ST. MARY'S UNIVERSITY
SCHOOL OF GRADUATE STUDIES

PRACTICES AND CHALLENGES OF QUALITY MANAGEMENT SYSTEM (ISO 9001-2008) IN THE PHARMACEUTICAL INDUSTRY: THE CASE OF EPHARM ETHIOPIA

BY

KIDUS FREW BAYISSA

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A THESIS SUBMITTED TO ST. MARY'S UNIVERSITY, SCHOOL OF GRADUATE STUDIES IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE AWARD OF THE DEGREE OF MASTER OF BUSINESS ADMINISTRATION

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APPROVED BY BOARD OF EXAMINERS

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DEDICATION

I dedicate this thesis to my beloved patient wife, our little princess and my mother. Gelila, It is difficult to imagine forget to resume the journey without your perseverance, thank you for your love, encouragement, patience and unconditional support. My little blessing your arrival to our life has changed our house enormously. My Mother W/ro Atsede Mekonen much gratitude for the words of courage you preach me during my low points.

DECLARATION

I, the undersigned, declare that this thesis is my original work, prepared under the guidance of Asst. Professor Shoa Jemal. 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.

_____ _____

Name Signature

St. Mary's University, Addis Ababa **January, 2016**

ENDORSEMENT

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

Shoa Jemal _____

Advisor Signature

St. Mary's University, Addis Ababa **January, 2016**

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LIST OF ACRONYMS AND ABREVIATIONS

ISO	International Standards Organization (International organization of standards)
QMS	Quality Management System
GMP	Good Manufacturing Practice
FMHACA	Food Medicine Healthcare Administration and Control Authority of Ethiopia
APF	Addis Pharmaceuticals Factory
EPHARM	Ethiopian Pharmaceutical Manufacturing S.C
PDCA	Plan Do Check Act
TQM	Total Quality Management
KPI	Key Performance Indicators
SPSS	Statistical Package for Social Sciences
EFQM	European Foundation of Quality Management
QC	Quality Control
CGMP	Current Good Manufacturing Practice
MEDTECH	Pharmaceuticals and Medical Equipment Importer and Distributor

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Abstract

Quality is a widely used concept that has become one of the primary agenda in most manufacturing and service providing organizations. Several literature and empirical studies showed that Implementation of ISO based QMS has been proclaimed to have importance in improving quality of products, organizational performance and bringing customer satisfaction. Most of the pharmaceuticals manufactures in Ethiopia are not practicing this system and little or no information is available on what were the benefits obtained and challenges faced by those companies which have undergone the implementation and certifications processes of ISO 9001:2008 QMS. This research basically focuses on trying to get answers to these questions. A descriptive research approach was employed using a self-administered questionnaire to get primary data from employees of EPHARM S.C. These findings are concrete and valuable hence it can be concluded that implementing the system brings the benefits of building the image of company, creating a better competitive advantage on top of its competitors, improved awareness of employees to quality, increased profit and reduced or fewer rejections of products. There has been a reduction in cost of raw materials, effective management system is performed, production volumes have increased and customer orders are shipped on time unlike before. Efforts to determine the challenges of implementing quality management system revealed that lack of adequate information, lack of management commitment and lack of capacity by personnel to be the major challenges that impede the effective implementation of the system. In spite of the few challenges faced by the company to develop, implement and maintain ISO 9001:2008 Quality Management System, broadly asserted benefits of implementing it were found significant as a whole and has resulted in good impact on the performance of the company. This study finally recommends, it is important 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.

Keywords: *QMS, ISO 9001:2008, Implementation, Pharmaceuticals Industry, practice, benefits, challenges.*

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CHAPTER ONE: 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 definitions of some terminologies.

1.1 Background of the Study

An effective Quality Management System focuses on systematically developing and communicating a customer-focused mission, strategies and action plans; listening and responding to the customers' 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).

Quality is a widely used concept that has become one of the important agendas in most organizations. This is 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 filings) and other internal and external customers (Samrinah, 2011).

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. To identify and implement appropriate product quality improvements, process improvements, variability reduction, innovations, and pharmaceutical quality system enhancements, thereby increasing the ability to fulfill a pharmaceutical manufacturer's own quality needs consistent quality follow up. Quality risk management can be useful for identifying and prioritizing areas for continual improvement (Shemwell, 1998).

Ethiopia has been registering a remarkable growth in its economy in the last ten years and the trend is estimated to continue. 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).

Leadership is essential to establish and maintain a company-wide commitment to quality and for the performance of the pharmaceutical quality system. A better understanding and effective implementation of appropriate quality management system enables a pharmaceutical organization to fulfill the requirements of end users, regulatory bodies and the society at large. Moreover, as the pharmaceutical industry moves into different forms of partnerships and vendor arrangements the implementation of a structured quality management system in drug safety, regulatory affairs and medical affairs is necessary in order to guarantee compliant delivery of services and products. Pharmaceutical industry is amongst most astringently regulated manufacturing units (Daniel Amare, 2010).

The pharmaceutical industry, in Ethiopia, is governed by rules, and manufacturing conditions, at all levels–Good Manufacturing Practice (GMP) which have been enforced by the Food Medicine Healthcare Administration and Control Authority (FMHACA). The GMPs are a regulatory requirement mandated by law for manufacturing pharmaceuticals for distribution that a pharmaceuticals manufacturer must be in compliance with these regulations. ISO, on the other hand, is a voluntary certification obtained by a company when they determine that the certification is beneficial to their operations and/or marketing strategies. All pharmaceuticals manufacturing companies have to get a GMP approval prior to marketing their products to ensure that their products will be of the required quality (FMHACA, 2014).

ISO 9001 is one of the standards within the range of ISO 9000 standards. It is a document of approximately 30 pages which is available from the national standards organization in each country. The specific requirements for an organization are: needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements and aims to enhance customer satisfaction through the effective application of the system. All requirements are generic and are intended to be applicable to all organizations, regardless of type, size and product provided. It is widely acknowledged for: improves business, often having a positive effect on investment, market share, sales growth, sales margins, competitive advantage, and avoidance of litigation (ISO, 2000).

Contrary to the widely spread benefits of implementing quality management system, most of the pharmaceuticals manufactures in Ethiopia are not practicing this system and little is known about what the benefits gained and challenges faced by implementing the QMS in those firms currently practicing the system. This needs a closer investigation and it is the main reason that motivates the researcher to conduct this study and the current study tries to make a closer exploration of the subject matter.

1.3 Statement of the Problem

In Ethiopia there are about 16 pharmaceutical manufacturing companies. Out of these, only three manufactures are currently implementing the ISO 9001:2008 QMS (Pharmanet, 2014). Although all the 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 were benefits

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 systems 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 9001:2008 QMS. This research basically tries to answer the following research questions:

- What does the practice of ISO 9001:2008 quality management system looks like at EPHARM S.C.?
- What are the most important benefits of implementing the quality management system in the EPHARM S.C?
- What are the major challenges of implementing the quality management system in the EPHARM S.C?
- What is the best possible strategy for strengthening and promoting the implementation of ISO 9001:2008 quality management system by the EPHARM S.C?

1.4 Objectives of the Study

1.4.1 General Objective

The general objective of this study is to describe the practices and challenges of quality management system (ISO 9001-2008) in the pharmaceutical industry: The case of EPHARM Ethiopia.

1.4.2 Specific Objectives

- To explore the practice of ISO 9001:2008 quality management system EPHARM S.C.
- To find out the most important benefits of implementing the quality management system.
- To identify the major challenges of implementing the quality management system.
- To forward appropriate recommendations to the company based on the findings of the study.
- To come up with an important strategic directions to be further researchable by the company on the topic of quality management system.

1.5 Significance of the Study

This study has significance in that it:

1. Helps to determine the status and impact of implementing QMS in the EPHARM S.C.
2. Enables in showing business organizations on the importance, if any, of implementing QMS for improving their organizational performance and ensuring quality products services and by so doing getting a competitive advantage.
3. Adds to the body of knowledge by providing additional experience in the Ethiopian context.

1.6 Scope of the Study

This research is limited to exploring the implementation of the Quality Management System in the selected pharmaceutical manufacturing firm- EPHARM S.C. It tries to address the practices, benefits and challenges of implementing ISO 9001:2008 Quality Management System. The study does not include customers and suppliers of this company. Hence interpretations should be made carefully.

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 Organization of the Study

This study is divided into five chapters. The first chapter provides a background about the study problem and objectives and its approach. The second chapter discusses on relevant literature review on the topic to gain understanding of the fundamental requirements, practices, benefits and challenges in the development implementation and maintenance of quality management system. Chapter three gives an account of the research methodology description and justification of the design and research procedure followed in this study. Chapter four presents and analyses data to find out results which could answer the research questions. Chapter five focuses on drawing conclusions based on the findings, and making pertinent recommendations.

CHAPTER TWO: REVIEW OF RELATED LITERATURE

This chapter provides an overview of literature that is related to the research problem presented in the previous chapter. Definitions of quality, quality management system, definition of ISO its implementation, benefits and relations with GMP, overview of the key criteria of a QMS, drivers for certification and perceived impacts and challenges as well as summary of the literature findings are briefly discussed.

2.1 Quality Management System and the ISO

Quality has been characterized by many authors as something that relates to the results of an ongoing improvement that includes products, services, processes and people to fulfill customer expectations and customer satisfaction. Formal writing on the concept of quality can be found from quality gurus such as Deming (1986), Juran (1994), Crosby (1979), Feigenbaum (1991) and Ishikawa (1985). These gurus have laid the foundation for understanding most concepts of quality management such as Total Quality Management (TQM), Total Quality Control (TQC) and Quality Management System (QMS) Samad (2009), Knowles (2011).

The International Organization for Standardization (ISO) was founded in 1946 in Geneva, Switzerland, where it still is based. Its mandate is to promote the development of international standards to facilitate the exchange of goods and services worldwide. Several countries have adopted the ISO 9000 series as their national standards and thousands of organizations throughout the world have quality systems registered to the standard, Besterfield (2003), David & Stanley (2003).

According to a recent report by the ISO Secretariat Committee (ISO/SC), until October 2012, the International Organization for Standardization (ISO) has a membership of 164 national standards bodies from countries large and small, industrialized, developing and in transition, in all regions of the world. ISO's portfolio of more than 19400 standards provides business, government and society with practical tools for all three dimensions of sustainable development: economic, environmental and societal (ISO, 2011). Of these, ISO 9001 and ISO 14001, which give the requirements for, respectively, quality management and environmental management systems, are among ISO’s most well-known and widely implemented standards ever.

The ISO 9001 series of standards is generic in scope. By design, the series can be tailored to fit any organization's need whether it is large or small, a manufacturing or service organization (Besterfield, 2003). They are used worldwide by businesses and organizations large and small, in public and private sectors, by manufacturers and service providers, in all sectors of activity.

ISO 9001 Standard had its latest revision by 2008. This has 8 clauses of requirements, as below:

Clause 1–Scope
Clause 2–Normative References
Clause 3–Terms and Definitions
Clause 4_Quality Management System Requirements
Clause 5_Management Responsibility
Clause 6_Resource Management
Clause 7–Product Realization
Clause 8–Measurement, Analysis and Improvement

Clauses 1 to 3 are for information only. From clause 4 to 8 are for the organizations to comply with, especially the clause 4 being an umbrella clause, includes the requirements in a macro level. All these clauses 4 to 8 have detailed the requirements through multiple sub clauses. If any of such clause requirements not applicable (from the clause 7) shall be addressed in the exclusion section of the quality manual with suitable justification (ISO, 2011).

Central in the practice of Quality management system are the basic principles governing and which have gained a continuing importance. The system basically Involves 8 principles which include Customer focus, Leadership, involvement of people, process approach to decision making, system approach to management, factual approach to decision making, mutually beneficial relationship with suppliers and, Continual improvement (ISO,2011).

2.2 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 9001:2008 standards. In implementing a Quality Management System, 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 (EN-ISO 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 et al., 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.

2.3 ISO and GMP

The understanding and implementation of appropriate quality management system model enables a pharmaceutical organization to fulfill its ethical as well as regulatory responsibility including management of identity, quality, safety, purity and efficacy of finished medicinal products (Neetu et.al, 2011).

The concept of current pharmaceutical quality management system is based on an internationally harmonized guidance ICH Q10, which describes a model for a pharmaceutical quality system that encourages the use of science- and risk-based approaches and can be implemented throughout the different stages of a product lifecycle. It serves as an effective quality management system for the pharmaceutical industry. It integrates the fundamentals of good manufacturing practice (GMP) regulations, International Organization for Standardization (ISO) quality concepts, and complements ICH "Q8 Pharmaceutical Development" and ICH "Q9 Quality Risk Management (Neetuet.al, 2011). Fundamental elements for effective pharmaceutical quality systems are:

- Managerial review of process performance and product quality
- Process performance and product quality monitoring system
- Corrective action and preventive action (CAPA) system
- Change control management system

This is the minimum list of quality system elements for any pharmaceutical manufacturer. The objective is to establish, implement, and maintain a system that allows the delivery of products with the desired quality attributes. Quality risk management also help in developing effective monitoring and control systems for specified process performance that in turn establishes the capability of processes (Neetu et.al, 2011).

2.4 Drivers for Certification and Perceived Impacts and Challenges

The drivers for ISO 9001 certification vary from one company to another and from one country to another, though the basic themes supporting ISO9001 were the customer satisfaction and continual improvements. Kumar and Balakrishnan (2011) also cited Johannes (1996) summarizing these drivers as pressures from existing customers, promotional value and the desire of improving management processes and enhancing customer service. Magd and Curry (2003) as cited by Kumar and Balakrishnan (2011), studied ISO 9001 in Egypt and they

concluded that the most common reasons for seeking certification in Egypt were to improve the efficiency of the quality system and pressures from competitors/foreign partners.

Daniel (2010), in his study on the impact of ISO 9000 certification on Quality management practices in EFFORT corporations in Ethiopia, concluded that the main drivers for the decision to go for ISO 9000 implementation and certification inside the selected EFFORT organizations were improving the organizations public image and establishing a quality management system. The highest motivators improving process and procedures, improving product or service quality, while the least motivating factor reducing the number of customer audits.

Many researchers studied the ability of ISO 9001 in achieving its main objectives of adding value to organizations implementing it in different economies in general or by different sectors in particular. For example, Kumar and Balakrishnan (2011) referring studies made by Pan (2003) discussed ISO 9001 and ISO 14001 implementation in Far East Countries, namely in Taiwan, Japan, Hong Kong and Korea. The study involved investigating firms' motivation for certification, their implementation experiences and the benefits received. The main conclusion for implementing ISO 9001 in these countries was positive in general with some differences in motivation for and benefits gained after implementing ISO 9001. He concluded that there are common factors between these countries to go for ISO 9001 certification, namely, external pressure, gaining competitive edge, internal and external portions and improvement of public relations. The common benefits of ISO 9001 certification among these countries are improved competitive edge, and improved public relations.

Although to a varying level of importance, several empirical researches Forgaciu & Rahau (2008), and Giannopoulos et.al, (2007) also revealed that well-managed quality systems will have impact on:

- customer satisfaction, loyalty and repeat business
- market share
- operational efficiencies
- flexibility and ability to respond to market opportunities
- effective and efficient use of resources
- cost reductions
- competitive advantages
- participation and motivation of human resources

- improved internal communication
- industry reputation better advertising potentials
- control on all processes
- improved delivery and reduction of defective products

According to Daniel (2010) the benefits gained by implementing ISO 9001 QMS in the EFFORT corporate organizations were improved process and procedures, improved awareness of employees for quality, provision of better customer service.

Even though more than a million organizations have been certified to ISO QMS 9001 standard till date, and also despite the huge number of research findings revealing the perceived benefits of implementing QMS, there were certain common problems faced by majority of these certified organizations, which influenced their business performance. Kumar and Balakrishnan (2011) summarized these problems broadly as:

- Leadership related issues (Inadequate Commitment by Top Management)
- Lack of Motivation, Recognition, Organizational learning, Strategic Planning and long term focus
- Strategy Related Issues (Mission, Vision, Values, Strategic Planning, Strategy Mapping, Cascading down the line, KPIs and Initiatives)
- Quality System related issues (Weak PDCA cycle, generic system, internal audit not in depth, non-value adding meetings/trainings and excessive paperwork)
- Society oriented gaps (Corporate Social Responsibility, Environmental Management and Sustainability)

2.5 Relationship with ISO 9004:2000

(CDER Guidance) ISO 9001:2000 and ISO 9004:2000 are two stand-alone documents which were designed to be a consistent pair of standards. ISO 9001:2000 defines the requirements which have to be fulfilled in order to accomplish compliance with customer needs and continual improvement of the Quality Management System. In addition, if considered necessary, this standard can be used to achieve third-party certification. ISO 9004:2000 develops the concept in a more extensive and intensive manner as a roadmap for organizations on their way to excellence with links to:

- the European Foundation of Quality Management (EFQM) Business Excellence Model
- the Balanced Score Card Approach

2.6 Overview of the key criteria of a Quality Management System

(APIC/CEFIC) An effective QMS focuses on systematically developing customer-focused strategies and action plans, listening and responding to the customer, empowering employees to continuously improve their work processes, and gathering and analyzing key performance indicators. A facility addressing the key criteria of a QMS is systematically:

- Communicating a quality-focused mission statement;
- Conducting customer (resident/family) satisfaction surveys
- Conducting employee satisfaction surveys
- Gathering and analyzing performance data and information
- Recording and acting on customer concerns
- Continuously improving its processes and outcomes

2.7 Summary of the Literature Findings

From the foregoing discussion on the review of literature and empirical research the concept can be framed in such a way that, Quality Management System is a management system exercised to direct and control an organization with regard to quality. For companies to engage themselves in to the task of implementing an ISO based QMS, they should have a factor or factors that compels them to do so, and these factors could be internally driven or externally driven. The development and implementation of such new initiatives could face challenges at various levels in the process or from any corner within or outside the organization. Successful implementation of the system is generally followed by the benefits obtained or perceived to have been obtained and revealed in various forms post implementation which may be directly or indirectly related to the reasons that triggered the implementation.

Despite the presence of significant number of literature and research studies on quality management system in other parts of the world, similar studies are lacking in Ethiopian business firms in general, and in the pharmaceutical industry in particular. Hence, the status of such motives, benefits and challenges in the organizations that have undertaken implementation process particularly in the pharmaceuticals sector could not be traced and needs closer investigation.

CHAPTER THREE: RESEARCH METHODOLOGY

This chapter presents the activities and processes that were undertaken to gather data for the research work. It gives full details of how data are collected and processed for this research work. The discussion was centered on the following: Research design, population under study, sampling techniques and sample size determination, data sources and data collection tools, validity and reliability test, data analysis method and ethical considerations.

3.1 Research Design

Since the objective of this study was to describe the practices, benefits and challenges involved in the implementation of ISO QMS the study is a descriptive type of research. The research design employed in this study is descriptive research design. It presents an opportunity to fuse both quantitative and qualitative data as a means to reconstruct the 'what is' of a topic. The design was preferred for it is exploratory in nature and in the capacity of finding the truth and describing the situation systematically. It gives researcher the ability to look at whatever is being studied in so many various aspects and can provide a bigger overview.

3.3 Sampling Technique and Sample Size Determination

EPHARM S.C. a pharmaceutical company which has implemented the ISO 9001:2008 QMS were used for the study. A total of 460 employees (with the exception of casual and/or daily labourers and staff in finance) were the target populations included in the study. The research instrument used is a well-structured self-administered questionnaire distributed to people at various levels in the organization. Data obtained from the questionnaire was analyzed and the findings evaluated using mean, frequency standard deviation and other statistical tools.

There are about 16 pharmaceutical companies currently working in the country. Only three of them have implemented the ISO QMS. Out of which EPHARM was used as target populations for the study. All employees in the organization were included in the study, according to their stratum by staff attribution starting from the managerial position all the way to operations, and a sample size sufficient enough to represent the population was taken randomly for the questionnaire survey. Management members in these organizations are also included. Since the population under study is considered to be finite, the following formula is employed to calculate the sample size (Kothari, 2004).

$$n = \frac{z^2}{e^2} \quad \frac{p.q.N}{(N-1)+Z^2 .p.q} \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots (1)$$

Where, n=sample size

p=proportion of the population containing the major interest

q=1-p

z = number of standard deviation at a given confidence level (α= 0.05),

e = acceptable error (precision) and

N is the total population size

Hence the sample size computed out of the 508 employees (with the exception of casual and/or daily labourers and staff in finance) was 100 respondents in total. The number of questionnaire prepared was 100 accordingly.

3.4 Data Sources and Data Collection Tools

Both primary and secondary data sources were used for the study. A self-administered questionnaire designed for employees at all levels of the organization was employed to obtain primary data. The questionnaire method was preferred in its ability to find large amount of sample and relatively easy to analyse and cost effective. The questionnaire was designed using five levels Likert Scale (Cooper and Pamela, 2003) to obtain the required information. The Likert scale was 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.

Secondary data obtained from review of literatures, recorded documents, published and unpublished, including relevant books, reports, and journals and relevant materials were used as appropriate for the study. The primary data collected was checked, filtered and entered for further statistical analysis with the latest version of SPSS-21 (IBM, 2010) software and also employed ranking, the weighted average methods mean, and the mode.

3.6 Data Analysis Method

The quantitative data collected is checked by the researcher and entered into a data entry structure developed in SPSS (Statistical Package for Social Scientists) software. The quantitative

parts of the questionnaire are coded based on a Code Book prepared based on the questionnaire. The data entered into SPSS was cleaned/edited by the researcher before any analysis is made. Data analysis is made by using SPSS version 21 and based on the tabulation plan prepared for the purpose. Illustration like tables and charts were used to ensure easy and quick interpretation of data. This method is used because it describes the result in a way that is understandable to the reader, convenient to identify, compare, describe and reach at a conclusion.

3.6.1 Validity and Reliability 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 .70. This indicates that there was a high degree of internal consistency amongst the test items (Streiner and Norman, 1989).
As a result, Cronbach's alpha showed a satisfying reliability, above the 70% as indicated in the table below.

Table 3.1: Reliability Statistics

Cronbach's Alpha	N of Items
.927	28

Source: Own survey 2015 (SPSS)

Table one above shows the computed result for reliability test which is 0.927 indicates that there was a high degree of internal consistency among the test items. This means that the items were closely related in terms of idea and do not create confusion or cause misunderstanding to the respondents.

3.7 Ethical Considerations

The researcher maintained scientific objectivity throughout the study, recognizing the limitations of competence. Every person involved in the study was entitled to the right of privacy and

dignity of treatment, and no personal harm was caused to subjects in the research. Information obtained was held in strict confidentiality by the researcher. All assistance, collaboration of others and sources from which information was drawn is acknowledged.

CHAPTER FOUR: DATA PRESENTATION, ANALYSIS AND INTERPRETATION

This chapter provides information on the collected data procedure adoption, analysis of the data and findings. The responses from the respondents are described, analysed, and inferences made to established relationships. The data is presented in tables and diagram as well as analyzed and discussed in brief.

4.1 Profile of the Organization

The first part of the questionnaire was used to gather demographic information on the respondents and the organization. Data obtained from the questionnaire and secondary data sources are summarized.

EPHARM is the first pharmaceutical company in Ethiopia manufacturing human pharmaceuticals. It is making headway in implementing Current Good Manufacturing Practice (cGMP). As to the government's program to privatize public enterprise so that they could be competitive in the market both in price and quality, MEDTECH Ethiopia that has been a major customer of EPHARM, acquired the factory and started to transform it to a greater level. Currently EPHARM produces about 52 kinds of pharmaceuticals which are sold locally. As part of Ethiopia's effort to transform its economy from agriculture dominated into an industry led one using its successive plans including a five year Growth and Transformation Plan. EPHARM has continuously improved based on lessons it has learned in the past 50 years. EPHARM has been implementing ISO 9001: 2008 and 14001:2004 quality management systems since 2008 (EPHARM Bulletin, 2014).

The company currently has about 508 employees out of which are 460 are permanent employees which were taken as target population in the company. From the sample size computation we have observed a result of 100 samples to be collected that would represent the entire population. However, out of the 100 questionnaires distributed only 95 of them were filled and returned which were made ready for the analysis. The other five samples were not replied for reasons beyond the researcher's understanding.

Demographic characteristics of the respondents, analyses and interpretation based on the data collected from the respondents of the study area are presented in this chapter. Moreover,

summarized results of the demographic profile of respondents and the response towards the items included in the questionnaire as well as descriptive statistics were described, analyzed and synthesized in tables, percentage and charts with the help of Statistical Package for Social Science (SPSS) Version 21.

4.2 Demographic Characteristics of the Respondents

Demographic characteristics including: gender, age, current educational background, and response towards all variables are summarized using frequencies and percentages.

Table 4.1: Gender of the respondents

Item		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	F	27	28.4	28.4	28.4
	M	68	71.6	71.6	100.0
	Total	95	100.0	100.0	

Source: Own computation based on data collected (SPSS result)

Table Two above shows that the majority of the respondents 68(71.6%) are males while the remaining 27(28.4%) are females. This shows that the large majority of the EPHARM staffs are males and this study is also conducted based on respondents which is largely made out of males.

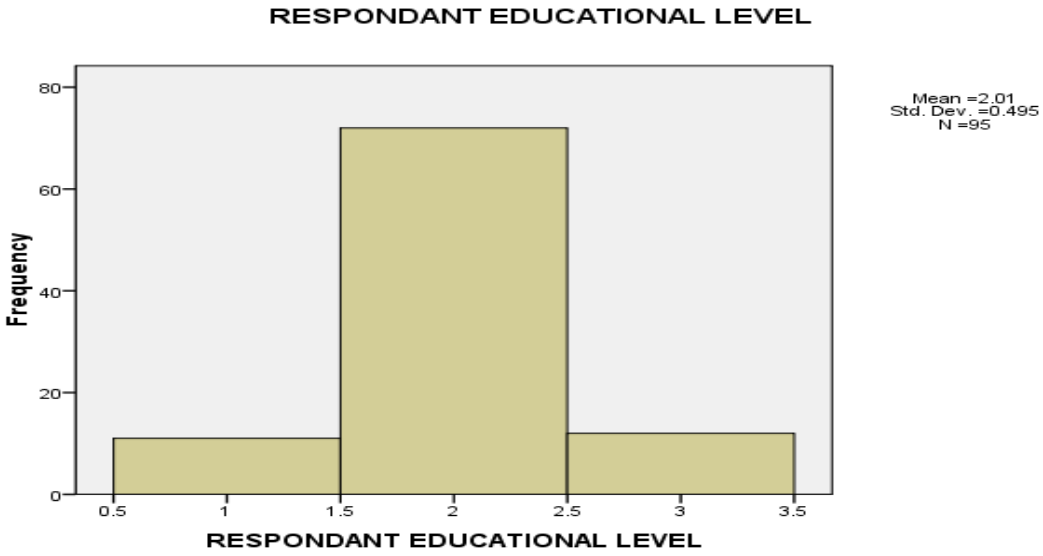
Table 4.2: **Age of Respondents**

Item		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	BELOW 24	1	1.1	1.1	1.1
	25-35	57	60.0	60.0	61.1
	36-45	22	23.2	23.2	84.2
	46-55	12	12.6	12.6	96.8
	ABOVE 55	3	3.2	3.2	100.0
	Total	95	100.0	100.0	

Source: Own computation based on data collected (SPSS result)

The age distribution of the participants were: 60% of the respondents were in the age group of 25-35, 23.2% of the respondents were in the age group of 36-45, 12.6 % were in the age group of 46-55 and 3.2% of the respondents were above 55. This shows that majority of the participants i.e. 60% of them were between the ages of 25-35. The main advantage of EPHARM in terms of hiring large number of young employees is the degree of ease to accept change quickly. Which is why the results of the implementation of QMS was effective and efficient with in short period of time.

Figure 4.1: **Educational level of the Respondents**



Source: Own computation based on data collected (SPSS result)

The respondents were asked to indicate their highest level of education they had achieved and 72 (75.8%) of the respondents have bachelor degree, 12(12.6%) have Masters Degree and 11(11.6%) of the respondents have Diploma. It can be seen from the table as well as the following graph that most of the respondents i.e. 75.8% are first degree holders. Surely the educational level of the employees positively affects the organization in implementing QMS quickly and effectively. Educated employees are quick to receive new ideas and incorporate and implement them as well. This in return benefits the organization in terms of return on investment and higher profitability in short period of time. Furthermore, these employees are active in understanding the benefits of QMS at all levels of the organization and endeavor more to come up on how to improve and also anticipate and predict customers need effortlessly.

4.3 Data Analysis

4.3.1 Practices and Benefits of QMS

It is important to note here that the benefits, both tangible and intangible, are difficult to quantify. However a list of 24 benefits cited in literature (Forgaciu and Rahau 2008, Lundmark and Westlius 2006; Giannopoulos, *et.al*, 2007; ISO 2011; Thilakarathne and Chithrangani 2014), were used for this study and subjected for rating by the respondents. Responses obtained by employing the 6 item benefit questions rated on a Likert scale of 1 to 5 ranging from very low to very high respectively were used to analyze the benefits of implementing ISO 9001:2008 QMS in the organizations. Cronbach alpha reliability analysis of the 24 items revealed 0.927 indicating an acceptable level of internal consistency and reliability.

Table 4.3: Summary of Improvement of Customer Service

Statistics		Production is more aligned with customer requirements	The organization is geared towards putting the customer first as opposed to before	Customer orders are shipped on time unlike before	Most customer orders are filled from existing stock more than before(back-orders)	Customer complaints have reduced	The level of stock-outs in the market has improved
N	Valid	95	95	95	95	95	95
	Missing	0	0	0	0	0	0
Mean		3.95	3.80	3.89	3.88	3.86	3.52
Mode		4	4	4	4	4	4

Source: Own computation based on data collected (SPSS result)

As the above table indicates the most frequently given response by the respondents regarding the measurements of an improvement of customer service is “I agree response” indicating that these indicators of customer services are supposed to be the outcomes of the implementation of the QMS at EPHARM S.C. Customer service is the center of QMS and its positive effect is clearly seen on the above table which again increases customer satisfaction and retention.

Again the mean score value for the items of Production is more aligned with customer requirements. The organization is geared towards putting the customer first as opposed to before,

customer orders are shipped on time unlike before, most customer orders are filled from existing stock more than before (back-orders), customer complaints have reduced, The level of stock-outs in the market has improved are 3.95,3.80,3.89,3.88,3.86, and 3.52 respectively. Meaning that almost more than averages of the respondents have a positive response for all the indicators of customer service and quality improvements due to the implementation of the ISO. That is they are most important perceived benefits of implementing ISO 9001:2008 QMS.

It is important to note here that it was not possible to support some of the benefits obtained in relation to personal relation with customers and feedback collections, reduced cost with objective evidence as these information are sensitive and could not be easily declared by the respondents. Taking a sample and representative item for an improvement of customer service it was fond the above table that the number of those respondents with disagree, neutral, agree and strongly agree response are 8(8.4%), 15(15.8%),51(53.7%),and 21(22.1%) respectively. Therefore, the implementation of ISO 9001:2008 QMS has resulted in a good benefit for the attainment of customer service objective.

Table 4.4: Customer orders are shipped on time unlike before

	Items	Frequency	Percent	Valid Percent	Cumulative Percent
Valid	DISAGREE	8	8.4	8.4	8.4
	NEUTRAL	15	15.8	15.8	24.2
	AGREE	51	53.7	53.7	77.9
	STRONGLY AGREE	21	22.1	22.1	100.0
	Total	95	100.0	100.0	

Source: Own computation based on data collected (SPSS result)

Table six above clearly shows the benefits of shipping orders on time unlike before. This is beneficial mainly because it creates more efficient and effective operation. It also reduces waste and increases productivity while creating and retaining a satisfied customer. This in return motivates the employees and develops pride in them for achieving excellence.

Table 4.5: Summary of Improvement of Cost Management

Statitics		Warehouse transfer orders are easier to process	Raw material inventory holding has reduced	There has been a reduction in expired stock	Returns of finished goods are less frequent	Finished goods inventories have been reduced	There has been a reduction in cost of raw materials
N	Valid	95	95	95	95	95	95
	Missing	0	0	0	0	0	0
Mean		3.91	3.75	3.85	3.83	3.75	3.79
Mode		4	4	4	4	4	4

Source: Own computation based on data collected (SPSS result)

As the above table indicates the most frequently given response by the respondents regarding the measurements of an improvement of cost of management is "I Agree" response indicating that the indicators of cost management improvement warehouse transfer orders are easier to process and raw material inventory holding has reduced. There has been a reduction in expired stock, returns of finished goods are less frequent, finished goods inventories have been reduced and there has been a reduction in cost of raw materials which are supposed to be the benefits of the implementation of the QMS at EPHARM S.C .

The average score value for the items of warehouse transfer orders are easier to process. Raw material inventory holding has reduced, there has been a reduction in expired stock, returns of finished goods are less frequent, finished goods inventories have been reduced, there has been a reduction in cost of raw materials are 3.91,3.75,3.85,3.83,3.75, and 3.79 respectively. Meaning that almost more than average of the respondents has agreed with all the indicators of an improvements in cost management due to the implementation of the ISO. Hence, they are considered as the most important perceived benefits of the implementation of the ISO 9001:2008 QMS by EPHARM S.C.

Table 4.6: Improvements on Productivity

Statistics		Production volumes have increased	Waste material has reduced	Machine utilization in terms of idle downtime is Reduced	Machine downtime has Reduced	Energy utilization is improved	Number of people required per machine has reduced
N	Valid	95	95	95	95	95	95
	Missing	0	0	0	0	0	0
Mean		4.20	3.87	3.99	3.84	4.07	4.28
Mode		4	5	4	4	4	4

Source: Own computation based on data collected (SPSS result)

The above table shows that the highest frequency for five of the items is "I agree" and only one for "Strongly Agree". The indicators of productivity improvement include: Production volumes have increased with a mean score of 4.2, Waste material has reduced with a mean score of 3.87, Machine utilization in terms of idle downtime is reduced with a mean score of 3.99, Machine downtime has Reduced with a mean score of 3.84, Energy utilization is improved with a mean score of 4.07 and Number of people required per machine has reduced with a mean score of 4.28. Almost an average response of them have agreed that ISO 9001:2008 QMS has resulted in an increase in productivity at EPHARM S.C measured in terms of increment in production volume while the response is nearly neutral or the respondents have no knowledge about waste material has reduced, machine utilization in terms of idle down time is reduced and machine downtime has reduced.

Organizations that pursue ISO 9000 certification willingly and have a positive attitude towards it are more likely to report improved organization performance than organizations that pursue ISO 9000 certification in a reactionary mode due to customer pressure (Adolfas, 2010). The relationships noted imply that the major reasons for initiating quality management system were accompanied by the required benefits after implementation and subsequent certification for ISO 9001:2008 QMS.

Table 4.7: Summary of Improvement of Quality

Statistics		It is easier to locate the correct finished products for shipment	Information about process is readily available	Customer invoicing accuracy has improved	The picking of raw materials for manufacturing is more accurate than before	There is less defective products
N	Valid	95	95	95	95	95
	Missing	0	0	0	0	0
Mean		4.20	4.21	4.16	4.14	4.01
Mode		4	4	4	4	4

Source: Own computation based on data collected (SPSS result)

Quality as a measure of earned benefit due to ISO 9001:2008 QMS implementation is used in the above table. It is shown that, the most frequently given response by the respondents regarding the measurements of an improvement of quality service is "I agree response" indicating that these indicators of quality service provisions are considered as fruits of the implementation of the QMS at EPHARM S.C.

Again the mean score value for the items i.e. It is easier to locate the correct finished products for shipment, Information about process is readily available, Customer invoicing accuracy has improved, the picking of raw materials for manufacturing is more accurate than before, and there is less defective products are 4.2, 4.21, 4.16, 4.14 and 4.01 respectively.

This means that almost more than average of the respondents has a positive response for all the indicators of the quality service improvements due to the implementation of the ISO. That is quality improvement is the most important perceived benefits of implementing ISO 9001:2008 QMS at EPHARM S.C.

Table 4.8: There is less defective products

	Item	Frequency	Percent	Valid Percent	Cumulative Percent
Valid	STRONGLY DISAGREE	2	2.1	2.1	2.1
	DISAGREE	5	5.3	5.3	7.4
	NEUTRAL	12	12.6	12.6	20.0
	AGREE	47	49.5	49.5	69.5
	STRONGLY AGREE	29	30.5	30.5	100.0
	Total	95	100.0	100.0	

Source: Own computation based on data collected (SPSS result)

By considering the availability of less defective products as a proxy measure of quality improvement, it was found in the above table that the number of those respondents with strongly disagree, disagree, neutral, agree and strongly agree response are 2(2.1%), 5(5.3%), 12(12.6%), 47(49.5%) and 29(30.5%) respectively. Therefore, the implementation of ISO 9001:2008 QMS has resulted in an improved benefit in terms of quality service provision for its customers during the study period.

Table 4.9: There has been a Reduction in Cost of Raw Materials

	Item	Frequency	Percent	Valid Percent	Cumulative Percent
Valid	STRONGLY DISAGREE	5	5.3	5.3	5.3
	DISAGREE	1	1.1	1.1	6.3
	NEUTRAL	22	23.2	23.2	29.5
	AGREE	48	50.5	50.5	80.0
	STRONGLY AGREE	19	20.0	20.0	100.0
	Total	95	100.0	100.0	

Source: Own computation based on data collected (SPSS result)

Taking a sample and representative item for reduction in cost of raw materials was found on the above table that the number of those respondents with strongly disagree, disagree, neutral, agree and strongly agree response are 5(5.3%), 1(1.1%),22(23.2%), 48(50.5%) and 19(20%) respectively. Therefore, the implementation of ISO 9001:2008 QMS has resulted in reduction in cost of raw materials in the EPHARM S.C which is around 50.5%.

4.3.2 Challenges of QMS

As most literatures suggest that despite the widely proclaimed benefits quite a number of challenges are also faced by organizations in implementing ISO 9001:2008 QMS (Kumar and Balakrishnan 2011; Sabah and Maha 2011). These challenges were summarized in to a 6 item list of challenges for this study and the respondents were asked to rate them.

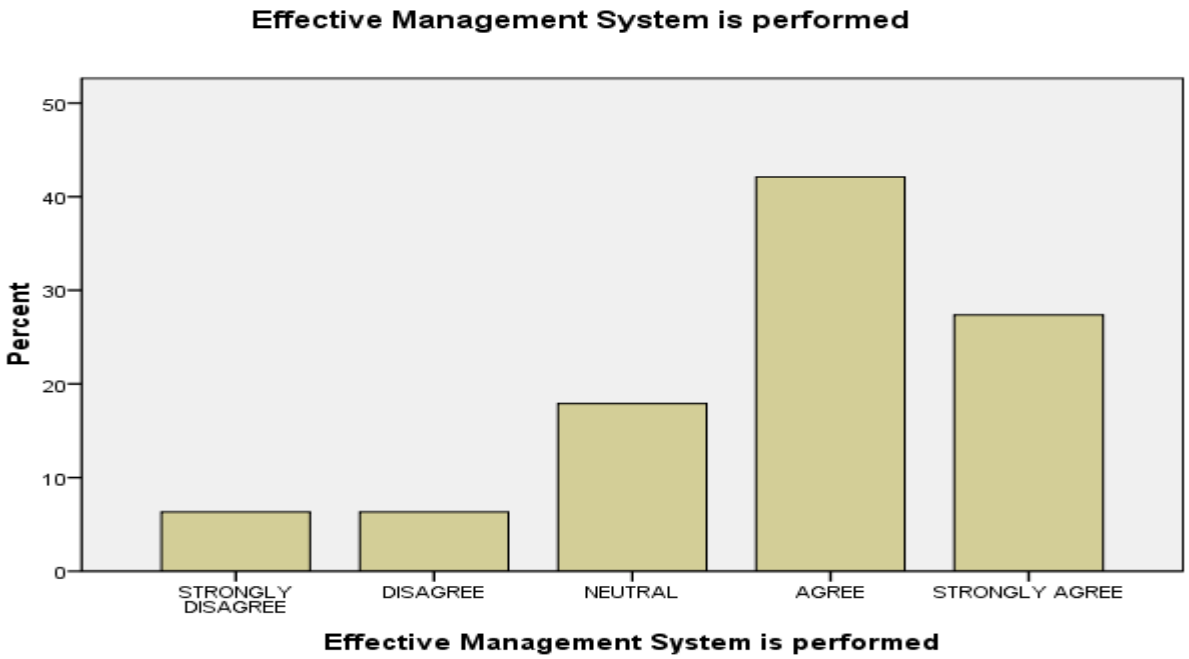
Responses to the 6 item challenges related to implementing ISO 9001:2008 QMS were then rated on Likert scale of 1 to 5 ranging from very low to very high respectively. Cronbach alpha reliability test for the 6 items found to be 0.896 indicating an acceptable level of internal consistency and reliability.

As can be seen from the summary in the following table, the mean score values for the 6 item challenges in implementing QMS range from 3.64, effective change management is applied to 3.98 for information technology infrastructure is implemented. There is no as such significant challenges faced by the respondents regarding the implementation of ISO 9001:2008 QMS at EPHARM S.C. However, from the open-ended questions and answer results obtained it was found that, the top three challenges rated by the respondents are lack of adequate information, lack of management commitment and lack of capacity by personnel. Also, cascading the system from the top to the lowest level of pyramid is found to be a major challenge faced by the EPHARM.

Though the order of importance for the remaining challenges may vary in different studies in general, the findings in this study are also supported by the findings of other studies mentioned above. (Sabah and Maha, 2011) identified that the most important barriers to ISO implementation to be lack of top management commitment, employee resistance, difficulty of performing internal audits, absence of consulting boards, unrealistic ISO 9001 requirements, financial resources, lack of human resources insufficient employee training and, insufficient knowledge about quality programs. Daniel (2010) also reported lack of top management commitment, experience and size of firms as major challenges.

The above table shows that most of the respondents have responded positively and in agreement with the success of QMS which is evidenced by item questions with a high frequency of "I Agree".

Figure 4.2: Effective Management system



Source: Own computation based on data collected (SPSS result)

The above histogram shows considering an effective management system as a sample and representative item for key drivers for the success or failure of QMS, it was found on the histogram that the number of those respondents with strongly disagree, disagree, neutral, agree and strongly agree response are 6(6.3%), 6(6.3%), 17(17.9%), 40(42.1%) and 26(27.4%) respectively. Therefore the implementation of ISO 9001:2008 QMS has resulted in a good improvement of the management in the EPHARM S.C which is supported by the "I Agree" response of around 42.1%.

CHAPTER FIVE: MAJOR FINDINGS, CONCLUSIONS AND RECOMMENDATIONS

5.1 Summary of Major Findings

An effective Quality Management System focuses on systematically developing and communicating a customer-focused mission, strategies and action plans, listening and responding to the customers' needs and expectations, empowering employees to continuously improve and increase their satisfaction with their work processes and environment, gathering and analyzing key performance indicators to improve organizational and process results.

Currently there are about 16 registered pharmaceutical manufacturing companies in the country through the federal regulatory authority (FMHACA). All of these manufacturers have got their GMP approval from FMHACA. EPHARM S.C is one of the companies who has implemented quality management system as per the ISO 9001style. Accordingly in order to assess whether the practice of this quality management system has resulted in a good benefit to the company or not this paper was conducted. The study also tried to show the challenges that the company has faced while implementing the system. The finding of the result depicts that almost more than average of the respondents have a positive response for all the indicators of the customer service improvements due to the implementation of the ISO. That is they agree with the fact that they have got a benefit from the implementation of ISO 9001:2008 QMS.

However, it is important to note here that it was not possible to support some of the benefits obtained in relation to personal relation with customers and feedback collections, reduced cost with objective evidence (supporting figures) as these information are sensitive and could not be easily declared by the respondents. Also improvements in cost management due to the implementation of the ISO are the other most important perceived benefits of the implementation of the ISO 9001:2008 QMS by EPHARM S.C. Quality service has also been improved due to its implementation. The findings in this study identified that the most important barriers to ISO implementation to be lack of top management commitment, employee resistance, lack of human resources insufficient employee training and insufficient knowledge about quality programs.

5.2 Conclusions

Literature and empirical studies highlighted that quite huge number of companies are implementing and getting certifications for ISO 9001:2008 QMS in the developed world. Despite the wide spread use of the system in other parts of the world, the implementation and certification for the system is quite low in the developing world in general and in Ethiopia in particular.

This study was one of such a few studies conducted regarding QMS implementation – practices and challenges in the case of EPHARM S.C. The general objective of the research was to investigate the implementation of Quality Management System (ISO 9001-2008). Particularly the research has tried to find out the perceived practices and benefits of implementation and associated challenges in implementing the system.

From the analysis it was observed that the most important reason for the organization to practice implementing quality management system being improving the quality of its products and services, addressing the needs and expectations of its customers to improve its confidence and satisfaction and the inherent reason of increasing its market share and reducing costs of exporting its products, QMS is also considered as means of avoiding export barriers and getting better access to the international market.

The researcher has tried to describe the practices and benefits obtained by the EPHARM S.C in implementing quality management system. The findings were improvement of customer service, improvement of cost management, improvements on productivity, improvement of quality benefits obtained or perceived to have been obtained by the company's implementing ISO 9001:2008 QMS.

It can be concluded that implementing the system will bring the benefit of building the image of company, creating a better competitive advantage on top of its competitors, improved awareness of employees to quality, increased profit and reduced or fewer rejections of products. An interesting relationship was noted among the different benefits of the implementation of ISO 9001:2008 quality management systems. A significant relationship was found between: reduction in cost of raw materials and customer orders are shipped on time unlike before,

reduction in cost of raw materials and effective management system is performed and that of production volumes have increased and customer orders are shipped on time unlike before.

Hence it can be concluded EPHARM S.C has greatly benefited from its initiatives of implementing ISO 9001:2008 QMS through which it was able to realize enhanced quality and efficiency, achieve improved satisfaction of their customers improve their internal communications, gain competitive advantage and achieve an increase in market share as well as reduce costs**.**

Efforts to determine the challenges of implementing quality management system revealed that lack of adequate information, lack of management commitment and lack of capacity by personnel to be the major challenges that impede the effective implementation of the system. In spite of the few challenges faced by the company to develop, implement and maintain ISO 9001:2008 Quality Management System, broadly asserted benefits of implementing it were found significant as a whole and has resulted in good impact on the performance of the company.

5.3 Recommendations

Based on the findings and conclusions drawn, the following points are worth recommending.

From literatures it is known that several empirical studies in different countries and this study have shown that organizations can be benefited (either internally or externally) from their practice of implementing a quality management system. The benefit could be much more important to those manufacturing organizations like EPHARM S.C as it can serve as a means of improving the quality of products and their organizational performance.

Here, EPHARM S.C could have benefited further from supplementary advantage of integrating the fundamentals of Good Manufacturing Practice regulations with that of the ISO. Therefore, EPHARM S.C need to consider engaging themselves in the practice of further strengthening and promotion of the implementation and maintenance of ISO based QMS in its manufacturing system.

In view of the current greater attention paid by the government for export oriented manufacturing industries, EPHARM S.C also need to consider implementing QMS to capture the additional

external benefits of avoiding export barriers to get access to the international markets, and to gain competitive advantages on top of the various imbedded internal benefits.

Implementing ISO based is a change initiative. As it is the case for any change initiative in organizations, challenges are inevitable. Therefore, it is important 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.

Directions for future research:

This study is an exploratory effort which only attempted to provide 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 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. The general status of ISO QMS implementation in services and other manufacturing industries also needs to be investigated.

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ST. MARY'S UNIVERSITY

APPENDIX

QUESTIONNAIRE

Dear Participants

I am conducting my Masters thesis at the St. Mary's University. This questionnaire is part of my Master thesis, the purpose of it being a tool for data collection, in which I am interested in analysing the competitive advantages that EPHARM has encountered after the adoption and implementation of Quality Management System. I would like to know your perceptions and general overview of QMS on your daily activities for the past three years**.** I really appreciate your participation which will contribute to my successful completion of this programme. This questionnaire will take approximately 10 to 15 minutes of your precious time. Please note that any information that you provide will be treated in confidential manner and will only be used for research purposes. Your participation in the study will be greatly appreciated. Thank you very much for your time.

Section 1: Variables of the Respondents

Please attempt to answer all the questions and tick one appropriate letter that best suits your perspective for each statement**.**

1.1	Your Gender	F ☐			M ☐	
1.3	Your Age	<24 ☐	25-35 ☐	36-45 ☐	46-55 ☐	>55 ☐
1.5	Education Level	Certificate-Diploma ☐		Degree ☐	Master and above ☐	

ST. MARY'S UNIVERSITY

Section 2: Opinion survey pertaining to the Study

2.1 Improvement of Customer Service

No.	Statement	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
2.1.1	Production is more aligned with customer requirements					
2.1.2	The organization is geared towards putting the customer first as opposed to before					
2.1.3	Customer orders are shipped on time unlike before					
2.1.4	Most customer orders are filled from existing stock more than before(back-orders)					
2.1.5	Customer complaints have reduced					
2.1.6	The level of stock-outs in the market has improved					
For Your Additional Comments						

2.2 Improvement of Cost Management

No.	Statement	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
2.2.1	Warehouse transfer orders are easier to process					
2.2.2	Raw material inventory holding has reduced					
2.2.3	There has been a reduction in expired stock					
2.2.4	Returns of finished goods are less frequent					
2.2.5	Finished goods inventories have been reduced					
2.2.6	There has been a reduction in cost of raw materials					
For Your Additional Comments						

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2.3 Improvements on Productivity

No.	Statement	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
2.3.1	Production volumes have increased					
2.3.2	Waste material has reduced					
2.3.3	Machine utilization in terms of idle downtime is Reduced					
2.3.4	Machine downtime has Reduced					
2.3.5	Energy utilization is improved					
2.3.6	Number of people required per machine has reduced					
For Your Additional Comments						

2.5 Improvement of Quality

No.	Statement	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
2.5.1	It is easier to locate the correct finished products for shipment					
2.5.2	Information about process is readily available					
2.5.3	Customer invoicing accuracy has improved					
2.5.4	The picking of raw materials for manufacturing is more accurate than before					
2.5.5	There is less defective products					
For Your Additional Comments						

2.4 Key Drivers for the Success or Failure of QMS

No.	Statement	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
2.4.1	QMS team Composition was perfect					
2.4.2	Information Technology Infrastructure is implemented					
2.4.3	Effective Management System is performed					
2.4.4	Top Management Commitment and Sponsorship is high					
2.4.5	Effective Change Management is applied					
For Your Additional Comments						

Thanks for your assistance! It is Greatly Appreciated