) of the respondents agreed that the organization recruits suppliers and have a way to retain them that supported the organization to improve quality, followed by 35.8% (24) average, 10.4%(7) disagree and 4.5%(3) agree. These results imply that the organization recruits suppliers and have a way to retain them that supported the organization to improve quality.

For the same table in item V holding the responses of respondents for the question if the organization have closer relationship with its suppliers, which helped the organization to get technical support from its suppliers when needed, rather than merely exchange of goods 35.8%(24) agreed and 4.5%(3) strongly agreed. The facts that 50.7% (34) were average; this is may be their job type may prevent them from knowing about the subject. Respondents with disagree and strongly disagree responses share the remaining 9% (6) of the respondents with 7.5% (5) and 1.5% (1) respectively.

4.4 Analysis of interview Questions

The responses of employees selected for the interview asking about their knowledge on QMS, shows that they have good understanding about QMS. They raise some points about QMS such as; - QMS is used to achieve quality with improved organizational culture and satisfied employees in a way that can help the organization to achieve its vision.

-QMS is one of the systems used to satisfy the customer by improving the quality of the product and the way of the process.

-QMS should include documentation process in the organization about quality and over all process in the organization.

The response of the respondents about customer management tells that the organization made marketing research to satisfy the customer needs. The marketing research committee under the close supervision of R&D manager conducts marketing research so as to assess the market demand.

The respondents participate in the interview believes that, top managements involvement have significant effect on quality improvement. The respondent says that top management of the organization have monthly meeting about the report of quality department, work environment and customer demand satisfaction.

Top management made decisions on quality issue by made a discussion on quality related problem occur in the organization and on its probable solutions. Finally they select the proper solution to the problem and apply it to make proper decisions.

The respondents raise some points about supplier managements; supplier must be in conformance to stated purchase requirements or adherence to specifications, implied and regulatory requirements. The organization receives the test sample of the ordered material and make test on some quality related issues. Another point raise by the respondents on supplier management was the organization maintains successful partnerships with suppliers through good communication and information exchange.

Some of the major challenges of the organization stated by the respondents to implement QMS properly and quickly were lack of employee's commitment, difficulty of performing internal auditing, lack financial resources, Insufficient knowledge about QMS, lack of QMS training, organizational structure limitation, documentations problem and so on. The benefits of the organization from implementation of QMS practices also listed by the respondent such as, improvement in productivity, improvement in efficiency, reduction in cost and waste, competitive advantage, increase in sale and market share, good customer relations, increase customer satisfaction.

CHAPTER FIVE

5. Summary of Finding, Conclusion and Recommendations

5.1 Summary of findings

The objective of this research has been to assess the practices of QMS and to identify the challenge faces to implement QMS (ISO 9001-2015) in EPHARM. For achievement of the research scientific method has been followed.

The seven QMS principles have been examined for this study to check whether properly practices or not in the organization. A questionnaire containing 39 items has been prepared for these seven principles and made interview for top management to get some information about the understanding of QMS, Customer and Supplier management of the organization, the benefits of the organization from practices of QMS and the challenges face to implement QMS properly and quickly in the organization. The reliability of the items has been done by using Chronbach's α coefficient and got 0.798 which is acceptable to make further analysis.

The demographic characteristics of the respondent shown in the analysis indicates that the most of them have an adequate education level and experiences in their assigned position to practice and implement QMS in the organization.

The major finding regarding to employees knowledge about implementation QMS indicates that the employees of the EPHARM use different forms of QMS in the organization and communicate with senior managements about QMS and they believes that QMS helps the organization to reduce defective work and number of problem. The majority of them agree that top management is responsible for implementing quality plan and check list.

Descriptive analysis of every variable has shown that the average mean value of customer focus 3.48, leadership 3.40, Engagement of people 3.25, process approach 3.39, continuous improvement 3.32, evidence base decision-making 3.60 and relationship management 3.39. From the finding the minimum average mean was 3.25 which is engagement of people and the maximum was 3.60 which is evidence-base decision making.

The overall mean average of customer focus was 3.48 which is above average value. From this finding, the researcher can understand that the company (EPHARM) works hard to satisfy its customers by assessing its current and future needs, formally collects compliance and resolve frequently and designing new product. Literatures on QMS system implementation say that focus on satisfying customer is the basic element in QMS. Westcott (2006) in the finding states that customer plays a major role in determining the level quality. The study done by Hackman and Wageman as cited in Abegaz states that getting information about customer is one of the most widely used QM implementation practices to improve the quality performance of the organization (Abegaz,2015).

The finding of the study reveals that the mean average of leadership and engagement of people was 3.40 and 3.25 respectively, which are also above average. This implies that top managements and senior executives' works hard to bring quality in EPHARM and the organization is try to creates good working environment which is suitable for employees to engage in activities that enhance quality system in the organization. Samson and others (1999) believes that leadership and human resources management are among strong predictors of the performance of QMS practices.

The mean average value of process approach variable was 3.39 which is also between averages and agree responses. From this result and the above analysis of process approach questions, the organization is applying a different process approach method which helps the organization to produce quality products but it has some gap on uses of innovation and creativity to improve processes.

The overall mean average of the variable continuous improvement is 3.32 which is above average. But the mean of the question asking about if the organization support the employees in personal care development was 2.96. The finding implies that the organization moderately try to continuously improving the quality of the product, but it needs some work on the improvement of employee's ability which is important to implement QMS quickly. Mohammed (2016) on his research conclude training and development have important impact on employee performance and productivity (Mohammod , R. 2016).

Evidence base decision making variable provide the average mean value of 3.60 that is the highest average mean value from all of the other six variables. This mean value

shows that the responses of the subject skewed towards agree responses that indicate the organization works hard on decision making based on evidence. Literatures on QMS support the argument of the needs of decision making based on evidence. ISO 2000 also support the need to make decisions based on facts (Hoyle, 2001).

The overall average mean of the last variable relationship management was 3.39. By looking the mean value which is between averages and agree responses, one can infer that the organization works moderately on the subject of relationship management to maintain relationship with suppliers. Newman (1988), suggested that the benefit from improved quality and process performance and continuous cost reduction comes from a company pursuing long term relationship with suppliers.

This study identify lack of employees commitment, difficulty of performing internal auditing, lack of financial resources, in sufficient training about QMS implementation, Organizational structure limitation and documentation problem as the major challenge of the organization (EPHARM) to implement QMS properly and Quickly and also identify improvement in productivity, improvement in efficiency, reduction in cost and waste, competitive advantage, increase in sale and market share, good customer relations, increase customer satisfaction as a benefits of EPHARM from implementing QMS practices. The research done by Forgaciu and others in 2008 on the title of Advantage achieved by the implement of QMS in Romanian pharmaceutical organization presents the benefits of QMS implementation, such as increase of domestic sales and exports, competitive advantages, flexibility and ability to respond to market opportunities and challenges faces in the organization to implement QMS such as profitability on a fluctuating market, competitiveness with foreign companies, globalization, speed of change, adaptability, growth and technologies (Forgaciu and others, 2008). Husseine and others (2017) in their research identify lack of awareness, resistance to change, existence of accreditation, commitment of top management, time management, and resource availability as challenging factors in the implementation of QMS.

5.2 Conclusion

Data analysis, interpretation, and presentation of the results enabled to draw many lessons on the practice of quality management system among internal customers (Employees of EPHARM) which helps the company to draw lessons and conduct improvement plan in relation to the management's responsibility in implementing and practicing QMS.

The researcher concludes that:

-EPHARM has the employees with an adequate educational level, experiences and a good awareness about QMS implementation.

-The organization fairly work to satisfy the customer by assessing its current and future needs, formally collect compliance and resolve frequently and designing new product.

-Top managements of the organization and senior executives are committed in implementation and practices of QMS to improve the quality of the product.

-EPHARM need more works on creating effective system for employees to make suggestion to management on how to improve quality.

-The organization (EPHARM) have some gap on uses of innovation and creativity that used to improve process and quality of product.

-EPHARM moderately works on continuous improvement by identify and managing the common types of faults and using different types of continuous improvement tools like brainstorming, check sheet and statistical process control and need some investment on employees personal career developments like training and sponsoring for education .

-The organization works hard on making quality related decision based on evidence and also has good communication and exchange information with supplier.

It can also conclude that lack of employees commitment, difficulty of performance internal auditing, lack of financial resources, insufficient training about QMS implementation, Organizational structure limitation and documentation problem are major challenges that faces to EPHARM to implement QMS properly and Quickly and it can also conclude implementing the system in EPHARM bring the benefit of improvement in productivity, improvement in efficiency, reduction in cost and waste,

competitive advantage, increase in sale and market share, good customer relations, increase customer satisfaction.

Finally, the researcher concludes that the Questionnaire asking about the practices of the seven principles of QMS and interview bring positive results and also the organization successfully practicing QMS principles.

5.3 Recommendation

From the conclusions of the research findings, the following recommendations were forwarded:

- The researcher recommend the organization to creates effective systems or methods to employees like prepare meeting and log books to give suggestion to management about work related problems and its solution, because it is very important to improve the quality of the product on time.
- To use new technological machine, give training to employees to upgrade the knowledge, make the work place suitable for employees to work freely to solve the gaps on using innovation and creativity.
- Management should to prepare awareness creation program on the purposes and benefits of QMS in all level to solve some challenges faces to quickly implement QMS.
- To sustain operational and production effectiveness it should further maintain the continuous assessment and consequent revision of the QMS implementation process.

Recommendation for future research:

This research is describing effort which only attempted to give answers to the research questions that triggered the study. It also contributes some understanding to the body of knowledge by presenting additional experience on QMS Practices and implementation at EPHARM S.C. However, it could not be complete by itself and further investigations need to be made for better understanding of the situation. An important area that needs the attention of future researchers will be to include: the impact of integrated implementation of GMP and ISO quality management systems.

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Appendix

ST. MARY'S UNIVERSITY

School of Graduate Studies

Institute of Quality and Productivity Management (IQPM)

QUESTIONNAIRE

This questionnaire is to be filled by selected respondents from Ethiopia Pharmaceuticals Manufacturing S.C. (EPHARM).

Dear Respondents:

This questionnaire is designed to collect information regarding the implementation of Quality Management system in your company (EPHARM). Moreover, the study will contribute towards the fulfillment of the researcher's Degree of Masters of science Degree in quality and productivity Management.

I kindly ask you in all regard to fill the questionnaire carefully at your best knowledge. The accuracy of information you provide determines the ultimate reliability of the study.

Note: Your answers will be strictly confidential and will only be used for academic purposes.

Contact Address: Berhanu Degu Tel:- +251913700035 or

E-mail; - berhanudegu12@gmail.com

Thank you in advance for your cooperation and timely response!

Part One: Demographical Information - Please put 'X' in the box.

1. Age ☐below 25 ☐25-30 ☐30-35 ☐35-40 ☐>40

2. Years of experience in the organization

☐<5yrs ☐ 5-10yrs ☐10-15yrs ☐>15yrs

3. Education Level ☐Certificate ☐Diploma ☐1st Degree ☐Master and above

4. Your position in the organization ……

Part Two. Questions to be responded Yes or No, and with Comments

This part helps the researcher to identify basic information regarding to quality management system (QMS) implementation in your respected company's activities. Please respond to each of the listed statement by saying yes or no and put you comment on it.

No	Statement	Yes	No
1	Have you used any form of QMS in your current Company?		
2	Have you ever been communicated about QMS from Senior Management in your current Company?		
3	Do you think the company should have a Quality Manager responsible for implementing Quality Plans and Checklists?		
4	Do you agree QMS helps to reduce defective work and the number of problem that occurs in your Organization?		
5	Have you ever received training in any form of QMS		

Part Three

This part of the questionnaire was developed based ISO 9001-2015 standard, which focuses on seven quality management principles that Top management can apply for organizational improvement: Therefore, the following questions are helpful to the researcher **to know the level of the management responsibility in your Company.** Can you please show your response to the statements by circling the numbers in the column using the following rating scale (Likert Scale). Where: 1 = strongly Disagree 2 = Disagree 3 = Average (Undecided) 4 = Agree 5 = Strongly Agree

Item	Statement	Ratings				
With respect to customer focus						
1	Your organization emphasizes on assessing current and future customers' needs and expectations	1	2	3	4	5
2	Customer complaints are frequently resolved by your organization	1	2	3	4	5
3	The organization adopts formal ways to collect customer complaints	1	2	3	4	5
4	Customers' complaints are studied to identify patterns and prevent the same problems from recurring.	1	2	3	4	5
5	The company incorporates data on customer expectations and/or satisfaction when designing new products	1	2	3	4	5
With regard to leadership						
1	The senior executives of the organization provide highly visible leadership in maintaining an environment that supports quality improvement	1	2	3	4	5
2	Top management is a primary driving force behind quality improvement efforts	1	2	3	4	5
3	The senior executives consistently participate in activities to improve the quality	1	2	3	4	5
4	The senior executives have demonstrated an ability to manage the changes (e.g., organizational, technological) needed to improve the quality	1	2	3	4	5
5	The senior executives appreciate efforts that improve quality throughout the organization	1	2	3	4	5
6	Senior executives involve on activities that enhance customer satisfaction by obtaining information on needs and suggestions for quality improvement directly from customers.	1	2	3	4	5
In relation to engagement of people						
1	Every employee's thought has been used as an input to make any quality decision.	1	2	3	4	5
2	Employees' involvement and empowerment encourages them to exert the best of their abilities to improve quality	1	2	3	4	5
3	Employees at work are interested in and positive, even excited about their jobs and are prepared to go the extra mile to improve quality	1	2	3	4	5
4	The organization's employees are given education and training in statistical and other quantitative methods that support quality improvement	1	2	3	4	5

5	The organization has an effective system for employees to make suggestions to management on how to improve quality	1	2	3	4	5
With a view of process approach						
1	The organization identifies the key business processes by prioritizing on the basis of the value chain, customer needs and strategic significance, and using process models and definitions	1	2	3	4	5
2	The organization Manages processes systematically by giving process ownership to the most appropriate individual or group and resolving process interface issues through meetings or ownership models	1	2	3	4	5
3	The organization reviews processes and sets improvement targets by empowering process owners to set targets and collect data from internal and external customers	1	2	3	4	5
4	The organization uses innovation and creativity to improve processes by adopting self-managed teams, business process improvement and idea schemes	1	2	3	4	5
5	The organization change processes and evaluate the benefits through process improvement or re-engineering teams, project management and involving customers, and suppliers.	1	2	3	4	5
With respect to improvement within the Company						
1	Everyone in the organization is aware of the need to improve continuously and show their efforts for improvement	1	2	3	4	5
2	The organization supported employees even in their personal career developments like sponsoring for education and providing scholar ships	1	2	3	4	5
3	The causes of all the possible faults are identified, informed and employees are well trained on common types of faults and how to manage problematic situations when happened	1	2	3	4	5
4	Continuous improvement tools (brainstorming, check sheet and other statistical process control) are applied on regular basis	1	2	3	4	5
5	The organization is continuously improving itself by trying to apply the latest knowledge and technologies in the industry	1	2	3	4	5

In regard to Evidence-based decision-making						
1	The organization encourages statistical measurements and analysis throughout the organization	1	2	3	4	5
2	Every activity in the organization is recorded by employees	1	2	3	4	5
3	Top management seeks summarized reports of the facts recorded on a daily basis to make quality related decisions	1	2	3	4	5
4	The organization provides planned targets for every employees and subsequent decisions are made based on deviations of actual and targeted outcomes	1	2	3	4	5
Regarding to Relationship Management						
1	The organization plans and manages the external partnerships which is in line with its overall policies and strategies, being designed and developed to support the effective operation of its processes	1	2	3	4	5
2	The organization maintains successful partnerships with its suppliers through good communications and exchange of information	1	2	3	4	5
3	The organization recruit suppliers and have a way to retain them that supported the organization to improve quality	1	2	3	4	5
4	The organization have closer relationship with its suppliers which helped the organization to get technical support from its suppliers when needed rather than merely exchange of goods	1	2	3	4	5

Interview

Survey Instruments; Interview Questions

1. What do you understand about QMS?

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2. How do you manage your relationship with customers? What do you do to satisfy your customers by providing quality services?

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3. Do you believe top management involvement have significant effect on quality? Can you explain Top management's activities in your organization to enhance quality system? ---
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4. How do you make decisions on quality issues? Can you explain the way decisions are made in your organization?---
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5. How do you manage your suppliers? Do you believe your relationship with suppliers affected quality in the organization? How do you explain it? ---
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6. What are the major challenges faced by your Company in practicing quality management system?

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7. What are the benefits of QMS practices implementation in your organization?

Thanks for your assistance! It is Greatly Appreciated