ST. MARY'S UNIVERSITY

SCHOOL OF GRADUATE STUDIES

ASSESSMENT OF QUALITY MANAGEMENT PRACTICES IN CADILA PHARMACEUTICALS (Ethiopia) MANUFACTURING PLC.

BY: JENBERU GETACHEW

June, 2023

Addis Ababa, Ethiopia

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ID. No: SGS/0537/2012A

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A THESIS SUBMITTED TO ST. MARY'S UNIVERSITY, SCHOOL OF 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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Approved by Board of examiners

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External examiner	Signature

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.

Signature_____

Name: JENBERU GETACHEW

Date: June, 2023

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

St. Mary's University

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Acronyms

EFDA ---------- Ethiopian Food, Drug and Agency
CPEL ---------- Cadila pharmaceuticals (Ethiopian) PLC
CPL ---------- Cadila Pharmaceuticals Company (India).
cGMP ---------- Current Good Manufacturing Practices
FMHACA ---------- Food, Medicine, and Healthcare Administration, Control Agency
PDCA ---------- plan–do–check–act
ISO ---------- International Organization for Standardization
QA ----------Quality assurance
QC ----------Quality Control
QMS ---------- Quality Management System
SPSS ---------- Statistical Package for Social Science
Std. ---------- Standard deviation
TQM ---------- Total Quality Management

Abstract

This study has been conducted on the assessment of practices in quality management at Cadila Pharmaceuticals (Ethiopia) Manufacturing PLC. A descriptive research approach was employed using a questionnaire and interview to get primary data from employees of CPEL and secondary data from self-observation. Key principles of quality management practices such as customer focus, leadership or management commitment, engagement of employees, continuous improvement in the company, evidence-based decision-making, and relationship management were used as independent variables accompanied by different measurement instruments under each variable to measure organizational quality management. The data were collected with a 100% response rate to the distributed principle of QMS questionnaires and analysed using descriptive statistics focusing on the mean, standard deviation, and percentages, which are calculated using the statistical package for the social sciences (SPSS) version 23. The validity of the instrument was checked, and the internal consistency of the instrument was measured using Cronbach's alpha, and the result was greater than 0.7, which signifies that the reliability of the data was very good. The results of this study show that the majority of the employees agree that Cadila Pharmaceuticals (Ethiopia) is practicing all these QMS principles. The research work has identified lack of employee commitment, difficulty in performing internal auditing, lack of financial resources or currency, lack of sufficient or consistent training about QMS implementation, organizational structure limitations, and documentation problems as challenges to the implementation of a quality management system in the Organization. The benefits of the CPEL from the implementation of QMS practices are also listed in this study, such as, improvement in productivity, improvement in efficiency, reduction in cost and waste, competitive advantage, increase in sales and market share, good customer relations, and increased customer satisfaction. This study finally recommended that all potential problems identified in the implementation practice of QMS be given due attention and appropriate preventive and corrective actions planned ahead during the planning and development stages of the system.

***Key words**: Assessment, Practices, Quality Management, Quality Management System.*

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, scope of the study, Limitation of the study, operational definition, organization of the study .

1.1. Background to the study

Nowadays, medicines are used to treat diseases. However, different changes have occurred in this field. Generation has become more and more quality conscious and pharmaceuticals of better quality are asked for. This is mainly due to fatal incidents which occurred in the past concerning pharmaceuticals manufacture. Fortunately, in different world organizations have been set up in order to make sure that pharmaceutical products reaching patients comply with quality standards recommended. Also, governments from around the world have shown their mainly concern of about quality matters by allocating a substantial proportion of its total health budget to drugs. According to the World Health Organization (WHO), this proportion tends to be greatest in developing countries, where it may exceed 40%.
Quality is a well-known concept in human history, and today, thanks to the rapid development of information and communication technologies, more informed consumers with a wider range of options are also becoming a reality. Businesses strive to get a competitive advantage over rivals in order to meet the wants of these modern clients. Quality is one tool to gain this competitive advantage. John Okland is an elite who backed the aforementioned claim. Any organization competes based on its reputation for quality, dependability, and affordability, but quality is still the most crucial of these competitive advantages, according to him (Okland, 2004).

To support the aforementioned claim, ISO-9001 defines quality as a strategic goal that is designed to meet the needs and an expectation of all parties involved and, as a result, is equivalent to corporate goals (Hoyle, 2001). Similar to this, Vokurka et al. found that Businesses turned to quality management system (QMS) as the solution to improving overall performance as a result of customers expecting quality and competitors meeting these demands. Quality changed from being a product-specific effort to an organization-wide effort as customer expectations rose and performance improvement efforts were put in place. It also changed from being a distinct manufacturing function to a strategic business endeavor. With the growth of the quality function came new practices for ongoing improvement (Vokurka et al., 2000).

TQM is a vast collection of philosophies, concepts, methods, and tools now being used throughout the world to manage quality (Juran, 1999). It is a method that has evolved to achieve, sustain, and improve quality (Hoyle, 2001). Gharakhani et al., as cited in Abdaziz et al. (2016), defined Total Quality management as a constituent of several quality instruments and techniques, in addition to various values and beliefs that all staff within the same organization share (Abdaziz et al., 2016). In support of this argument, Lakhal et al., as cited in Abdaziz et al. (2016), claimed that TQM can be defined as a strategy that aims to generate and transfer more efficient and superior services through achieving cooperation between organizational members. Studies support the idea that achieving, sustaining, and improving quality will give organizations a competitive advantage over others. In the same manner, Lagersen, as cited by Ndubuisi, supported the above argument. He claimed companies all over the world found it necessary to have good quality management practices in order to stay competitive (Ndubisi, 2012).

The nation has quality-related concerns, thus hearing about them in conferences, seminars, workshops, and the like is not unusual in Ethiopia. Numerous researches carried out in the nation discovered issues with the application, personalization, and adaptation of QM systems. The results of research done by the Addis Ababa University Institute of Technology on the recipients of the Ethiopian Quality Award in 2009, which was used to support this argument, proved that quality will be Ethiopia's future competitiveness challenge (Birhanu and Daniel, 2013).

Despite the issues revealed by several studies conducted in the nation, not much is being done to address them, thus this research paper will attempt to shed some light on the situation by assessing.

The business established two distinct departments to carry out its quality control policies. Incoming raw materials and final goods are continuously inspected by the quality control department to make sure they adhere to compositional standards, microbiological standards, and numerous legal requirements. In order to ensure alignment with the company's policies and regulatory body standards, the quality assurance department designs quality systems, standard operating procedures, and document control programmes. It verifies that all necessary production, packing, and testing records are complete and accurately reflected to meet the needs of customers and regulatory bodies.

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 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).

It states that despite previous studies identifying problems with quality management in the **country** little has been done to address these issues. Therefore, this research paper aims to assess the quality management practices at Cadila Pharmaceuticals (Ethiopia) PLC, specifically focusing on the principles of quality management system (QMS)**.**

1.2. Statement of the problem

Based on the Ethiopian Quality Award (EQA) self-assessment model, quality management practice in Ethiopian manufacturing and service industries was found to be poor (Kitaw, 2014).
One major wrong practice made by organizations is letting the production department take responsibility for producing quality products, believing quality is a factor of the production process only. However, many scholars believe that quality should not be the sole obligation of the production process. All members of the organization should be involved to ensure quality. Okland, for instance, stated that traditionally, quality has been regarded as the responsibility of quality assurance and quality control departments, but it has not yet been recognized in some organizations that many quality problems originate in the commercial, service, or administrative areas (Okland, 2004). Good quality management is essentially a way of planning, organizing, and understanding each activity and depends on each individual at each level. For an organization to be truly effective, each part of it must work properly together towards the same goals, recognizing that each person and each activity affect and are in turn affected by others (Okland, 2004).

In the same vein Mohanty and Lakhe as cited in Elfaituri argued that organizations face considerable difficulties in developing countries, and thus, their ability to adopt QMS was limited. These difficulties are composed of lack of employee involvement and participation in quality improvement efforts, lack of top management commitment and motivation, perception that quality is the optional extra and not a necessity for development, poor internal communication, lack of focus on the needs of consumers, lack of political support, lack of established quality standards and inadequate test facilities, lack of advanced or modern technologies, insufficient education and training resources, resistance to change at different levels, and inadequate knowledge and information about QMS (Elfaituri, 2012).

Another known scholar Juran supported these arguments, he suggested that many companies have found that all of their radical restructuring, reengineering, downsizing and numerous quality programmers may have helped them survive, but that still do not have a distinctive advantage. Their future will be determined by three key areas. Alignment, linkage and replication combined with the fundamental concepts of quality management (continuous improvement, customer focus and the value of every member of the organization). Their work in these three key areas is transforming the way they are managing the entire organization (Juran, 1999).

These arguments show that for total quality management to be fully practiced all the principles should be placed in practice. If so, what are the other variables that contribute for the existence of quality? Birhanu and Daniel stated in their article that since all quality awards are derived from the tenants of quality management, they look alike. However, they have some differences in their focus area and weight of criteria (Birhanu and Daniel, 2013). In the same vein Vokura et al asserted that award criteria for successful and established programmes continue to improve, reflecting changes in the quality arena. And as national and regional award criteria include updated strategic content, a trend towards a uniform, international model of organization wide quality performance is evolving (Vokura et al, 2000).

Another wrong belief held by many organizations is quality costs more time and money, which hinders owner's and top level management to strive for quality. MelsaJ.L stated that this problem is a universal believe. He wrote that some organization would argue that if one wants a higher quality product it will take longer to design and manufacture, and it will cost more (Melsa, 2009). However, it was a wrong belief. He stated a research that proved the belief wrong and even on the contrary quality in the long- run is the most important single factor affecting a business unit's performance in relation to its competitors (Melsa,2009).Supporting this argument Youssef et al as cited in Elfaituri asserted that the benefits of QMS include such examples as products with fewer defects, a reduction in rework and lead times, cost reductions, improved business competitiveness, increases in market share and profitability, increased flexibility, and enhanced employee and customer satisfaction (Elfaituri, 2012).

Many researches made in our country from past to present found quality system practice problems. They found poor practices in all total quality management principles (Birhanu and Daniel, 2014), (Ezra, 2004). Others also found that even though Ethiopian organizations are conscious about the importance of total quality management, they were not practiced the complete and comprehensive components of total quality management (Haile and

Satya, 2016).Other scholars Daniel and Fasikaalso supported the lack of complete and comprehensive implementation and practices of QMS principles in Ethiopia (Daniel and Fasika, 2003). They believe the reason for poor practices were failure to recognize the importance of culture and organizations structure (Danil and Fasika, 2003). This means that though a system proven useful in a given environment might not work in another set up, some adjustments should be made (Daniel and Fasika, 2003). In the same vein Tata and Prasad as cited in Elfaituri have stated that the lack of significant success in implementation is often not viewed as a failure of the QMS philosophy, but more as a result of not paying sufficient attention to the cultural factors that affect it (Elfaituri, 2012).

When compared to industrialized countries, the aforementioned studies revealed a gap in quality management practices in developing nations, and little is still being done to address the issue. Supporting these claims, Lakhe and Mohantyas were cited by Elfaituri (2012) as saying that developing countries' attempts to expand their economies and engage more completely in the global economy have failed, and as a result, their consumers continue to endure subpar goods and services. Therefore, this research will not significantly advance our understanding of the subject but can serve as a starting point for future research for other professionals.

Additionally, this research's goal is to examine how the fundamentals of a good overall quality management system are put into practice by using these principles as variables.

The study focuses on Cadila Pharmaceuticals (Ethiopia) (CPEL), which has implemented Quality Assurance/ quality control (QA/QC) as its Quality Management System (QMS). In whatever, the company has received complaints from customers regarding the quality of drugs or medicines and delivery time. The primary concern of the company is to meet the demand for high-quality drugs or medicines on time. The study aims to assess the practice of QMS in CPEL which focus on internal customers.

1.3. Research questions

1. To what extent the objectives of quality practiced in CPEL
2. What is the main quality management practices implemented in CPEL?
3. What are the challenges the organization face to practice quality management system?

1.4. Objective of the study

1.4.1. General objective

To study quality management practice of Cadila pharmaceutical (Ethiopia) manufacturing plc.

1.4.2. Specific objective

- To identify major challenges of quality practices in CPEL.
- To know how the objective of quality and quality management are implemented in CPEL.
- To propose measures for effective quality management practices in CPEL.

1.5. Significance of the study

The study was enabled to show the QMS practice in Cadila pharmaceuticals (Ethiopia) and understanding of quality management practice and performance in organization. The study would help management of the company to identify challenges QMS practices found in the company and how to solve these ineffective practices. This would help the management to come out with better strategies which would help improve quality practice performance to meet standards at national and international level to lead to meet customer satisfaction. And finally, serves as a benchmark for further studies.

1.6. Scope of the study

This study has delimited to exploring and describing the implementation of the Quality Management System in the selected Pharmaceutical industry of Cadila pharmaceuticals (Ethiopia) plc. 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

The ideas and procedures of quality management ensure that an organization provides consistent, high-quality goods or services that satisfy consumer needs. Customer focus, leadership or/and management commitment, employee involvement, ongoing business improvement, evidence-based decision-making, and relationship management are among the core tenets of quality management practices. As independent variables, these ideas are applied in.

1.7. Limitation of the study

As only one company, Cadila Pharmaceuticals (Ethiopia) plc was the subject of the study, its findings and conclusions might not be applicable to other pharmaceutical industries, but it can help the management of other companies in Ethiopia. The study also could not focus on the facets of quality management in the pharmaceutical business, specifying things like quality control and quality assurance, and only focused on the evaluation of quality management system principles. Quality control is the process of making sure that a good or service meets the required standards of quality, whereas quality assurance is the process of making sure that the quality control process is successful and efficient.

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

Quality management: - according to (ISO 9000:2005) define quality management as the coordinated activates to direct and control an organization with respect to quality.

QMS: is a comprehensive collection of policies, processes, and procedures designed to ensure and maintain uniform and high quality in the production of pharmaceutical products (www.google.com).

Internal audit: - An examination and assessment of all or part of a QMS with the specific purpose of improvement. An internal audit should be conducted by an independent (i.e. of the function to be audited) team of competent auditors as designated by the management for this purpose (WHO Expert Committee on Specifications for Pharmaceutical Preparations Fifty-fourth report).

TQM: - is an enhancement to the traditional way of doing business. It is the art of managing the whole to achieve excellence. It is defined both a philosophy and a set of guiding principles that represent the foundation of a continuously improving organization. It is the application of quantitative methods and human resources to improve all the processes within an organization and exceed customer needs now and in the future. It integrates fundamental management techniques, existing improvement efforts, and technical tools under a disciplined approach.

1.9. Organization of study

The work was organized into five chapters. Chapter one covered the background to the study, the problem statement, the objectives of the study, research questions, significance of the study, limitations of the study and organization of the study. Chapter two covered the literature review. Chapter three covered methodology which comprises the research design, population and sampling technique, data source and data collection tools, data analysis method, reliability and validity test and ethical considerations. Chapter four considered data analysis and interpretation. Chapter five summary of findings, conclusions and recommendations.

CHAPTER TWO

REVIEW OF RELATED LITERATURE

2. Introduction

This chapter reviews relevant literature with respect to the study**.** Topics covered in this chapter are: quality concept, ISO 9000 standards, Quality Management, Evolution of Quality Management, quality management in the drug industry, Pharmaceutical industrial development in Ethiopia, Cadila pharmaceuticals (Ethiopia) PLC Profile and The benefits of QMS.

2.1. Concept of Quality

Quality is degree of excellent (Dictionary) or it is the general standard or grade of something (Encarta dictionary).Quality is a strategic instrument widely used by companies to gain better market share. Many manufacturing companies have realized the importance of quality. This, time quality is a competitive dimension for companies by which they can excel their competitive and achievement of market share. (Awoku, 2012) ISO 9001 defines quality as "The degree to which a set of inherent characteristics fulfills requirement." To fulfill requirements is to meet customers' needs and regulatory requirements. The difference of one from another by company product and service provided.

Quality can be defined in terms of conformance, performance, reliability, features, serviceability of product and durability in manufacturing company (Awoku,2012). Reliability is the probability that a device will perform its required functions under stated conditions for a specific period of time. Conformance is the degree at which a product's characteristics meet set standards, while performance how the product functions efficiently. The products produced have features that would enable efficient usage and to have durability and be easily repaired. Different scholars define quality in different ways, according to Joseph Juran, quality means "fitness for use" and Philip Crosby, it is" conformance to requirements" (Diaz, 2014).

2.2. ISO 9000

The International Organization for standardization (ISO) is an international organization whose purpose is to establish agreement on international quality standards. It has been created to develop and promote quality. ISO 9000 consists of a set of standards and a certification process for companies. By receiving ISO 9000 certification, companies demonstrate that they have met the standards specified by the ISO. The standards are applicable for all types of companies and have gained global acceptance. In many industries ISO certification has become a requirement for doing business. One strong indication of the continued relevance of quality management to companies competing in the global market is the recent revision of the ISO 9000 series of quality standards. The 2000 version of ISO 9000— ISO 9000:2000—represents a fundamental shift from quality assurance to quality management, a significant change in approach to quality from one that is totally compliance based to one that includes the evaluation of management techniques. This change has been described as moving the standard away from a technical-practical tool toward a management tool (Larsen and Haversjo, 2000).

It sets the stage for understanding the basic elements of quality management ISO 9000:2000 is based on eight principles that are easily recognizable as the key elements of quality management. They are: customer focus, leadership, involvement of people, process approach, systems approach to management, continuous improvement, factual approach to decision making, and mutually beneficial supplier relationships. Aside from the mandate to adopt quality management practices as a result of ISO 9000:2000, it appears that many organizations have continued in their efforts to transform the way they business.(Foley'2003). Quality does not only refer to goods and services but includes quality of time, place, equipment and tools , processes, people, the environment and safety, information and measurement(Dale, 2003: Schonberger,1990). Quality is an ongoing process that has to be so pervasive throughout the institution, that it becomes the philosophy and culture of the whole institution. The institution need to adopt a strategy to serve the customer with

better quality products, at lower cost, with quicker response and with greater flexibility (Schonberger, 1990). There appears to be no uniform understanding and definition of the meaning of the term quality and even well-known authors seem to have different perspectives on this issue. According to Reeves and Bednar (1994), a search for the definition of quality has yielded inconsistent results.

2.3. Quality Management

Quality management is a general term used to express the total composition of all systems employed to improve product and service quality of the organization. ISO 9000: 2000 defines quality management as "coordinated activities to direct and control an organization with regard to quality" (www.iso.org). Thus quality management falls within the overall management function of a company. Here the emphasis is on understanding and meeting customer requirements and expectation and on "getting it right first time". It comprises the organizational structure, procedures, processes and resources needed to implement quality management." It establishes quality policy, quality objectives and allocates responsibilities within the organization for achieving the stated quality policy and objectives. The means used to implement the quality policy and attain objectives are quality planning, quality control, quality assurance and quality improvement (Amare, 2006).
The first study by Yu-chung, H. and others (2005) identified several critical factors, including benchmarking strategy, knowledge structure, organizational culture, information technology, employee involvement and training, leadership and commitment of senior management, a learning environment, and resource control and evaluation of professional training and teamwork. These factors were found to be important in adopting a QMS in the pharmaceutical industry.

The second study by Rana and others (2009) focused on the role of quality management in the pharmaceutical industry in Islamabad and Lahore. The study found that the application of QMS principles, culture of continuous improvement, and overcoming a lack of trust and understanding of the QMS process were some of the key challenges facing organizations in implementing QMS.

These studies show the importance of various factors such as organizational culture, leadership commitment, employee involvement and training, and continuous improvement in successfully implementing a QMS in the pharmaceutical industry. They also identify challenges such as lack of trust and understanding of the QMS process, which need to be addressed for successful implementation.

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).

Challenge to practice QMS in organization

The pace to maximize benefits from manufacturing industry is far below expectation due to quality management and other different problems. Recently Ethiopian manufacturing organizations are demanded to improve their products quality in order to improve their competitiveness and verify the current strategy of the government to export their products abroad. In the same time the government opened the Ethiopian market to receive a variety of foreign products from different markets. However the problems pointed out by Daniel and Fasika are still not resolved. A study supporting this argument is research made by Daniel, one of the researchers studied in the area back in 2003, with his associate Birhanu, in 2014. They found that generally, quality management practices in Ethiopia was found to be low in all the tenants including leadership, policy and strategy, resource management, process management, customer satisfaction, business performance and impact on society (Birhanu and Daniel, 2014). Another study carried out by Ezra found that quality problems including poor quality supplies of raw

material, poor relationship with customers and suppliers and poor product design (Ezra, 2004). Another research made by Haile and Dr. Satya supported the above arguments. The researchers concluded that firms in their survey are found to have implemented certain kinds of quality management programs. This means that they are generally conscious of the importance of TQM. However, firms were not practiced the complete and comprehensive components of TQM as their original proponents (American and Japanese TQM gurus) had convinced them (Haile and Satya, 2016).

2.4. Evolution of Quality Management

Quality management in the past was mainly focused on checking products to ensure they met specific standards. During World War II, statistical sampling techniques were introduced to evaluate quality, and quality control charts were used to monitor the production process. This led to a more statistical approach to quality management, where data was used to monitor and improve quality.

In the 1960s, quality gurus like Juran broadened the meaning of quality management by emphasizing the importance of quality planning, control, and improvement. Since the 1970s, competition based on quality has become increasingly important, leading to a greater focus on improving quality in all industries. The evolution of quality management has led to a more comprehensive approach that includes statistical techniques, planning, control, and improvement. This comprehensive approach has helped companies become more competitive by producing higher quality products and services. By using statistical techniques, companies can identify areas for improvement and make data-driven decisions to improve quality. Quality planning helps companies set goals and develop strategies to achieve those goals. Quality control ensures that products and services meet the desired quality standards. Quality improvement involves continuously improving processes and products to achieve better quality.

2.4.1. Quality Inspection

In the past time, there was a way that led to the formation of a new inspection department with a "chief inspector" who reported to the person in charge of manufacturing or the works manager. This new department was responsible for ensuring that products met certain standards and that measuring equipment was accurate. It became clear that the responsibilities of the chief inspector went beyond just product acceptance. There was a need to address defect prevention, which led to the evolution of quality control inspections. This involved not only inspecting products but also implementing measures to prevent defects from occurring in the first place. The new department also had to provide training and maintain accurate records of data. In general, the evolution of quality control inspections was a response to the need for more comprehensive and proactive approaches to ensuring product quality (Azeb Fisseha, 2021).

2.4.2. Quality Control

In 1920s, statistical theory began to be applied effectively to quality control, and in 1924, Shewhart made the first sketch of a modern quality control chart. His work was later developed by Deming and others, which constitutes much of what today comprises the theory of statistical process control (SPC). Way those, these techniques were not widely used in manufacturing companies until the late 1940s.

In the early 1950s, quality management practices developed rapidly in Japanese plants and became a major theme in Japanese management philosophy. By 1960, quality control and management had become a national preoccupation, and the quality control era started

2.4.3. Quality Assurance

Quality assurance is any systematic process of determining whether a product or service meets specified requirements. It is a process that comes after quality control and involves all the processes that directly affect the quality of a product or service, such as production planning and control, post-production operations,

maintenance, stores, purchasing, contracts, corporate quality planning, design and development, document control, quality control, internal quality auditing, training, and after-sales service. Quality assurance has been largely understood and practiced since the introduction of ISO 9000.

Quality assurance is a process that ensures that all the processes that affect the quality of a product or service are maintained. It involves various activities, including production planning and control, post-production operations, maintenance, stores, purchasing, contracts, corporate quality planning, design and development, document control, quality control, internal quality auditing, training, and after-sales service**.** Production planning and control involve the planning and management of resources to ensure that the production process runs smoothly and efficiently**.** Post-production operations refer to the activities that take place after the product has been manufactured, such as packaging, labeling, and shipping**.** Maintenance involves the upkeep and repair of equipment and facilities to ensure that they are functioning properly**.** Stores refer to the management of inventory and stock levels to ensure that there is an adequate supply of raw materials and finished products**.** Purchasing involves the procurement of raw materials and other resources needed for the production process**.** Contracts refer to the legal agreements between the company and its suppliers, customers, and other stakeholders**.** Corporate quality planning involves the development of policies and procedures to ensure that the company's products and services meet the required quality standards (Azeb Fisseh, 2021).

Design and development refer to the process of creating new products or improving existing ones. Document control involves the management of documents and records to ensure that they are accurate, up-to-date, and accessible. Quality control involves the inspection and testing of products and services to ensure that they meet the required quality standards. Internal quality auditing involves the review of the company's quality management system to ensure that it is effective and efficient. Training involves the development of skills and knowledge among employees to ensure that they are able to perform their jobs effectively. After-sales service involves the provision of support and assistance to customers after they have purchased the company's products or services.

The main purpose of quality assurance is to verify that the process is being maintained and that the resulting information is provided to those who have a need to know. This ensures that the company's products and services meet the required quality standards and that customers are satisfied with their purchases

2.4.4. Quality Engineering

Quality engineering is a set of methodologies, processes, and principles that help an organization improve its business processes to achieve a certain level of quality for its products or services. It involves creating products that meet customer needs while minimizing costs and losses due to quality issues and it is a multidisciplinary field that combines various areas such as engineering design, process operations, post-sale services, economics, and statistics. The goal of Quality Engineering is to improve the management of quality in an organization.

Engineering design refers to the process of designing new products that meet customer requirements and are cost-effective to produce. Process operations involve the methods and procedures used to manufacture products. Post-sale services refer to the support provided to customers after they have purchased a product. Economics involves the study of how resources are allocated to produce goods and services. Statistics is used to analyze data and make informed decisions (Azeb Fisseha, 2021).

Quality Engineering has led to improved management of quality in organizations and focusing on customer needs and minimizing costs and losses due to quality issues, organizations can improve their competitiveness and increase customer satisfaction.

2.4.5. Total Quality Management

Total Quality Management (TQM), which is a philosophy and set of guiding principles that aim to continuously improve an organization. TQM is a customer-driven, process improvement approach to management that involves knowledge of principles and techniques of behavioral science, quantitative and non-quantitative

analysis, economics, and system analysis. It integrates fundamental management techniques, existing improvement efforts, and technical tools under a disciplined approach.

TQM represents the foundation of a continuously improving in organization and involves a disciplined approach to integrating fundamental management techniques and principles, existing improvement efforts, and technical tools. It is a customer-driven, process improvement approach to management that aims to continuously improve the quality of all activities and relationships and a management approach that focuses on continuous improvement and customer satisfaction. It involves a disciplined approach to integrating fundamental management techniques, existing improvement efforts, and technical tools. TQM is a customer-driven, process improvement approach to management that aims to continuously improve the quality of all activities and relationships, According to Besterfield (1995).

2.5. Quality management in the drug industry

The QMS is responsible for maintaining and supporting the quality of the company's products, and is overseen by executive management and a team of qualified technical staff. The QMS is regularly monitored through self-audits, internal facility audits, and Quality Assurance compliance audits as per regulatory requirements and standards. The QMS uses a variety of tools to achieve its objectives, including training of personnel, quality documentation, and validations. In-process controls, systematic sampling, testing, validation exercises, environmental monitoring, and periodic auditing of materials, facilities, systems, and procedures are used to ensure the quality of the company's products throughout their shelf-life.

The QMS is supported by Standard Operating Procedures (SOPs) that are approved for all operations, including Production, Quality Assurance, Quality Control, Warehousing & Distribution/ marketing, Human Resources and Development, Area cleaning or Housekeeping, and Engineering. The Quality Assurance Department has a well-defined system to ensure the implementation and adherence to these procedures.

Periodic self-inspection twice-a-year and audits are conducted to monitor the effective implementation of quality systems, and are conducted by designated personnel from different departments of the company. Key personnel from Production, QC, QA, Warehouse, and Engineering are involved in the implementation of the quality systems, and they meet periodically to review the self-inspection, audit, training, complaint, and validation reports(from company profile).

The company is assessed regularly by local regulatory officials EFDA for conformation to the cGMP. The objective of quality is achieved through the Quality policies and principles as laid down in the manual and with relevant Standard Operating Procedures to ensure that each product meets the applicable customers' requirements for safety, identity, potency, strength, quality, purity, uniformity, reliability, and stability.

It is a comprehensive system that ensures the quality of the company's products through a variety of tools and processes at Cadila Pharmaceuticals (Ethiopia) Manufacturing PLC.

2.5.1. Quality assurance (QA) in pharmaceutical

Quality assurance is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product and the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended purpose. Quality assurance therefore incorporates GMP and other factors, including those outside the scope of this guide such as product design and development. (WHO, guideline-Volume 2, 2nd updated edition).

2.5.2. Good manufacturing practices for pharmaceutical products (GMP)

Alongside other industries where safety is critical, the pharmaceutical industry is heavily regulated and for obvious: mistakes in product design or production can have severe and even fatal, consequences for patient. The manufacturer shall establish and implement effective pharmaceutical quality assurance (QA) system involving the active participation of the management and personnel of the service involved. To ensure quality and safety of the products, pharmaceutical companies build their quality approach around good manufacturing practices (GMP).

Good manufacturing practice is that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization. GMPs are aimed primarily at diminishing the risks inherent in any pharmaceutical

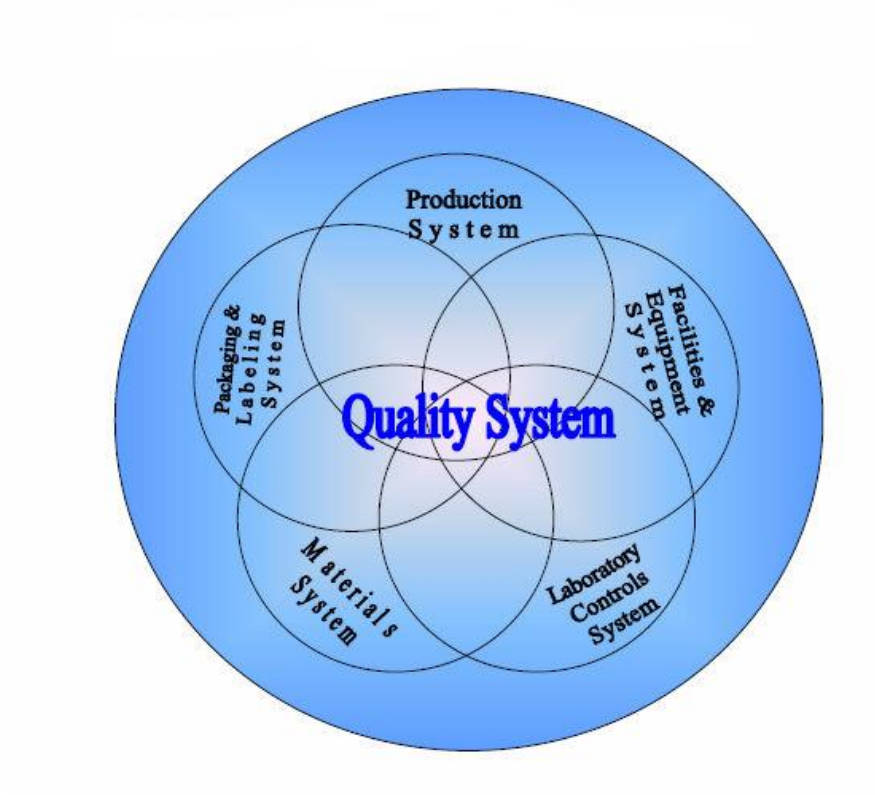
production. Such risks are essentially of two types: cross contamination (in particular of unexpected contaminants) and mix-ups (confusion) caused by, for example, false labels being put on containers. GMP has its elements thus are Sanitation and hygiene, Qualification and validation, Complaints Product recalls, Contract production and analysis, Self-inspection and quality audits, Personnel, training. Both production and quality control are under the control of GMP to follow all their process and activities must pass through out. (WHO, guideline- Volume 2, 2nd updated edition)

Pharmaceutical industry needs strictly to follow the GMP principles by all workers of the company and national and international regulations. The principles of QMS should be practiced and implemented to all workers thought training.

QMS is supported by the process approach concept, plan–do–check–act (PDCA) cycle and risk-based thinking. The PDCA cycle requires to carry out planning, performing (implementing), checking (evaluating) and acting (to improve) processes in the QMS.

- Plan: establish the objectives of the system and its processes, obtain the resources needed to deliver results in accordance with customers' requirements and policies, and identify and address risks and opportunities
- Do: implement what was planned
- Check: monitor and where applicable, measure processes and the resulting products and services against policies, objectives, requirements and planned activities and report the results;
- Act: take actions to improve performance, as necessary.

PDCA cycle: plan–do–check–act (taken from company profile).



Source FDA, Pharmaceutical GMP regulations, 2004

Table 2.5.1 Principles of quality management system

Principles	Rationale	Key benefits
1. Customer focus	Sustained success is achieved when an organization attracts and retains the confidence of customers and other interested parties	• Increased customer value • Increased customer satisfaction • Improved customer loyalty • Enhanced repeat business • Enhanced reputation of the organization
2. Leadership	Creation of unity of purpose, direction and engagement of people enable an organization to align its strategies	• Increased effectiveness and efficiency in meeting the organization's quality objectives Better coordination of the organization's processes • Improved communication between levels and functions of the organization
Engagement of people	To manage an organization effectively and efficiently, it is important to involve all people at all levels and respect them as individual	• Improved understanding of the organizations quality objectives by people in the organization • Enhanced involvement of people in improvement activities • Enhanced personal development, initiatives and creativity. • Enhanced people satisfaction • Enhance trust and confabulation through the organization
4. Process approach	The quality management system consists of inter related processes understanding how results are produced by this system enables an organization to optimize the system and its performance.	• Enlaced ability to focus effort on key processes and opportunities for improvement • Consistent and predictable out comes through a system of aligned processes
5. Continuous improvement	Improvement is essential for an organization to maintain current levels of performance, to react to changes in its internal and external conditions and to create new opportunities	• Improved process performance, organizational capabilities and customer satisfaction. • Enhance focus on root cause investigation and termination, followed by prevention and corrective actions. • Improved use of learning for improvement • Enhanced drive for innovation
6. Evidence based decision making	Decision making can be a complex process and it always involves some uncertainty. Facts evidence and data analysis lead to greater objectivity and confidence in decision making	• Improved decision making process • Improved assessment of process performance and ability to achieve objectives • Improved ability to review, challenge and change opinions and decisions

7. Relationship Management	Interested parties influence the performance of an organization. sustained success is more likely to be achieved when the organization manages relationships with all of its interested parties to optimize their impact on its performance	• Common understanding of goals and values among interested parties. • A well-managed supply chain that provides a stable flow of goods and services

Note: This table is incorporated from WWW.ISO.org posted at 2015

2.6. Pharmaceutical industrial development in Ethiopia

In the establishment of pharmaceutical industry in Ethiopia during its early stages of development the majority of the pharmaceutical industries were established only 15 to 20 years ago, and at the time of establishment, their production capacities were below 50% of their installed capacity. This was due to various factors such as high tariffs on raw materials, shortage of experienced human resources, high turnover of technical staff, shortage of technical manpower, and an absence of any training center on good manufacturing practices (GMP) and pharmaceutical management. Additionally, there were no GMP-certified inspectors at the regulatory authority, making it difficult for the industry to ensure consistent production and control according to quality standards.

Other challenges faced by the industry included difficulty in obtaining working capital from banks, management problems in the industries, absence of qualified equipment calibration and maintenance centers, lack of sustainable supply chain and weak relationship university-industry linkages. These challenges made it hard for the industry to produce their products efficiently and effectively. To address these challenges, the Ethiopian government created benefit packages and undertook policy reforms to support local manufacturing. The government also introduced duty-free service for pharmaceuticals that imported raw materials and chemicals from abroad and packaging. New pharmaceutical companies are still facing challenges such as lack of financial resources, insufficient or inconsistent training about QMS implementation, organizational structure limitations, lack of supply chain and documentation problems.

To ensure the consistent production and control according to quality standards, pharmaceutical and food industries in many countries are required to pass certification for GMP. GMP covers all aspects of production, from active pharmaceutical ingredients (APIs) and their handling to premises and facilities, the training of staff, and detailed documentation showing procedures are followed consistently at each production stage and every time a product is made. The United States of America, Canada, members of the European Medicines Agency, Switzerland, Norway, Australia, Japan, and others are recognized as having highly developed or "stringent" GMP requirements (Maureen et al, 2016).

The ‘reform and revival’ period began in 2005. The Ethiopian Pharmaceutical and Medical Supplies Manufacturers Association (EPMSMA) and other key stakeholders appealed to the government for appropriate measures to be taken in support of local manufacturing. To address the crisis the local manufacturers were facing, the government created benefit packages and undertook policy reforms. There was another benefit for pharmaceuticals that can use duty-free service while they brought raw materials from abroad and packaging. New Days Companies of pharmaceuticals are suffering of foreign currency and political problems lack to produce their products efficiently and effectively.

2.7. Profile of the study company (CPEL)

Cadila pharmaceuticals (Ethiopia) PLC is one of medics or drugs manufacturing industry of Ethiopia? It is the joint venture Ehio-India pharmaceuticals company between Cadila pharmaceuticals Ltd. India and Almeta Implex PLC, Ethiopia. The plant at Ethiopia is Cadila India oversee as formulation manufacturing facility

approved by Ethiopian food , Medicine, and healthcare Administration and control authority and confirming to GMP standards by world Health organization (WHO). Its Headquarter is located in Bole sub city around Meskel flower, Addis Ababa. Cadila is currently producing different dosage forms of, drug. It has been producing high quality and price –competitive drugs that have addressed the critical Health problems of the Ethiopian people for more than 15 years. The existing facility is at Gelan in Oromia region near to Addis Ababa of manufacturing factory. The manufacturing has 3 lines tablets, capsules and Liquids with manufacturing capacity of tablets is 390 million, capsules 165 million and oral liquids 1.44 million bottles per year in one shift (8 hours/day).

2.7.1. Pharmaceutical Manufacturing Activities As Licensed by National Authority

Cadila Pharmaceuticals (Ethiopia) PLC manufactures and distributes wide variety of pharmaceutical dosage forms which includes Tablets, Capsules and oral liquids. Cadila Pharmaceuticals (Ethiopia) PLC is licensed by the Investment Authority under license number EIA-0L/1845/07 and by the local regulatory body (FMHACA) 013/2010 to manufacture the above oral dosage forms. Cadila Pharmaceuticals Ethiopia PLC also received GMP certificate from PIC/s in August 2011 for complying with the established principles of the GMP guidelines of EU and PICs and WHO. Cadila Pharmaceuticals Limited establishes the quality of its products right at development stage with strong support of its R&D center which is very well equipped, and more than 100 scientists of various disciplines are working.

The company has fully equipped laboratories and Utilities capable of producing different dosage. Cadila is one of GMP certified pharmaceuticals in Ethiopia has been Approved by European audit Agency and has the accreditation of PIC/ s Certificate. Good manufacturing practice (GMP) standards – an explanation of GMP is a system for ensuring consistent production and control according to quality standards to minimize the risks involved in pharmaceutical production. GMP covers all aspects of production, from active pharmaceutical ingredients (APIs) and their handling to premises and facilities, the training of staff and detailed documentation showing procedures are followed consistently at each production stage and every time a product is made. In many countries pharmaceutical and food industries are required to pass certification for GMP. The United States of America, Canada, members of the European Medicines Agency, Switzerland, Norway, Australia, Japan and others are recognized as having highly developed or "stringent" GMP requirements.

The World Health Organization (WHO) Medicines Prequalification Program is also highly recognized internationally; this was set up to provide United Nations (UN) agencies that procure medicines, such as the United Nations Children's Fund (UNICEF), with a range of good-quality products that meet international standards requirement of quality, safety and efficacy. The WHO prequalification program and the drug regulatory authorities of these countries are also used as reference or "trusted" authorities by other countries that do not have the capacity to make the assessment of each product and facility, and by international funding agencies. The procurement guidelines of the Global Fund to Fight AIDS, Tuberculosis and Malaria, for example, state that grant funds may be used only to procure products that meet WHO prequalification or are authorized for use by a stringent drug regulatory authority. There are regional cooperation schemes with respect to GMP. The European Union (EU) GMP is used mainly within Europe. The Association of South- East Asian Nations (ASEAN) has harmonized its requirements, and the Gulf Cooperation Council (GCC) is recognized for active regional GMP cooperation. PIC/S is similar to European GMP but includes membership from authorities from the rest of Europe and countries in the Americas (Argentina and Canada)

2.7.2. Quality Management System in CPEL

Quality management (QM) focuses not only on the quality of the product but also on the means to achieve it. It is centered on the following four activities: quality planning, quality control, quality assurance and quality improvement. Quality management system can be defined as managing structure, responsibilities, procedures, processes, and management resources to implement the principles and action lines needed to achieve the quality objectives of an organization. Quality in the pharmaceutical industry is linked with client's satisfaction and the implementation of a Quality management system. Quality management system is a key tool in consistently and reliably managing the goal of client or regulatory body satisfaction. A good QMS will Set direction and meet

customers‘ expectations, Improve process control, Reduce wastage, Lower costs, Increase market share, Facilitate training, Involve staff, Raise morale etc.

The QMS is regularly monitored through self-audits, internal facility audits, and Quality Assurance compliance audits as per regulatory requirements. The QMS uses a variety of tools to achieve its objectives, including training of personnel, quality documentation, and validations. In-process controls, systematic sampling, testing, validation exercises, environmental monitoring, and periodic auditing of materials, facilities, systems, and procedures are aimed to ensure the quality of the company's products throughout their shelf-life.

Under the QMS, Cadila Pharmaceuticals (Ethiopia) has Standard Operating Procedures approved for all operations, including Production, Quality Assurance, Quality Control, Warehousing & Distribution, Human Resources and Development, Housekeeping, and Engineering. The Quality Assurance Department has a well-defined system to ensure the implementation and adherence to these procedures, and periodic self-inspections and audits are conducted to monitor the effective implementation of quality systems. Key personnel from Production, QC, QA, Warehouse, and Engineering are involved in the implementation of the quality systems. They meet periodically to review the self-inspection, audit, training, complaint, and validation reports. The company is assessed regularly by local regulatory officials for conformation to the cGMP. The objective of the QMS is to ensure that each product meets the applicable customer requirements for safety, identity, potency, strength, quality, purity, uniformity, reliability, and stability. Cadila Pharmaceuticals (Ethiopia) is established under the regulation of the local regulatory body, FMHACA (now EFDA), and has rich technical experience to share with CPEL (taken from company profile).

2.7.3. Quality control system

Quality control is a method used to monitor specific task results to determine if they conform to relevant standards. The goal of quality control is to improve quality and monitor project outputs to ensure they meet quality standards based on stakeholder expectations. Technical processes and procedures are set up by team members to ensure each step of the activities provides a quality output, from design to development through implementation and maintenance. Each step's output must conform to the overall quality standards and quality plans to ensure that quality is achieved. In the pharmaceutical industry, quality control plays an incomparable role in monitoring specific product results to determine if they comply with relevant quality standards or specifications. The performance documents should comprise a clear, complete, and accurate description of the company to be performed, correctly conveying the intent of the owner regarding the characteristics of the organization needed to serve his or her purposes. Quality control is essential in ensuring that the final product meets the required quality standards and specifications, which is crucial in industries such as pharmaceuticals where the quality of the product can have a significant impact on human health.

There are many factors affecting the quality of pharmaceutical quality, such as design, materials, machinery, and methods of operation, technical measures, and management systems and so on. Construction companies must follow to the principle of quality first, and sustain on quality standards, to provide more high quality, safe, efficient products. Harold (2003) stated that a good quality control system will; ―Select what to control, set standards that provide the basis for decisions regarding possible corrective action, establish the measurement methods used, compare the actual results to the quality standards, act to bring nonconforming processes and material back to the standard based on the information collected, monitor and calibrate measuring devices and include detailed documentation for all processes‖ (Harold, 2003). Similarly Juran quality control relies on five basics: a clear definition of quality; a target, a clear goal; a sensor, a way to measure actual performance; a way to interpret the measurement and compare with the target; and a way to take action, to adjust the process if necessary(Juran, 1999).

The company adopted two separate departments to execute its quality control policy. The quality control department continually monitors incoming raw materials, packaging and finished products and packaging to ensure compliance with compositional standards, microbiological standards and various government regulations. The quality assurance department develops quality systems, standard operating procedures and document control programs, ensuring alignment with the company’s policy and

regulatory body requirements. It confirms that all pertinent manufacturing, packaging and testing documents are complete and reflected accordingly to satisfy customers and regulatory body requirements. The company is certified with GMP based quality system for it's quality operations since 2011 (taken from company profile).
Cadila pharmaceuticals (Ethiopian) Manufacturing plc. (CEPL) is committed to; meet the needs of its customers and other stakeholders by providing pharmaceuticals of proven quality, safety and efficacy through the application of internationally accepted practices, management systems and through fulfillment of regulatory requirements.

2.7.4. Quality assurance Vs quality control

QA activities in the pharmaceutical industry include:
1. Setting quality standards: establishing the specifications and requirements for the final product and for each step of the drug development process.
2. Implementing quality Management systems: developing and implementing systems and procedures to ensure that the standards are met and that the final product meets the required specifications.
3. Training employees: Providing training to employees on the quality standard, procedures and regulations that they must adhere to.
4. Conducting internal audits: periodically reviewing and evaluating the quality management system and processes to ensure that they are being followed, and to identify area for improvement.
5. Suppliers qualification and management: qualifying, selecting and managing vendors, contractors and suppliers that provide materials, services and equipment that are necessary for the production and development of the drug.
6. Document control: Maintaining the documentation of the development, production, quality control and distribution process to ensure that the records are accurate, up-to-date, and retrievable.
7. Compliant handling: Establishing and maintaining systems for receiving, documenting, and reporting customer complaints and evaluating the effectiveness of corrective action taken.
8. Management review: periodically reviewing the overall performance of the quality management system and making decisions on its improvement.

Quality Assurance	**Quality control**
Focuses on the overall process	Focuses on the specific results
Preventative in nature	Detection and correction-oriented
Responsibilities of upper management	Responsibilities of laboratory, QC department
More strategic	More operational
Conducts internal audits	Conducts testing and inspection
Implements quality management systems	Monitors production processes
Ensures compliance with regulations	Detects and corrects defects and non-conformities
Provides framework for QC	Provides feedback to inform QA improvements

It's important to remember that QA and QC are interdependent and both critical components to maintaining the quality of the final product, in this case, the drugs. A strong QA program will help ensure that the necessary controls are in place, while a robust QC program will help identify areas where the QA program can be improved.

Quality Assurance and Quality Control are two essential components of the pharmaceutical industry that play a critical role in ensuring the safety and efficacy of pharmaceutical products. QA is a systematic process that focuses on the overall management of the product development and manufacturing process to ensure that the product meets the required quality standards, while QC is a reactive approach that focuses on the inspection and testing of products to ensure that they meet the established quality standards. Both QA and QC are essential for ensuring compliance with regulatory requirements and industry standards and work together to provide a

comprehensive quality management system that helps to ensure that pharmaceutical products are safe, effective, and of the highest quality (www.pharmaceuticalsky.com).

2.8. The benefits of QMS

Implement quality management systems successful can contribute to an increase in product quality, improvements in workmanship and efficiency, a decrease in wastage, and increased profit. An external quality system help to inspiring confidence in the client that the supplier‘s quality system will provide a product or service that will satisfy the client‘s quality requirements.

Adequate implementation of QMS brings the following for an organization.

- Improved customer satisfaction;
- Improve relations with suppliers;
- Improved promotion of corporate image
- Improved quality of products and services;
- Improve process interfaces and internal communication;
- Improve staff involvement by identifying the role of their output to involving them in the review and improvement of their work.
- Better management and a more effective organization;
- Review the organizational structure, clarifying managerial responsibilities;
- Identify processes that are unnecessary or inefficient, and then remove or improve them;
- To review business goals, and assess how well the organization is meeting those goals(Azeb Fisseha ,2021)

The benefits of Quality Management Systems (QMS) helps organizations meet two requirements of customer requirements and the organization's requirements. Customer requirements used to the confidence customers have in the organization's ability to consistently deliver products and services that meet their needs and expectations. The organization's requirements refer to meeting internal and external requirements at an optimum cost with efficient use of available resources such as materials, human resources, technology, and information.

The QMS helps organizations achieve their goals and objectives by providing consistency and satisfaction in terms of methods, materials, equipment, and ending with customer satisfaction at every transaction interface. QMS is needed in all areas of activity, whether large or small business, manufacturing, service, or public sectors. QMS helps organizations meet customer and organizational requirements, achieve their goals and objectives, and provide consistency and satisfaction in all areas of activity (www.google.com).

The QMS uses a variety of tools to achieve its objectives, including training of personnel, quality documentation, and validations. In-process controls, systematic sampling, testing, validation exercises, environmental monitoring, and periodic auditing of materials, facilities, systems, and procedures are used to ensure the quality of the company's products throughout their shelf life.

The QMS is supported by Standard Operating Procedures (SOPs) that are approved for all operations, including Production, Quality Assurance, Quality Control, warehouse and distribution, human resources and development, housekeeping, and Engineering. The Quality Assurance Department has a well-defined system to ensure the implementation and adherence to these procedures.

Periodic self-inspection and audits are conducted to monitor the effective implementation of quality systems and are conducted by designated personnel of the company. Key personnel from Production, QC, QA, Warehouse, and Engineering are involved in the implementation of the quality systems, and they meet periodically to review the self-inspection, audit, training, complaint, and validation reports.

The company is assessed regularly by local regulatory officials for conformance to cGMP. The objective of quality is achieved through the Quality policies and principles as laid down in the manual and relevant Standard Operating Procedures to ensure that each product meets the applicable customers' requirements for safety, identity, potency, strength, quality, purity, uniformity, reliability, and stability (taken from CPEL document).

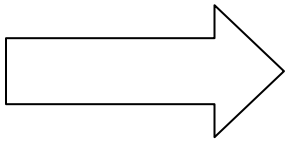
2.9. Conceptual Framework

This section showed the 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, 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 below (Brihanu Degu, 2021).

Management responsibilities

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



Practices and implementation

CHAPTER THREE

3. Research Methodology

This chapter describes the research methodology used in this research and clarifies how the research problem was solved. It would present brief explanations on how the research was conducted basically includes; research design and approach, population and sampling technique, data sources and data collections tools, data analysis methods, Reliability and validity test and ethical considerations were included.

3.1. Research Design and Approach

The study employed to use both qualitative and quantitative methods to collect, analyze, and produce results by mixing both types of data at some stage of the research process within a study. The approach comprised two complementary methods: questionnaire survey and interview. The questionnaire generated quantitative data, while the interview provided richer qualitative details, at the same time used to validating the quantitative findings.

This study aimed to assess the practices of quality management and challenges involved in the implementation of QMS. A descriptive survey method was used to measure the characteristics described in the research question. The descriptive survey method is a method of investigation that attempts to describe and interpret what exists in the company at present in the form of conditions, practice, process, trends, effects, attitudes, beliefs, common understanding, etc.

The data collected in the study were both qualitative and quantitative. Qualitative data were gained during the interview and reviewing of quality-related materials from the organization. On the other hand, quantitative data were obtained using questionnaires. The study applied both qualitative and quantitative methods design, which was a procedure for collecting, analyzing, and producing results by mixing both types of data at some stage of the research process within this study.

Hurmerinta-Peltomaki and Nummela (2006) have found that there is value-adding to results based on the implementation of mixed methods when compared with using a single method. Therefore, the study used as both qualitative and quantitative methods to provide a more comprehensive understanding of the practices of quality management and challenges involved in the implementation of QMS.

3.2. Population and sampling Technique

The target population for this study was CPEL which is found in Gelan town. This Pharmaceutical industry was selected because of its experience in the pharmaceutical sector and company which had implemented QMS in their organizational system. It is well-organized and produces different kinds of drugs or medicines.

The sample size of the study included all permanent employees of CPEL, including managers, supervisors, experts, seniors, pharmacists, and all quality assurance and quality control department employees. The organization has 200 employees from these 60 are permanent and others are not permanent (casuals). The selection of these participants was purposive, meaning they were chosen because they were the focal and more responsible persons in the practice of quality in the company and implementation of QMS in their organization.

The reason for choosing this sampling technique was that these participants were assumed to be rich in information of QMS principles and could share ideas related to the practice of QMS in the organization and practicing in day to day work. This sampling technique helped to understand the problem and the research question.

The study targeted the population of organization employees from all departments, and the sample size included all permanent employees of CPEL, including managers, supervisors, experts, seniors, pharmacists, and all department employees. The purposive sampling technique was used to select participants who were more responsible for the practice of quality in the company and implementation of QMS in their organization.

3.3. Data Sources and Data Collection tools

The research tried to obtain both primary and secondary data. The primary data was obtained from employees of CPEL using semi-structured questionnaire. Interview questions were also given to the management and supervisors of CPEL. The secondary sources of data were the literatures available and the documents related to QMS which are kept by the organization.

The study used both primary and secondary data sources, including questionnaires, interviews, and direct observations. Questionnaires, interviews, and direct observations are considered the most important means of data collection tools according to Kothari (1985).

The questionnaire used in the study was designed using a five-level Likert Scale, which is a commonly used rating scale in research. The Likert scale allows respondents to rate their attitudes towards a particular attribute or factor presented as a question on a scale of 1 to 5, with 1 being the least and 5 being the most. This scale or system helps to measure the degree of agreement or disagreement, approval or disapproval of the respondents towards the questions asked (Cooper and Schindler, 2008).

Therefore, in this study, both questionnaires and interviews were employed as primary data collection tools to obtain the required information. The study used the Likert scale to measure the attitudes of the respondents towards the key principles of quality management practices. The use of both questionnaires and interviews helped to gather comprehensive data from the employees of Cadila Pharmaceuticals (Ethiopia) Manufacturing PLC.

3.3.1. Data collection By Questionnaire

The questionnaire had both open-ended and closed-ended questions and was designed based on the key principles of quality management practices such as customer focus, leadership/management commitment, engagement of employees, continuous improvement, evidence-based decision making, and relationship management. The questionnaire was a simple and time-saving method to collect data effectively from a large number of respondents.

The questionnaire had two types of questions: open-ended and closed-ended. Open-ended questions allow respondents to answer the questions in their own words, while closed-ended questions provide a set of options for respondents to choose from given options. The study formulated questions based on the identified variables and used the questionnaire to gather data from professional workers of the company working in this organization.

The questionnaire was a suitable method for data collection as it allowed the study to gather data from a large number of respondents in a short period of time. It also ensured that the data collected was standardized and could be easily analyzed using statistical methods.

So, the questionnaire was an effective tool for data collection in this study and helped the researcher to gather valuable insights into the quality management practice of CPEL.

3.3.2. Interview

It is believed that interviews had an advantage over other methods as they allowed for more probing and clarification of information, as well as capturing different understandings of the interviewees. The interviews were conducted face-to-face with the interviewees of company managers and supervisors at working place, either individually or in group discussions, depending on their interest. The interviews were unstructured, meaning that open-ended questions were asked to gather information on various aspects of the organization's quality management, quality problems, factors affecting the quality of medicines, and other relevant information. This information collected through the interviews was then discussed in the literature review section of the study.

The company established of procedures for documentation and training personnel in a timely manner during employment and on jobs. This means that the organization has set up a system to ensure that employees are trained and documented in a timely manner based on their performance and observations made by their supervisors or managers. However, these procedures are often neglected for various reasons, which can have a negative impact on quality practices and the application of Quality Management System (QMS) concepts. This means that despite having established procedures, they are not always followed due to various reasons such as lack of resources, time constraints, or lack of awareness. This can have a negative impact on the quality practices and the application of QMS concepts, which can ultimately affect the overall quality of the product or service.

The company is facing challenges such as shortages of raw materials due to financial and political issues, which can affect both the quality of the final product and the production process. This means that the company is facing external challenges that are beyond its control, such as financial and political issues that are causing shortages of raw materials. This can affect the quality of the final product and the production process, which can ultimately affect the company's reputation and profitability.

Improving QMS principles can be challenging for the company since QA/QC is considered a quality management system implementation. This means that the company may face challenges in implementing QMS principles since Quality Assurance/Quality Control (QA/QC) is considered a part of QMS implementation. This can lead to a fragmented approach to quality management, making it difficult to implement QMS concepts throughout the organization. This can ultimately affect the overall quality of the product or service and the company's reputation.

3.4. Data Analysis Methods

The study used a descriptive type of data analysis to examine the collected data and find constructs, themes, and designs that were used to describe and explain the phenomenon being studied. Descriptive statistics analysis was used to present, interpret, and discuss various dimensions of the evaluation system.

Frequency tables, percentages, mean and standard deviation were used to analyze, interpret, tabulate, and present the results of the study. The data gathered through questionnaires was checked, filtered, coded, and entered for further statistical analysis using the SPSS-23 software. The study also employed ranking, weighted mean and standard deviation to analyze the data and percentage and presented the results in the form of tables.

The results of the interview questions were integrated with the responses of employees through questionnaires and analyzed accordingly and company documents and observations were included in analysis. Finally, conclusions were made based on the results of the study, and recommendations were forwarded based on the data analyzed.

In general, the study used various statistical methods to analyze the data collected from the questionnaires and interviews. The results were presented in the form of tables, and conclusions were made based on the analyzed data. The recommendations were made based on the findings of the research study.

3.5. Reliability and Validity test

In this section, the reliability and validity test discuses of the survey instrument used in this research. Reliability refers to the consistency and accuracy of the data collected on survey, while validity refers to the extent to which the instrument measures to reflect what it is intended to measure. The study used a survey method to collect data and checked the reliability of the scale to ensure that the collected data was free from random error. Study used something called inter-item reliability consistency (alpha) to measure the internal consistency or reliability of the psychometric instrument. Cronbach's alpha is a statistic used to measure internal consistency, and the data should exceed a threshold of 0.70 to be considered reliable (Streiner and Norman, 1989). The questionnaire used in the study was designed with a five-point Likert scale ranging from strongly disagree to strongly agree, and the data collected using this questionnaire was analyzed and presented with tables and percentages using SPSS-23

software. And also used construct validity to ensure that the questions explained the answers given. The reliability and validity of the survey instrument were checked using SPSS-23 software, and the test checked out as reliable and valid (0.92). A table blew showing the reliability analysis test result and descriptive statistics. Overall, it took great care to ensure that the reliability and validity of its survey instrument to ensure the accuracy of this research findings and validity test.

It was checked out that the survey measures for accuracy and consistency when testing the research questions data. To see how reliable the instrument was, it used something called inter-item reliability consistency (alpha). It was also used something called construct validity, which looks at how well certain questions explain the answers given. The research took the questionnaire evolution methods from scientific methods and other studies.

Table 3.5.1Reliability analysis test result and descriptive statistics

Case Processing Summary			
		N	%
Cases	Valid	60	100.0
	Excluded[a]	0	.0
	Total	60	100.0

Reliability Statistics	
Cronbach's Alpha	N of Items
.920	33

Source: own data 2023
The test checked out as reliable and valid according to SPSS-23 software.

3.6. Ethical Considerations

It ensured that the data provided by the respondents was kept confidential and anonymous. The respondents were not required to provide their names on the questions and were assured that their responses would be treated with strict confidentiality. The company's confidential information was also kept in accordance with the guidelines provided in the questionnaire, and there would be no disclosure of this information without permission of the company's consent.

The information collected also maintained the originality of the study and acknowledged all previous research findings and facts with their respective authors. The purpose of the study was solely for academic purposes, and ensured that all ethical considerations were taken into account to maintain the integrity of the research.

CHAPTER FOUR

4. DATA ANALYSIS AND INTERPRETATION

4.1. Introduction

This chapter presented the analysis of the data collected from the company of research and the discussion of the results and content analytic approach. Primary data was gathered on QMS principles practices. The analysis covered personal details, QM practices in CPEL, effectiveness of the QM practices at CPEL, effect (challenges) of QM on organizational performance, and Management view on organizational performance. The chapter presents the study findings, starting with descriptive statistics and followed by interviews. Data analysis for descriptive statistics was made possible with the help of Statistical Package for Social Science (SPSS-23) software. This data were presented to 60 peoples in the company from all departments which contained high level managers (technical Manager), middle level managers (department managers and assistant managers), lower level (supervisors) and workers of different back grounds.

Table 4.1.1Response Rate and Demographic Description of Respondents

Age of respondents					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	<25 years	2	3.3	3.3	3.3
	25-30 years	18	30.0	30.0	33.3
	30-35 years	30	50.0	50.0	83.3
	>40 years	6	10.0	10.0	93.3
	5	4	6.7	6.7	100.0
	Total	60	100.0	100.0	

Source: own data 2023

Table 4.2.1 shows that out of the 60 respondents, the majority (50%) were in the age category of 30-35 years old. 30% of the respondents were in the age category of 25-30 years old, while 10% were above 40 years old and 3.3% were below 25 years old. From the above data the information is important because it provides insight into the age range of the employees who participated in the study. It also suggests that the majority of the respondents were in their productive age, which could have implications for the results of the study.

Table 4.1.2 Years of experience respondents in the organization

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	<5 years	15	25.0	25.0	25.0
	5-10 years	25	41.7	41.7	66.7
	10-15 years	13	21.7	21.7	88.3
	.15 years	7	11.7	11.7	100.0
	Total	60	100.0	100.0	

Source: own data 2023

Table 4.2.2 shows the years of experience of the respondents in the organization. The table indicates that 25% of the respondents had less than 5 years of experience, 41.7% had 5-10 years of experience, 21.7% had 10-15 years of experience, and 11.7% had more than 15 years of experience. The information years' experience is important because it provides insight into the level of experience of the employees who participated in the study. It also suggests that the majority of the respondents had at least 5 years of experience, which could have implications for their understanding and perception of quality management practices in the organization.

Both tables used to show frequency and percentage to present the data. Frequency refers to the number of respondents in each category, while percentage refers to the proportion of respondents in each category relative to the total number of respondents. The tables also include valid and cumulative percentages, which provide

additional information on the distribution of the data. Valid percentages exclude missing or invalid responses, while cumulative percentages show the proportion of respondents up to a certain category.

These tables provide important demographic information about the respondents in the study, which can help contextualize the results and provide insights into the characteristics of the employees who participated in the study.

Table 4.1.3Education Level

		Frequency	Percent	Cumulative Percent
Valid	diploma	2	3.3	3.3
	first degree	51	85.0	88.3
	master and above	7	11.7	100.0
	Total	60	100.0	

Source: own data 2023

A table that showed the education level of the respondents who participated in the practice of quality management. The respondents were employees of Cadila Pharmaceuticals (Ethiopia) Manufacturing PLC (CPEL). The table has three columns: Frequency, Percent Valid, and Cumulative Percent.

The Frequency column shows the number of respondents who reported having a particular education level. From table, two respondents reported having a diploma, 51respondents reported having a first degree, and seven respondents reported having a master's degree or above.

The Percent Valid column shows the percentage of respondents who reported having a particular education level out of the total number of respondents who completed the survey 3.3% of respondents reported having a diploma, 85% reported having a first degree, and 11.7% reported having a master's degree or above.

The Cumulative Percent column showed the cumulative percentage of respondents who reported having a particular education level of 3.3% of respondents reported having a diploma, and when added to the 85% of respondents who reported having a first degree, the cumulative percentage becomes 88.3%. The final row of the table shows that all 60 respondents completed the survey.

Therefore, the table provides information about the education level of the respondents, which could be useful in understanding the demographics of the sample and interpreting the results of the study.

4.2. Descriptive analysis of variables

The quality management system principle practices considered in this research study as defined in the standard questionnaire and discussed in the literature part are Costumer focus, Leadership/Management commitment, Engagement of employees, Continuous improvement in the company, Evidence-based decision making, and Relationship management. The data tables showed blow indicates the respondents agree the quality management system principles practices had positive effect on the performance quality management practice of the organization in a relatively small variation.

Table 4.2.1Costumer focus

Response Rate 1=strongly Disagree 2=Disagree 3=neutral 4=Agree 5= strongly agree

Description	**N**	**Response Frequency / Percentage**					**mean**	**Std.**
		1	**2**	**3**	**4**	**5**		
Your organization have good trend of assessing future customer needs and expectations.	60	2 3.3%	5 8.3%	21 3.5%	26 43.3%	6 10%	3.48	0.911
The organization adopts formal strategies or ways to collect customer complaints	60	4 6.7%	8 13.3%	25 41.7%	17 28.3%	6 10%	3.22	1.027

The company developed the ways of data collection on customer expectations and/or satisfaction when designing new products	60	4 6.7%	13 21.7%	21 35%	18 30%	4 6.7%	3.08	1.030
The customer's complaints coming to the organization	60	2 3.3%	11 18.3%	16 26.7%	26 43.3%	5 8.3%	3.35	0.988
Where servicing is specified in the contract, procedures are established to verify that servicing meets the indicated requirements	60	4 6.7%	12 20. %	20 33.33%	17 28.3%	7 11.7%	3.18	1.097

Source: own data 2023

Customer focus is one of the key principles of quality management practices that were used as an independent variable in this study to measure the organizational quality management of Cadila Pharmaceuticals (Ethiopia) Manufacturing PLC.

Table 4.2.1 presents the results of the questionnaire that was used to collect primary data from the employees of CPEL regarding their organization's customer focus.

The first row of the table shows that 43.3% of the respondents agreed and 10% strongly agreed that their organization has a good trend of assessing future customer needs and expectations, with a mean rating of 3.48 and a standard deviation of 0.911, which indicates that the organization is customer-focused.

The second row of the table shows that 41.7% of the respondents were neutral, 28.3% agreed, and 28.3% strongly agreed that their organization adopts formal strategies or ways to collect customer complaints, with a mean rating of 3.22 and a standard deviation of 1.02, which indicates that the organization values customer feedback and takes it seriously.

The third row of the table shows that 35% of the respondents were neutral, 30% agreed, and 30% strongly agreed that their company developed ways of collecting data on customer expectations and/or satisfaction when designing new products, which indicates that the organization considers customer needs and preferences when developing new products, with a mean rating of 3.08 and a standard deviation of 1.03.

The fourth row of the table shows that 43.3% of the respondents agreed and 8.3% strongly agreed that customer complaints coming to the organization were handled effectively, with a mean rating of 3.35 and a standard deviation of 0.99, which indicates that the organization is responsive to customer complaints and took appropriate actions to address them.

The fifth row of the table shows that 28.3% of the respondents agreed and 11.7% strongly agreed that procedures are established to verify that servicing meets the indicated requirements, with a mean rating of 3.18 and a standard deviation of 1.09, which indicated that the organization ensured that its services meet customer requirements and expectations, with some of them having reservations.

This indicates that the organization assesses the current customer's needs and expectations. Moreover, during the review of the organization's documents on the product development procedure, it was clearly stated that the R&D manager coordinates and initiates marketing research. Here, the marketing research committee, under the close supervision of the R&D manager, conducts marketing research so as to assess the market demand and those coming from stakeholder requests and also from the prepared annual plan of CPEL. When we refer to research in this area, Khan pointed out the argument that customer satisfaction transforms into customer delight when goods or services exceed customers" expectations. Thus, understanding what the customer wants is crucial (Khan, 2015).

Response Rate 1=strongly Disagree 2=Disagree 3=neutral 4=Agree 5= strongly agree

Table 4.2.2 Leadership/Management commitment

Descriptions	N	Response Frequency / Percentage					Mean	Std.
		1	2	3	4	5		
The senior executives of the organization provide highly visible leadership in maintaining an environment that supports quality improvement	60	5 8.3%	11 18.3%	21 35.0%	18 30.0%	5 8.3%	3.12	1.075
The senior executives appreciate efforts that improve quality throughout the organization	60	1 1.7%	12 20.%	17 28.3%	24 40%	6 10%	3.37	0.974
Senior executives involve on activities that enhance customer satisfaction by obtaining information on needs and suggestions for quality improvement directly from customers	60	2 3.3%	4 6.7%	27 45 %	22 36.7%	5 8.3%	3.40	0.867
The senior management leadership role to find solution for the problems	60	1 1.7%	17 28.3%	12 20%	25 41.7%	5 8.3%	3.27	1.023

Source: own data 2023

Table 4.2.2 presents the results of the questionnaire that was used to collect primary data from the employees of CPEL regarding their organization's leadership/management commitment.

The first row of the table shows that 30.0% of the respondents agreed and 8.3% strongly agreed with the senior executives' visible leadership in maintaining an environment that supports quality improvement, with a mean rating of 3.12 and a standard deviation of 1.08, which indicates a moderate level of agreement among employees.

The second row of the table shows that 40% agreed and 10% strongly agreed that the senior executives' appreciation of efforts that improve quality throughout the organization has a higher mean rating of 3.37 and a standard deviation of 0.97, indicating a higher level of agreement among employees.

The third row of the table shows that 45% of the respondents' neutral, 36.7% agreed, and 8.3% strongly agreed that the senior executives' involvement in activities that enhance customer satisfaction, indicates a high level of agreement among employees, with a mean rating of 3.4 and a standard deviation of 0.87.

The fourth row of the table shows that 41.7% of the respondents agreed and 8.3% strongly agreed that the senior management leadership role in finding solutions for problems has a mean rating of 3.27 and a standard deviation of 1.02, indicating a moderate level of agreement among employees. From these responses, we can infer that the senior executives of the organization provide highly visible leadership in maintaining an environment that supports quality improvement. During an interview with the General Manager of the organization, he raised the point that top management holds meetings every month about the work environment, reports from the quality assurance department and the marketing department about customer situations. All the decisions of these meetings were recorded in the minutes of the meetings and documented. When we look at the literature, David Hoyle, in his book on the ISO 9000 system, raises the presumption that management that is committed to the development, implementation, and continual improvement of a management system will be committed to quality because it believes that the management system is the means by which quality is achieved (Hoyle, 2001).

The above table also showed that the majority of employees agreed that senior executives appreciate efforts that improve quality throughout the organization, involve themselves in activities that enhance customer satisfaction, and take a leadership role in finding solutions for problems. However, there were some employees who disagreed or were neutral on these questions.

Response Rate 1=strongly Disagree 2=Disagree 3=neutral 4=Agree 5= strongly agree

Table 4.2.3Engagement of employees

Descriptions	N	Response Frequency / Percentage					Mean	Std.
		1	2	3	4	5		
Organizational structure that allows employees to exercise corrective actions based on their authority is appreciated by employees and helped to improve quality.	60	1 1.7%	8 13.3%	25 41.7%	19 31.7%	7 11.7%	3.38	.922
The organization's employees are appreciated when they take necessary risks to improve quality	60	5 8.3%	15 25%	17 28.3%	16 26.7%	7 11.7%	3.08	1.154
The organization's employees are given education and training in statistical and other quantitative methods/ tools that support quality improvement	60	5 8.3%	13 21.7%	18 30%	16 26.7%	8 13.3%	3.15	1.162

Source: own data 2023

Table 4.2.3 shows the response rate of employees on different aspects of employee engagement in quality management practices.

The first row of the table shows that 31.7% agreed and 11.7% strongly agreed. The study found that an organizational structure that allows employees to exercise corrective actions based on their authority was appreciated by employees and helped to improve quality, with a mean score of 3.38 and a standard deviation of 0.922.

The second row of the table shows that 28.3% of the respondents' neutral, 26.7% agreed, and 11.7% strongly agreed. The mean score of 3.08 with a standard deviation of 1.15 indicates that employees are appreciated when they take necessary risks to improve quality.

The third row of the table shows that 26.7% of the respondents agreed and 13.3% strongly agreed. The mean score of 3.15 with a standard deviation of 1.162 indicates that employees are given education and training in statistical and other quantitative methods and tools that support quality improvement.

Analyses were conducted for the questions related to employee engagement. We have seriously competed for it and have developed clear and organized quality awareness training for all employees. Typically, the training is delivered to everyone in the organization, then to all new employees as part of their orientation upon joining. These results imply that every employee thought have been used as input to make any quality related decisions. Quality advocator Okland pointed out that the key medium for motivating employees and gaining their commitment to quality is face-to-face communication and visible management commitment (Okland, 2001).

Response Rate 1=strongly Disagree 2=Disagree 3=neutral 4=Agree 5= strongly agree

Table 4.2.4 Continuous improvement in the company

Descriptions	N	Response Frequency / Percentage					Mean	Std.
		1	2	3	4	5		
Control charts, graphs and other methods of analysis determine how well a process is working and facilitate continuous improvement	60	3 5%	8 13.3%	18 30%	27 45%	4 6.7%	3.35	0.971
The organization promote improvements in a way that enhance competitive environment among members of the organization by recognizing best performing individuals and units and also giving frequent training.	60	4 6.7%	18 30%	17 28.3%	16 26.7%	5 8.3%	3.00	1.089
The organization is continuously improving itself by trying to apply the latest knowledge and technologies in the industry	60	7 11.7%	15 25%	16 26.7%	16 26.7%	6 10%	2.98	1.189
The organization uses benchmarking by comparing its results to those of competitors and best practices	60	4 6.7%	11 18.3%	21 35%	21 35%	3 5%	3.13	0.999
The company has training policies for employees	60	4 6.7%	9 15%	15 25%	20 33.3%	12 20%	3.45	1.171
There is continuous improvement reviews through internal and external quality audits	60	-	6 10%	14 23.3%	26 43.3%	14 23.3%	3.80	0.917

Source: own data 2023

Table 4.2.4 presents the results of the questionnaire that was used to collect primary data from the employees of CPEL regarding continuous improvement in the company.

The first row of the table shows that 45% of the respondents agreed and 6.7% strongly agreed, with a mean rating of 3.35 and a standard deviation of 0.97, which indicates that the organization uses control charts, graphs, and other methods of analysis to facilitate continuous improvement.

The second row of the table shows that 28.3% of the respondents were neutral, 26.7% agreed, and 8.3% strongly agreed, with a mean rating of 3.00 and a standard deviation of 1.09, which indicates that the organization promotes improvement by enhancing the competitive environment in individual and unit performance.

The third row of the table shows that 26.7% of the respondents' neutral, 26.7% agreed, and 10% strongly agreed that the organization is continuously improving itself by trying to apply the latest knowledge and technologies in the industry, with a mean rating of 2.98 and a standard deviation of 1.19.

The fourth row of the table shows that 35% of the respondents agreed and 5% strongly agreed the organization uses benchmarking by comparing its results to those of competitors and best practices, with a mean rating of 3.13 and a standard deviation of 0.999.

The fifth row of the table shows that 33.3% of the respondents agreed and 20% strongly agreed, with a mean rating of 3.45 and a standard deviation of 1.17, which indicates that the company has training policies for employees.

The sixth row of the table shows that 43.3% of respondents agreed and 23.3% strongly agreed, with a mean of 3.8 and a standard deviation of 0.92, on continuous improvement reviews through internal and external quality audits.

The continuous improvement principle involves using control charts, graphs, and other methods of analysis to determine how well a process is working and facilitate continuous improvement. The organization also promotes improvements in a way that enhances the competitive environment among members of the organization by recognizing the best performing individuals and units and giving frequent training. Additionally, the organization continuously improves itself by trying to apply the latest knowledge and technologies in the industry and uses benchmarking by comparing its results to those of competitors and best practices. As a result of the above table, the company also has training policies for employees and conducts continuous improvement reviews through internal and external quality audits.

Response Rate 1=strongly Disagree 2=Disagree 3=neutral 4=Agree 5= strongly agree

Table 4.2.5Evidence-based decision making

Descriptions	N	Response Frequency / Percentage					Mean	Std.
		1	2	3	4	5		
The organization encourages to use statistical measurements and analysis throughout the organization	60	3 5%	5 8.3%	20 33.3%	23 38.3%	9 15%	3.50	1.017
Every activity in the organization is recorded by employees and checked by supervisors for accuracy on a daily basis	60	6 10%	5 8.3%	13 21.7%	19 31.7%	17 28.3%	3.6	1.265
The decision-making is based on analysis of relevant data and information	60	3 5%	7 11.7%	21 35%	17 28.3%	12 20%	3.47	1.096
The organization applies objective tools to evaluate contributions of its internal and external stake holders in cases of rewarding and recognizing its employees, suppliers and customers	60	5 8.3%	7 11.7%	19 31.7%	21 35%	8 13.3%	3.33	1.115
The corrective action system (CAPA) focuses on identifying root cause of quality concerns and any corrective & preventive actions required	60	-	10 16.7%	19 31.7%	16 26.7%	15 25%	3.6	1.045

Source: own data 2023

Table 4.2.5 presents the results of the questionnaire that was used to collect primary data from the employees of CPEL regarding Evidence-based decision making in the company.

The first row of the table shows that 38.3% of the respondents agreed and 15% strongly agreed, with a mean rating of 3.5 and a standard deviation of 1.02, which indicates that the organization encourages the use of statistical measurements and analysis throughout the organization.

The second row of the table shows that 31.7% of the respondents agreed and 28.3% strongly agreed that with a mean rating of 3.6 and a standard deviation of 1.27, which indicates that every activity in the organization is recorded by employees and checked for accuracy by supervisors on a daily basis.

The third row of the table shows that 28.3% agreed and 20% strongly agreed that the decision-making is based on analysis of relevant data and information, with a mean rating of 3.47 and a standard deviation of 1.09.

The fourth row of the table shows that 35% of the respondents agreed and 13.3% strongly agreed that the organization applies objective tools to evaluate the contributions of its internal and external stake holders in cases of rewarding and recognizing its employees, suppliers, and customers, with a mean rating of 3.33 and a standard deviation of 1.12.

The fifth row of the table shows that 26.7% of the respondents agreed and 25% strongly agreed, with a mean rating of 3.6 and a standard deviation of 1.05, which indicates that the corrective action system (CAPA) focuses on identifying the root cause of quality concerns and any corrective or preventive actions required.

The organization encourages the use of statistical measurements and analysis throughout the organization, records every activity by employees and checks for accuracy on a daily basis, applies objective tools to evaluate the contributions of its internal and external stakeholders in cases of rewarding and recognizing its employees, suppliers, and customers, and focuses on identifying the root cause of quality concerns and any corrective and preventive actions required through the corrective action system (CAPA). When we review the literature, Okland suggests that objectives need to be clearly and completely understood by all members before good decision-making can begin. In order to make effective decisions, teams must develop the ability to collect information quickly and then discuss the alternatives openly. (Okland, 2004) ISO 2000 also incorporates the need to make decisions based on facts. Hoyle, in his book of ISO 2000-based quality system handbooks, pointed out those facts obtained from observations performed by qualified personnel using devices, the integrity of which is known. The factual approach to decision-making leads us to take certain actions. To make decisions based on facts, we need reliable mechanisms for collecting them, such as measurement systems (Hoyle, 2001).

Response Rate 1=strongly Disagree 2=Disagree 3=neutral 4=Agree 5= strongly agree

Table 4.2.6 Relationship management

Descriptions	N	Response Frequency / Percentage					Mean	Std.
		1	2	3	4	5		
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	60	2 3.3%	5 8.3%	22 36.7%	24 40%	7 11.7%	3.48	0.93
The organization maintains successful	60	1 1.7%	8 13.3%	13 21.7%	28 46.7%	10 16.7%	3.63	0.974

partnerships with its suppliers through good communications and exchange of information								
The customer complaints are dedicatedly addressed by the firm	60	1 1.7%	9 15%	27 45%	19 31.7%	4 6.7%	3.27	0.861
Top management establish trust and commitment to quality improvement by eliminating fear	60	2 3.3%	12 20%	23 38.3%	18 30%	5 8.3%	3.20	0.971
The company identifies, understands, and manages interrelated processes as a system.	60	4 6.7%	10 16.7%	22 36.7%	14 23.3%	10 16.7%	3.27	1.133

Source: own data 2023

Table 4.2.6 presents the results of the questionnaire that was used to collect primary data from the employees of CPEL regarding Relationships in the company.

The first row of the table shows that 40% of the respondents agreed and 17% strongly agreed, with a mean rating of 3.48 and a standard deviation of 0.93, which indicates that The organization plans and manages external partnerships that are in line with its overall policies and strategies and are designed and developed to support the effective operation of its processes.

The second row of the table shows that 46.7% of the respondents agreed and 16.7% strongly agreed, with a mean rating of 3.63 and a standard deviation of 0.97, which indicates that the organization maintains successful partnerships with its suppliers through good communications and the exchange of information.

The third row of the table shows that 31.7% agreed and 6.7% strongly agreed that the customer complaints are dedicatedly addressed by the firm, with a mean rating of 3.27 and a standard deviation of 0.86. Most of the respondents' responses were neutral; they may not have been involved in customer complaints.

The fourth row of the table shows that 30% of the respondents agreed and 8.3% strongly agreed that top management should establish trust and commitment to quality improvement by eliminating fear. A mean rating of 3.2 and a standard deviation of 0.97 showed that the respondents responded neutrally and agreed.

The fifth row of the table shows that 23.3% of the respondents agreed and 16.7% strongly agreed, with a mean rating of 3.27 and a standard deviation of 1.13, which indicates that the company identifies, understands, and manages interrelated processes as a system.

By looking at these results, it refers to the organization's ability to plan and manage external partnerships in line with its overall policies and strategies, which are designed and developed to support the effective operation of its processes.

The supplier selection criteria form states that every supplier must be in conformance with purchase requirements stated or adhere to specifications, implied, and regulatory requirements of the country.

It also includes maintaining successful partnerships with suppliers through good communication and exchange of information, dedicating efforts to address customer complaints, establishing trust and commitment to quality improvement by eliminating fear, and identifying, understanding, and managing interrelated processes as a

system. When we look at the review literature, theories of TQM Okland inferred the importance of knowing future customer focus when he pointed out that any organization will also need to establish customer requirements by reviewing the market needs, particularly in terms of unclear or unstated expectations or preconceived ideas held by customers. It is central to identify the key characteristics that determine the suitability of the product or service in the eyes of the customer. This may, of course, call for the use of market research techniques, data gathering, and analysis of customer complaints (Okland, 2004).

4.3. Analysis of interview Questions

Qualitative analysis of the responses of employees selected who are managers and supervisors from all departments of the company for the interview asking about their familiarity with QMS and its benefits. Their responses infer that they have a good understanding of quality management systems. They raise points about the need for quality and the principles of QMS. They point out that the need to implement QMS is to achieve superior quality with an improved organizational culture and satisfied employees in a way that can help the organization achieve its vision. They believe practicing TQM helps increase productivity, reduce damage and waste, and produce more qualified products, which leads to higher financial results. From these thoughts of employees, one can infer that employees of the organization have a satisfactory understanding of QMS principles and practices. Qualitative analysis of the responses of employees selected for the interview asking about the challenges the organization faces while practicing the QM system. The employees asked pointed out three major challenges:
Qualitative analysis of the responses of employees selected for the interview the responses of employees selected for the interview asked about their knowledge on quality and quality management system showed that they have good understanding about quality and QMS. They raised points about quality such as; - conformance to specification or standards, costumer expectation and/or satisfaction, fit for intended purposes/use…
Respondents raised that Management focus mainly on the output rather than quality of products and they demanded to produce more products.

QMS was used to achieve quality with improved organizational culture and satisfied employees in a way that can help the organization to achieve its vision.

QMS was one of the systems used to satisfy the customer by improving the quality of the product and the ways of the process.
QMS should be included documentation process in the organization about quality and over all process in the organization.

Quality in the company is the responsibility of every employee but few of them agreed on about top management. The involvement and empower of employees of the company was low according to the discussion of participants some compliance about management did not give participation on problem solving and ownership.

Problems that affected productivity and quality were lack of QMS consistent training, lack of job satisfaction (about salary, incentives, hardship payments...), empower of employee.

The response of the respondents about customer management told that the organization made marketing research to satisfy the customer needs. The marketing research established under marketing department and closed supervision of marketing manager and general manager that conducts marketing research so as to assess its' demand.

Participant of the interview believed that, top managements involvements have significant effect on quality improvement. The respondents said that top management of the organization have monthly meeting on the report of quality assurance department, work environment and on customers demand satisfaction but not regularly.
Top management made decisions on quality issue by making a discussion on quality related problem occur in the organization and on its solutions. The solution of the problem should be addressed to workers and training given.

The respondents raised some points about supplier managements; supplier must be approved vendors in conformance to stated purchase requirements or adherence to specifications, implied and regulatory requirements. The organization received the test sample of the ordered material (raw materials, finished materials, packaging materials and others) and made test on quality parameters according to the specifications. Another point raised by the respondents on supplier management was the organization maintains successful partnerships with suppliers through good communication and information exchange.

Other the major challenges of the organization stated by the respondents to practice the implement and practice of QMS properly and quickly were lack of employee's commitment, lack financial resources and foreign currency, limited performing internal auditing, insufficient knowledge about QMS, poor QMS training, organizational structure limitation, documentations problem, lack of supplies of materials (here almost all materials are imported from abroad ex country) , government or regulatory body policy and so on. The benefits of the organization from practical implementation of QMS practices also listed by the respondent such as, improvement in productivity, improvement in safety, efficiency, efficacy and quality, reduction in cost and waste, competitive advantage, increase in sale and market share, good customer relations, increase customer satisfaction.

Daniel and Fasika on their work pointed out that organizations often fail to recognize the importance of culture and its influence in transplanting what has worked in a different cultural setup, organizational structure and individualism without reviewing its compatibility or incompatibility with different cultures (Daniel and Fasika, 2003).

CHAPTER FIVE

5. SUMMARY OF FINDINGS, CONCLUSIONS AND RECOMMENDATIONS

5.1. Summary of findings

The goal of this research was to evaluate QMS practices and determine obstacles to QMS implementation in CPEL. The scientific method was used to achieve the research goals.

The six QMS principles have been examined for this study to check whether properly practices or not in the organization. A questionnaire containing 33 items has been prepared for these six principles and made interview for top management and supervisors 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 0.92 which is excellent 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 CPEL 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 agreed 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 3.26, leadership 3.29, Engagement of people 3.20, continuous improvement 3.29, evidence base decision-making 3.50 and relationship management 3.37. From the finding the minimum average mean was 3.20 which is engagement of people and the maximum was 3.50 which is evidence-base decision making.

The overall mean average of customer focus was 3.26 which is above average value. From this finding, the researcher can understand that the company (CPEL) 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 3.29 and 3.20 respectively, which are also above average. This implies that top managements and senior executives' works hard to bring quality in CPEL 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 overall mean average of the variable continuous improvement is 3.29 which are above average. But the mean of the question asking about if the organization support the employees in personal care development was 2.98. The finding of the research 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 3.50 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 3.37. 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 (CPEL) 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 CPEL 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.

To improve an appropriate working environment for the quality system in the organization, senior management and leaders in CPEL engage the employees of the organization. As the data collected from the questionnaire indicated, the company showed continuous improvement, supported by the fact that more than half of the respondents agreed that the organization undergoes continuous improvement in the quality of its products and processes through validations. Evidence-based decision-making has been agreed upon as a quality management practice, and the majority of respondents from organizations responded that the company made its decision based on evaluations of the root cause of problems by applying the tools and analyzing them according to an organization's objectives. The evidence from the respondent showed relationship management in the company has been successfully maintained with communication information to customers by identifying, understanding, and managing interrelated processes with external partnerships and with its overall policies and strategies.

This study identifies on observations poor of training or education mainly on quality and QMS principles, financial limitations (foreign Currency and political problems), and QMS implications. Training should not be applied; organizational structure did not clearly define quality management but rather used a QA/QC department; and practice of documentation (GMP) are the major challenges of the organization to implement properly and to identify improvement in productivity, reduce cost and wastage, improve efficiency and efficacy, gain competitive advantage, lack of internal audit on schedules, increase market share, increase customer

relationships, and increase customer satisfaction in benefiting from CPEL's implementation and effective practice of QMS principles.

Overall, the QMS at Cadila Pharmaceuticals (Ethiopia) Manufacturing PLC is a comprehensive system that ensures the quality of the company's products through a variety of tools and processes.

5.2. Conclusions

The result of data analysis, presentation and interpretations helps to know many lessons on assessment practices of quality management and implementation of QMS for company (CPEL) to increase planning of management on responsibly for implementing and practice of QMS principles practically and quality as the core medium of all processes of produce products.

The conclusion of the research;

-Cadila has the employees with an adequate educational level, experiences and a good awareness about QMS implementation of quality practices.

-The company developed the ways of data collections on assessing customer expectations and satisfaction in order to collect complaint through specified procedures to verify that the servicing meets the indicated requirements.

-Top managers, senior executives lead the organization in maintaining conducive environment to improve quality in a role of finding solutions for the problems as to satisfy the customer needs.

-The organization promotes to use statistical tools analysis and continuously improving latest knowledge and technology used benchmarking by comparing its results with competitors and best practices of training polices reviews through internal and external quality audits continuous improvement.

-The organization encourages using statistical measurement and analysis in every activity in the organization to record data and information for decision-making by using these tools to evaluate contributions of internal and external stakeholders in cases of rewarding and recognizing its employees, suppliers and customers. The correction action system (CAPA) focuses on identifying root cause of quality control concerns and any corrective and preventive actions required.

-The organization plans and manages the external partnerships for overall policies and strategies and maintains successful partnerships with suppliers through good communications and information to customer complaints dedicatedly addressed by the firm. The company identifies, understands, and manages interrelated processes as a system.

-Implementing the system of quality management practice in Cadila pharmaceuticals (Ethiopia) PLC bring the benefit of improvement in productivity, improvement in efficiency, reduction in cost ,and waste and variability, competitive advantage, increase in sale and market share, good customer relations, increase customer satisfaction.

Finally, a Quality Management System (QMS) principle in Cadila Pharmaceuticals (Ethiopia) Manufacturing PLC has been successful. The study found that the company is practicing key principles of QMS such as customer focus, leadership/management commitment, engagement of employees, continuous improvement, evidence-based decision making, and relationship management. The study also identified some challenges to the implementation of QMS, such as lack of employee commitment, difficulty in performing internal auditing, lack of financial resources, insufficient or inconsistent training about QMS implementation, organizational structure limitations, and documentation problems. The benefits of implementing QMS practices in the company were also listed, such as improvement in productivity, efficiency, reduction in cost and waste, competitive advantage, increase in sales and market share, good customer relations, and increased customer satisfaction. The study recommends that potential problems identified in the implementation practice of QMS should be given due

attention, and appropriate preventive and corrective actions should be planned ahead during the planning and development stage of the system.

5.3. Recommendations

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

Management should raise awareness of QMS principles through proper and consistent training by experts via outsourcing and educational opportunities. The organization has to form meetings of employees or a committee for open discussions on quality issues to empower them and listen to their voice to gather information and evidence for appropriate problem solving.

➢ To improve skill and education, give training for employees on new machines, technology, systems, or methods to improve quality and productivity (using lean six sigma, kaizen, TQM, ISO) through innovation and creativity.

➢ Empower the employees involved in decision-making.

➢ Document everything and keep records.

Maintain a clean and organised work area.

➢ Use appropriate and approved materials and ingredients.

➢ Conduct regular equipment maintenance and calibration.

➢ Perform regular quality control checks.

➢ Follow proper sanitization procedures.

➢ Label everything accurately and clearly.

➢ Monitor environmental conditions such as temperature and humidity. It helps the organisation fulfil the cGMP criteria and QMS principles, which help increase productivity and quality.

➢The Company should focus on consistency training in QMS and GMP, system measurement, benchmarking, and a consistent internal quality audit.

➢ Ensure a successful validation and qualification process.

➢ The CPELs should consider how to determine and manage the organizational knowledge required to meet the CPEL's present and future needs.

Overall, the study recommends that potential problems in QMS implementation be addressed proactively, and appropriate preventive and corrective actions be planned ahead during the planning and development stage of the system. The benefits of implementing QMS practices, such as improvement in productivity, efficiency, cost and waste reduction, competitive advantage, increased sales and market share, good customer relations, and increased customer satisfaction, make it a worthwhile investment for organizations.

The paper suggests the following future works:

- Addressing the identified challenges in the implementation of Quality Management System (QMS) by giving due attention and planning appropriate preventive and corrective actions during the planning and development stage of the system.

- Conducting further research to identify and address issues related to the application, personalization, and adaptation of QM systems in Ethiopia.

- Continuously improving the QMS practices in Cadila Pharmaceuticals (Ethiopia) PLC to ensure compliance with the highest standards in the industry and become a leading pharmaceutical company in Ethiopia and a significant global player by providing high-quality affordable medicine.

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APPENDIX

ST. MARY'S UNIVERSITY

SCHOOL OF GRADUATE STUDIES

DEPARTMENT OF QUALITY and PRODUCTIVITY MANAGEMENT

Assessment of quality management practices in Cadila Pharmaceuticals (Ethiopia) Plc. Manufacturing (CPEL)

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QUESTIONNAIRE

The questionnaire is to be filled out by respondents from Cadila Pharmaceuticals (Ethiopia) PLC (CPEL).

This questionnaire is designed to collect information regarding the practices of quality management in Cadila Pharmaceuticals (Ethiopia) manufacturing company. It will include all departments in the company. This study will contribute towards the fulfillment of the researcher's Master of Science degree in quality and productivity management. I kindly ask you in all respects to fill out the questionnaire carefully to your best knowledge. The accuracy of the information you provide determines the ultimate reliability of the study.

Note: The **customers** expressed in this questionnaire can be considered regulatory, stakeholders, suppliers or vendors, promoters, distributors, wholesalers, pharmacy, company workers, end users, etc. It is strictly confidential and will be used for academic purposes only.

Part One: Demographic Information - Please put '√' in the box

1. Age

☐ Below 25yrs ☐ 25-30yrs ☐ 30-35yrs ☐ 35-40yrs ☐ > 40yrs

2. Years of experience in the organization

☐ <5yrs ☐ 5-10yrs ☐ 10-15yrs ☐ >15yrs

3. Education Level

☐ Certificate ☐ Diploma ☐ 1st Degree ☐ Master and above

Part Two: To assess QMS principles and practices, questions.

The following sections deal with your opinion about your organization's implementation and practices of quality management system principles. These questions are helpful for the researcher **to know the level of 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): **1 = strongly disagree, 2 = disagree, 3 = neutral, 4 = agree, and 5 = strongly agree.**

2.1 customer focus

1	Your organization have good trend of assessing future customer needs and expectations.	1	2	3	4	5
2	The organization adopts formal strategies or ways to collect customer complaints	1	2	3	4	5
3	The company developed the ways of data collection on customer expectations and/or satisfaction when designing new products	1	2	3	4	5
4	The customer's complaints coming to the organization	1	2	3	4	5
5	Where servicing is specified in the contract, procedures are established to verify that servicing meets the indicated requirements	1	2	3	4	5

2.2 Leadership/Management Commitment/

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	The senior executives appreciate efforts that improve quality throughout the organization	1	2	3	4	5
3	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
4	The senior management leadership role to find solution for the	1	2	3	4	5

	problems.					

2.3 Engagement of employees

1	Employees' involvement and empowerment encourages them to exert the best of their abilities to improve quality	1	2	3	4	5
2	Organizational structure that allows employees to exercise corrective actions based on their authority is appreciated by employees and helped to improve quality.	1	2	3	4	5
3	The organization's employees are appreciated when they take necessary risks to improve quality	1	2	3	4	5
4	The organization has an effective system for employees to make suggestions to management on how to improve quality.	1	2	3	4	5
5	The organization's employees are given education and training in statistical and other quantitative methods/ tools that support quality improvement	1	2	3	4	5

2.4 continuous improvements in the company

1	Control charts, graphs and other methods of analysis determine how well a process is working and facilitate continuous improvement.	1	2	3	4	5
2	The organization promote improvements in a way that enhance competitive environment among members of the organization by recognizing best performing individuals and units and also giving frequent training .	1	2	3	4	5
3	The organization is continuously improving itself by trying to apply the latest knowledge and technologies in the industry	1	2	3	4	5
4	The organization uses benchmarking by comparing its results to those of competitors and best practices	1	2	3	4	5
5	The company has training policies for employees	1	2	3	4	5
6	There is continuous improvement reviews through internal and external quality audits	1	2	3	4	5

2.5 Evidence- based decision making

1	The organization encourages to use statistical measurements and analysis throughout the organization	1	2	3	4	5
2	Every activity in the organization is recorded by employees and checked by supervisors for accuracy on a daily basis	1	2	3	4	5
3	The decision-making is based on analysis of relevant data and information.	1	2	3	4	5
4	The organization applies objective tools to evaluate contributions of its internal and external stake holders in cases of rewarding and recognizing its employees, suppliers and customers	1	2	3	4	5
5	The corrective action system (CAPA) focuses on identifying root cause of quality concerns and any corrective and	1	2	3	4	5

	preventive actions required.					

2.6 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 customer complaints are dedicatedly addressed by the firm.	1	2	3	4	5
4	Top management establish trust and commitment to quality improvement by eliminating fear	1	2	3	4	5
5	The company identifies, understands, and manages interrelated processes as a system.	1	2	3	4	5

Part three: Interview questions

The main objective of an interview is to grasp the real quality-related problems of the Cadila pharmaceutical manufacturing industry. This question contained questions used to understand the general awareness of quality and questions to grasp quality problems related to the principles and practices of quality. Your answers will be strictly confidential and will only be used for academic purposes.

3.1 What is quality?

3.2 Who do you think is responsible for product quality? What is your response if there is a quality issue? Do you document all deviations from quality?

3.3: Are you doing things according to quality standards or standard test procedures (STP)? Do you follow SOPs, STPs, and GMP principles strictly every time for all processes? If not, why?

3.4 Does the management actively participate in producing quality products? To what extent does the top management favor quality? What are the problems regarding management that affect the quality of the product?

3.5 How do you explain the empowerment and involvement of employees in improving quality?

3.6 What problems do you observe in workers that can affect the quality and productivity of the company? Would you participate in any decision-making in the company? What is the level of involvement of employees in decision-making on quality?

3.7 How does the company manage suppliers and vendors? Do you believe relationships with suppliers affect quality in the organization? How do you explain it?

3.8 What are the benefits of implementing quality management system (QMS) practices in your organization?

Thank you!!!