Addis Ababa University
College of Business and Economics
MBA Program (Distance)

Effect of Total Quality Management (TQM) Dimensions on Operational Performance of Ethiopian Pharmaceutical Manufacturing Plants

A Thesis Submitted to Addis Ababa University College of Business and Economics, School of Graduate Studies in Partial Fulfillment of the Requirements for the Master of Business Administration in Management (MBA)

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May, 2019

Declaration

I, Shegaw Aderaw, hereby declare this research entitled "***Effect of Total Quality Management (TQM) Dimensions on Operational Performance of Ethiopian Pharmaceutical Manufacturing Plants"*** is my own original work and that all the sources of materials used for this study have been identified and acknowledged as complete references. This research study has not been previously submitted in full or partial fulfillment for any degree in this university or any other recognized education institution. This research study is being submitted in partial fulfillment of the requirement for Master of Business Administration in Management.

Declared by Name: Shegaw Aderaw

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Date: _____

Letter of Certification

This is to certify that Shegaw Aderaw carried out this research on the topic entitled "***Effect of Total Quality Management (TQM) Dimensions on Operational Performance of Ethiopian Pharmaceutical Manufacturing Plants".*** This work is original in nature and is suitable for submission for the award of the Master of Business Administration.

Approved by:

Internal Examiner: _____ Signature: _____ Date: _____

External Examiner: _____Signature: _____ Date: _____

Advisor: _____ Signature:_____ Date: _____

Acknowledgment

First & Most, I would like to thank the Almighty God for all the blessings in my life, without Him, I would not have come this far. My deepest gratitude and sincere appreciation goes to my advisor Dr. Mohammed Seid for his advice and constructive comments from the very beginning of proposal development to the end of this thesis work. I am very much grateful to all members of the Management team of respective pharmaceutical industries who have provided me all the required information; special appreciation goes to Ato Kedir Sherif, Ato Abebe Hagos, W/ro Muna Ahmed, Ato Legese Hailu, Ato Tegene Aklilu, Ato Abayneh Tilaye, Ato Yared Hirpo, Ato Esubalew Mesenbet, Ato Eyob Assefa & Ato Alem Denekew for their unreserved support during distribution and collection of questionnaires.

Last but not least I would like to thank my wife W/ro Bizuayehu Tigabe and my children Bitanya, Yafet & Euael for their understanding, encouragement, support & prayers throughout my graduate program and this study.

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Acronyms

ANOVA	Analysis of Variance
WHO	World Health Organization
UNCTAD	United Nations Conference in Trade and Development
PD	Product Design
CI	Continuous Improvement
SQMT	Supplier Quality Management
TMS	Top Management Support
CF	Customer Focus
PEM	People Management
PRM	Process Management
GMP	Good Manufacturing Practice
TQM	Total Quality Management
DP	Delivery Performance
OP	Operational Performance
CP	Cost Performance
FP	Flexibility to Volume Performance
SME	Small & Medium Enterprises
UNIDO	United nations Industry Development organization
MOI	Ministry of Industry of Ethiopia
MOFED	Ministry of Finance & Economic Development of Ethiopia

Abstracts

The purpose of this study is to examine the effect of TQM dimensions on the operational performances of the pharmaceutical manufacturing companies operating in Ethiopia. Data for this study was collected using self-administered questionnaires that were distributed to the 13 companies. Census was carried out due to the relatively small number of Ethiopian pharmaceutical manufacturing companies. The target populations for study are plant technical managers, operational managers (production managers), quality control & assurance managers and other senior experts who are assumed to provide the most relevant information of the respective companies. Out of 65 questionnaires distributed to the companies a total of 57 were returned. Through comprehensive literature review, seven critical success factors of TQM that are relevant to the pharmaceutical industries were identified. Using correlation & regression analysis the relationship between TQM variables and common operational performance measures (Quality, Cost, and Delivery & Flexibility to volume) was investigated. The Correlation analysis reveals that there is strong relationship between TQM dimensions and operational performances of pharmaceutical manufacturing companies. The outcome of regression analysis indicate that customer focus, process management, product design and people management have significant contribution to at least one of the operational performance measures. Top Management support, supplier quality management and continuous improvement do not appear to contribute to higher performance. This study offers pharmaceutical companies and their managers a better understanding of the relationship and impact that some of TQM elements have on the performance of their operations. Thus managers will get an opportunity to take better & more effective decisions about the implementation of TQM. Due to nature of the study, the sample size is small and performance measures was based on the perceptions of managers, therefore generalization should be made with caution.

Key Words: Total Quality Management, Operational Performance, Pharmaceutical Manufacturing Companies, Ethiopia.

Chapter 1 - Introduction

1.1 Background of the Study

Manufacturing industries need to improve the quality of their products & services so as to remain competitive & cope up with increasing business challenges. To meet the challenge of global competition, many businesses have invested substantial resources in adapting and implementing Total Quality Management (TQM) strategies (Demirbag Mehmet, Tatoglu Ekrem, Tekinkus Mehmet & Zaim Selim, 2006). The challenge is even tougher for the manufacturing industries in least developed countries such as in Ethiopia where the industry is at infant stage & faces with stiff competition from imported products. The pharmaceutical industry is a vital segment of health care system which is regulated heavily because; any mistake in product design or production can result in severe, even deadly, consequences for patients which sometimes leads to recall of the drug from the market. Hence quality and its management are very critical in this industry (Kumar Virender, Jasbir Singh, Davinder Kumar & Mamta Antil, 2016).

The Ethiopian pharmaceutical industries are identified as one of the eight priority subsector for medium and large industries development in the Growth and Transformation plan (MOFED, 2010). A viable pharmaceutical industry in Africa is not only making an impact on the country's health system and its capacity to respond to the health needs of the people but also contribute to the overall socio-economic development of the continent (AU,UNIDO,2012).

A study by United Nation Conference in Trade and Development shows that producing pharmaceuticals locally is important as it will improve the country's economy through import substitution, employment opportunity and improved shelf life of the product by decreasing the long lead time it took during importation (UNCTAD, 2011).

Total quality management (TQM) is a firm-wide management philosophy of continuously improving the quality of the products and services by focusing on the customers' needs and expectations to enhance customer satisfaction and firm performance (Sadikoglu & Oclay, 2014).

It is a method which involves management and employees for continuous improvement of the production of products and services. TQM is a strategic management tool that can be used for improving the competitiveness, effectiveness and flexibility of the whole organization (Oakland, 2003 p. 30).

Prior studies had identified that implementation of TQM practices have a major impact on organizational performance (Dembirag et al, 2006; Munizu,2011;Brah & Lim,2006; Salaheldin,2009; Lakal,2009; Hassan et al,2012; Powell,1995).

In order to be competitive in both local and global market, Ethiopian pharmaceutical industries need to improve the quality of their products and services. Therefore this paper attempts to identify and analyze the significant Total Quality Control dimensions that influence the performance of the Ethiopian Pharmaceutical Manufacturing companies.

1.2 Statements of the Problem

The Ethiopian pharmaceutical Industry is characterized by lowest level of industrialization and poor performance, poor production capacity, poor innovation, poor product quality & poor export capacity. As a result Ethiopian pharmaceutical industry's contribution to the country's GDP is very low (MOH, MOI, 2015).

According to World health organization (WHO, 2011), most of the pharmaceutical industries in least developed countries work under constraints such as high operating costs and low production quality standards. The annual pharmaceutical market in Ethiopia is estimated to be worth US$ 400 to US$ 500 million and growing at an impressive rate of 25% per annum (MOH, MOI, 2015). In 2014, the Ethiopian industry exported pharmaceutical products worth almost US$ 2 million, which was far below the GTP-I target of US$ 20 million (MOH, MOI, 2015). Estimates on the share of the market held by local producers of pharmaceuticals vary between 15 and 30% of the market (UNCTAD, 2011).

Despite the growing need for pharmaceuticals, local pharmaceutical industries in Ethiopia are not utilizing their full capacity and they are facing fierce competition from imported products. Current manufacturing suffers from operational inefficiencies (MOH, MOI, 2015).

In today's competitive environment, where customers are more conscious about product quality, the importance and adoption of quality improvement initiatives are increasing day by day (Chaitanya, 2018).

Kamal (2012) pointed out that quality has become one of the most important engines to compete today, where the function of total quality management has become the critical determinant in the success and the continuation of industrial and service organizations in today's competitive environment.

Total quality management plays a major role starting from initial establishment of a pharmaceutical industry to safe guard the marketed product and controls the overall quality system chain of a pharmaceutical product (Patel & Maheswari, 2016). According to Chaitanya (2018), the success of any

health care industry depends on three important parameters i.e. quality, safety and efficacy.

Raja W, Bodla MA and Malik SA (2011) argued that there is a growing recognition with in the manufacturing sector that a holistic strategy is needed to bring competitive advantage in the market place and this can only be achieved by adaptation of TQM.

Ethiopian manufacturing organizations are expected to improve their products quality in order to enhance their competitiveness in global market. Ethiopia is in the accession to the World Trade Organization (WTO). Being a member to WTO requires the country to open up most of the sectors of the economy and local companies need to prepare a head for fierce competition from foreign companies (Haile & Raju, 2016).

World Health Organization (WHO) has issued a primary or fundamental regulation to pharmaceutical industries entitled good manufacturing practice (GMP) for pharmaceutical products (WHO Technical Report Series No. 986, 2014). According to WHO, GMP is that part of quality management which ensures that products are consistently produced and controlled according to the quality standards appropriate to their intended use and as required by the marketing authorization, clinical trial authorization or product specification.

Despite the fact that almost all of Ethiopian enterprises were still in the early stage of quality control and promoting quality assurance practices, the progress has also moved to, the subsequent diffusion of the ISO 9000 quality standards, and the concept of TQM in Ethiopia (Daniel & Fasika ,2003).

Therefore the Ethiopian pharmaceutical manufacturing plants are expected to implement certain TQM dimensions to achieve their organizational goals considering the highest emphasis given to quality issues in the sector. Continuous quality improvement is very important for the pharmaceutical industry to ensure safety, efficacy & quality of the products. Marinkovic Valentina, Bekcic Stana, Pejovi Gordana, Sibalija Tatjana, Majstorovic Vidosav and Tasic Ljiljana (2016) emphasized that medicinal products of inadequate quality are not only a health hazard, but also a waste of money for individual consumers & for the society at large.

The pharmaceutical products requires a strong quality focus, efficient production & best customers services, these cannot be accomplished without adopting effective manufacturing practices such as TQM that impact on operational performance. Despite some attempts on the applicability of TQM practices in organizations, there is lack of systematic empirical evidences regarding the effect of TQM on organizational performance of industries (Demirbag et al, 2006)

Therefore there is a need to conduct more studies that investigates the effect of TQM dimensions on the operational performance of manufacturing enterprises such as the pharmaceutical industry. The gap in literature also leads to the gap in knowledge on the effect of TQM on operational performance of the pharmaceutical industries.

Accordingly this study attempts to investigate the effect of TQM implementation on operational performance of the Ethiopian pharmaceutical manufacturing plants and to develop a model for applying TQM dimensions for better quality of products & services; and it is therefore fills the gap in the literature and knowledge regarding total quality management dimensions and its effect towards operational performance of the manufacturing industries. Furthermore, this research will contribute to the discipline of quality management of the manufacturing firms.

1.3 Research Questions

In line with the statement of the problem, the following questions are expected to be answered:

- What are critical success factors of TQM in the case of Ethiopian pharmaceutical manufacturing plants?
- What is the relationship between the implementation of TQM & operational performance?
- What kind of improvement can be made on implementation of TQM in Ethiopian Pharmaceutical Manufacturing context?

1.4 Objective of Study

The major goal of this research is to examine the impact of TQM practices on operational performance of the Ethiopian pharmaceutical manufacturing companies.

The following specific objectives are considered:

- Identify the critical success factors of TQM
- Establish the relationship between TQM on operational performance in the case of Ethiopian pharmaceutical Manufacturing plants
- To suggest improvements (if any) that can be made up on the implementation of TQM in Ethiopian pharmaceutical manufacturing context

1.5 Significance of the Study

This study is of great significance to the Ethiopian pharmaceutical manufacturing. It will enable the local manufacturing industries to identify the key TQM practices and their impact on improving towards

operational performance. This study will help managers to better understand the relationship between TQM elements & operational performance so that they can take better & more effective decisions about the implementation of TQM.

The academia and research institutions will gain an insight on the TQM practices applied by Ethiopian pharmaceutical manufacturing companies. Thus it can be used as a ground for those who wish to further research on TQM and related areas.

1.6 Scope of the Study

The scope of this study is focused on the impact of TQM on the operational performance of Ethiopian pharmaceutical manufacturing plants. The manufacturing plants included in the study are those companies which are engaged in the production of active pharmaceuticals (medicines). Due to time constraint, only pharmaceutical industries which are engaged in the production of medicine are included in the study, others similar industries such as food industries, medical device & supplies manufacturers were not part of the survey. According to the information obtained from MOI of Food, Beverages and Pharmaceuticals Development Institute, there are 13 companies in Ethiopia which can be considered for this study (surveyed companies are listed in Annex 3).

Total quality management is a very wide concept that can be applicable to any business sector and requires detail investigation of the practice and implementation, effectiveness and its challenges. However this study attempted to investigate its effect on operational performance of pharmaceutical industries based on the evidence obtained from surveyed companies. More specifically seven TQM success factors identified in the study ;which are Top Management Support, Process Management, People Management, Supplier Quality Management, Continuous Improvement, Customer Focus and Product Design & their impacts on contemporary operational performance measures i.e. Quality, Cost, Delivery & Flexibility to volume performances were examined.

1.7 Organization of the Thesis

This thesis is divided into five chapters. A brief description of each chapter is presented below to summarize the contents of the whole thesis.

Chapter one: Introduction:-This chapter describes the background of the study, statement of the problem, basic research questions, objective of the study, significance of the study, and scope of the study.

Chapter two: Literature Review: - This chapter discusses the literature review in relation to theoretical & empirical concepts of Total Quality Management practices, critical success factors, & operational performance measures. This chapter also discusses empirical investigation of TQM in Ethiopian & pharmaceutical industries aspect and contains a conceptual frame work that was proposed from previous studies.

Chapter Three: Research Methodology: - Under this chapter, research design, sources of data, target population, sampling methods, data collection techniques & method of data analysis will be discussed.

Chapter Four: Data Presentation & Analysis: - This chapter presents the analysis of data and findings from the primary data that was gathered from the respondents. It contains summary of the results & hypothesis testing.

Chapter Five: Summary of Findings, Conclusion and Recommendations: - On this chapter, summary of the findings from the previous chapter will be discussed & a conclusion will be made based on the results. Finally the recommendation, research limitations & future research direction will be stated.

Chapter 2 – Review of Related Literature

2.1 Introduction

In this section the theoretical and empirical literature review regarding TQM concepts & practices will be presented. The theoretical review helps in understanding of the current knowledge of TQM practices while the empirical review helps in understanding the findings of other related studies. Based on the literature review, a conceptual framework of the study is proposed.

2.2 The Concept of Total Quality Management

Various scholars and quality gurus have proposed different principles and practices about Total Quality Management. Crosby, Deming, Feigenbaum, Ishikawa and Juran can be considered as the most important gurus of the quality management movement (Martínez-Lorente, Dewhurst Angel R., Dale Frank & Barrie G. Dale, 1998). Though their approaches differ from each other, their works are the foundation to understand the concept of TQM. One of the TQM pioneer, William Edward Deming believed TQM as an approach in management which is characterized as management-led; everyone in the organization has to take part; based on a continuous process of improvement, scientifically-based and aim at serving the customers better all the time (Zairi, 1991 p. 21).

Another quality guru Joseph Juran proposes a universal way of thinking about quality, which he calls the quality trilogy**:** quality planning, quality control, and quality improvement. This concept fits all functions, levels of management, and product lines (Amitva Mitra, 2008 p. 78-79). According to Juran, Quality control is concerned with prevention of deficiencies in the product or services and rectifying such deficiencies to provide a product free from defects. Quality improvement is a proactive approach so that improvements are made prior to problems is happening and quality planning is driven based on meeting the needs and expectations of customers. Juran trilogy was the first method to assess the costs that come from poor quality (Juran & Godfrey, 1995 p.25; Amitva Mitra, 2008 p.78-79, Zairi 1991, p. 22).

Armand V. Feigenbaum was the first to argue that quality should be considered at all the various stages of the process and not just within the manufacturing function (Zairi 1991, p. 25). He defined Total Quality Control as “an effective system for integrating the quality-development, quality maintenance, and quality-improvement efforts of the various groups in an organization so as to enable production and service at the most economical levels which allow for full customer satisfaction”(Martínez-Lorente et al,1998). Feigenbaum believed that quality is a way of managing a business organization and is the

responsibility of everyone. He also emphasized the role of senior management in understanding the issues surrounding quality improvement and commitment to incorporate quality into their management practice is crucial to the successful installation of total quality system (Dale Barrie G., Bamford David and Ton van der Wiele, 2016).

Philip Crosby identified 14 step plans to help implement the quality improvement program. He argued that companies can increase profit through quality improvement as higher quality reduces cost & raises profit. He viewed quality as compliance with certain requirements (Dale et al, 2016 p 37).

Another Japanese quality guru, Ishikawa claimed that people at all levels of the organization should use simple methods and work together to solve problems, thereby removing barriers to improvement, co-operation and education and developing a culture that is conducive to continuous improvement. Ishikawa contributed to quality management by adding seven quality tools, the company-wide quality movement; and quality circles (Dale et al, 2016. p 45)

By reviewing the works of the above mentioned quality leaders, we can conclude that while each has their own understanding & explanation of quality management concept, there are common points which they share such as the importance of top management commitment, focusing on customer satisfaction; emphasis on prevention of product defects; continuous improvement and employee empowerment.

2.3 Total Quality Management Models

There are various TQM models and frameworks that can provide a standardized approach for TQM implementation or perform self-evaluation of organizational quality management. The most approved & well practiced TQM models are Deming Prize in Japan, the European Quality Award in Europe, and the Malcolm Baldrige National Quality Award in the United States of America (Zhang Zhihai, Waszink Ab and Wijngaard Jacob, 1999).

According to Zhang et al (1999) each model is based on a perceived model of TQM. The TQM models do not focus solely on either product or service quality management methods, but consider a wide range of management activities, behavior and processes that influence the quality of the final products or services. These models provide an insight into the practical way of applying TQM. They are briefly discussed as follows:

Deming Prize Model

The Deming Prize in Japan was the first formal quality award framework established by The Union of Japanese Scientists and Engineers in 1950. The Deming Prize proved an effective instrument for

spreading TQM philosophy throughout the Japanese industries. The examination viewpoints include: top management leadership and strategies; TQM frameworks, concepts and values; Quality assurance and management systems; human resources; utilization of information; scientific methods; organizational powers; realization of corporate objectives (Oakland, 2003 p. 28, Zhang et al ,1999).

Malcolm Baldrige National Quality Award (MBNQA) Model

The USA Baldrige Award aims to promote performance excellence and improvement in competitiveness through a framework of seven categories which are used to assess organizations: leadership; strategic planning; customer and market focus; information and analysis; human resource focus; process management; business results (Oakland, 2003 p. 28, Zhang et al ,1999).

European Foundation for Quality Management (EFQM) Model

Fourteen multinationals which were grouped in the European Foundation for Quality Management in the early 1990s developed the (EFQM) business excellence model with the aim of improving management quality in Western Europe. The European (EFQM) Excellence Model operates through a simple framework of performance improvement through involvement of people in improving processes (Oakland, 2003 p. 28, Zhang et al, 1999).

These models provide an insight into the practical way of applying TQM, as well as a better understanding of the concept of TQM. Although each award has its own unique categories and emphasis, there are some common areas. Each award model has two parts: One is TQM implementation (that is, the enablers); the other is the overall business results. TQM implementation makes overall business results happen. All three award models emphasize the importance of leadership, human resources management, employee participation, employee education and training, process management, strategy and policy, information, supplier quality management, and customer focus.

2.4 TQM and Operational Performance (Empirical Evidence)

Many researchers have indicated that there is strong positive relationship between TQM practices and organizational performance. For example Samson and Terziovski (1999) as cited in Munizu (2011), investigated the effect of TQM practices on organizational performance of manufacturing companies in Australia and New Zealand. They found out that there is strong relationship between TQM practice & organizational performance but not in all categories of TQM. The categories of leadership, management of people and customer focus were the strongest significant predictors of operational performance.

Similarly Dembirag et al, (2006) on their study of Turkish Small & Medium Enterprises (SMEs), reveal that there is a strong positive relationship between TQM practices and non-financial performance of SMEs. There is only weak influence of TQM practices on financial performance of SMEs. Brah and Lim (2006) found out that TQM and technology play important roles in improving the performance of an organization. Their analysis shows that both high technology firms and high technology TQM firms perform significantly better than their low technology peers.

The empirical analysis conducted by Munizu (2011) demonstrated that there was a positive effect of critical TQM practices which consists of strategic, tactical, and operational factors on operational performance of manufacturing industries in Makassar. Tactical factors were the strongest significant predictors of operational performance.

Salaheldin (2009) surveyed Small & Medium Enterprises (SMEs) in Qatar to investigate relationship between TQM and performance of the firms. The findings confirm the significant relationship between TQM and organizational performances of the SMEs.

Lakhal (2009) studied impact of quality improvement on competitive advantage & organizational performance of companies in Tunisia & found out that quality improvement can lead to enhanced competitive advantage and improved organizational performance.

Hassan et al (2012) on their study of impact of TQM on manufacturing firms in Pakistan reported that successful adoption and implementation of TQM practices results in improving the performance of organization. The main implication of the findings for managers is that with TQM practices, manufacturing organizations are more likely to achieve better performance in customer satisfaction, employee relations, quality and business performance than without TQM practices.

On the other hand Powell (1995) while investigating the impact of TQM on competitive advantage of US companies suggested that most features generally associated with TQM such as quality training, process improvement, and benchmarking do not generally produce advantage, but that certain features such as open culture, employee empowerment, and executive commitment can produce advantage.

There are few researches available that are focusing on TQM implementation in Ethiopian manufacturing sector. For example Haile & Raju (2016) have attempted to survey 300 medium and large manufacturing firms in Ethiopia to assess the status of TQM implementation. They found that firms in the survey have implemented certain kinds of quality management programs. This means they are generally conscious of the importance of TQM. However, firms were not practicing the complete, and

comprehensive components of TQM as their original proponents (American and Japanese TQM gurus) had conceived them.

Daniel & Fasika (2003) have studied the quality management practices in Ethiopian manufacturing companies. Their research is based on a survey conducted on 55 representative industries all over the country using the Ethiopian Quality Award model. They found out that the level of awareness and understanding of TQM and ISO 9000 was very low.

Similarly Birhanu & Daniel (2014) conducted research on Ethiopian companies using Ethiopian Quality Award (EQA) self-filled assessment manual. According to their study, quality management practices in Ethiopia was found to be low in all the tenets including leadership, policy and strategy, resources management, process management, customer satisfaction, business performance and impact on society. Among these factors, policy and strategy is the most critical problem area despite the least weight given by the EQA.

Gebremehdine & Raju (2016) in their study of TQM implementation in Tigray state indicated that there is positive association between TQM variables and organizational performance, among which Top Management Commitment has the strongest positive relation with performance of the surveyed firms. Though there is no study with regard to the TQM practice of the existing Ethiopian pharmaceutical manufacturing, considering the highest emphasis given to quality issues in the sector, it can be expected that at least certain aspects of TQM practices are implemented by the local companies.

In general, operational performance is defined as the extent to which an operation meets performance goals, the major steps in order to meet customer needs (Slack Nigel, Brandon Alistair & Johnston Robert, 2013).

The successful implementation of TQM results in improved product quality, more effective and efficient process design, reduction in the waste of resources, and thus higher productivity. Operational performance deals with the process and evaluates the performance of internal operation of the company in term of cost, customer services, delivery, quality, flexibility, and product/services process quality (Brah and Lim, 2006).

Review of the above empirical studies indicated that there is positive relationship of proper implementation of TQM practices and operational performance of an organization.

2.5 TQM in Pharmaceutical Industry

The pharmaceutical industry deals with manufacturing and marketing of pharmaceuticals and biological products and medicinal devices, used for the diagnosis and treatment of diseases as well as conducts research for development of new products (Kumar et al, 2016).

Bhandari & Baldi (2014) noted that TQM is the most effective tool in quality management of pharmaceuticals which essentially requires adherence to quality practices in all areas of pharmaceutical production.

Marinkovic et al (2016) further elaborated that the poor qualities of medicines are not only a health hazard, but also a waste of money for both individual consumer & society at large.

Mittal and Singh (2012) insisted that an effective quality assurance policy with defined mission and objectives is the most important goal of pharmaceutical industry. They further elaborated that quality assurance and quality control together develops towards assuring the quality, safety and efficacy of pharmaceutical products.

Kumar et al (2016) in their study of the importance of implementing TQM in pharmaceutical industry identified that top management commitment, leadership, quality management, people management and training, customer focus and supplier & vendor quality as the most recognized success factors.

In another study of TQM practices in selected pharmaceutical industries in India, Kumar & Prasad (2017) pointed out TQM as a strategic Management tool which can be used for improving the competitiveness, effectiveness and flexibility of the organization.

Accordingly we can consider that TQM could be an important management tool for pharmaceutical industries to maintain quality, efficacy and safety of the products.

2.6 Critical Success Factors (CSF) of TQM implementation

The critical success factors can be defined as the critical areas which organization must accomplish to achieve its mission by examination and categorization of their impacts (Oakland, 2006, p.36). CSF's are the critical areas of managerial planning and action that must be practiced to achieve effective quality management in a business unit. They are critical and absolutely essential for the success of TQM (Poongothai S., Ilavarasan R., Karthikeyan and L., Arul S., 2011).

The identification of key factors of TQM helps the companies to better understand the concepts of TQM & for its successful implementation on respective companies.

Flynn, B., Sakakibara, S. & Schroeder, R. (1995) developed the quality management framework for manufacturing companies, including top management support, workforce management, quality information, supplier involvement, product design, process management, and customer involvement.

According to Cua, K. O., McKone, K. E., and Schroeder, R. G. (2001), there are nine practices that are commonly cited as part of a TQM program. These practices are cross-functional product design, process management, supplier quality management, customer involvement, information and feedback, committed leadership, strategic planning, cross-functional training, and employee involvement.

Tummala, V.M.R., Whitfield, R.W., Tang, C.L. (1995) identified seven core concepts of TQM as the basic elements to achieve the quality improvement goals and objectives, which are: Customer focus, Leadership, Strategic quality planning, Design quality, speed and prevention, People participation and partnership, Fact-based management, and Continuous improvement.

Kumar et al (2016) in their study of recognizing the importance of TQM practices in Indian pharmaceutical industries have emphasized there are six factors affecting the implementation of TQM. These are: Top Management Commitment, Leadership, Quality Management, People Management and Training, Customer Focus and Supplier Quality.

Demirbag et al. (2006) conducted an empirical study to identify factors critical to the success of TQM in the Turkish small & medium size enterprises. They concluded that there are seven CSFs of TQM practices, i.e. quality data and reporting, role of top management, employee relations, supplier quality management, training, and quality policy and process management.

In another study, Anderson J.C., Rungtusanatham M., and Schroeder R.G. (1994) identified seven factors using Delphi method. These are visionary leadership, internal and external cooperation, learning, process management, continuous improvement, employee fulfillment, and customer satisfaction.

Salaheldin (2009) surveyed 139 small and medium sized enterprises (SMEs) in the Qatari industrial sector. The study found out three levels of critical success factors of TQM implementation, namely the strategic factor (leadership, organizational culture, continuous improvement, benchmarking, quality goals and policy), the tactical factor (team building and problem solving, employee empowerment, involvement and training, use of information technology, supplier management) and the operational factors (product and service design, process control, customer orientation, resources value addition process, resources conservation and utilization, inspection and checking work).

Haile & Raju (2016) while examining the extent of TQM implementation of Ethiopian manufacturing firms indicated that most recognized success factors of TQM in literature are: Top Management

Leadership & Commitment, Customer Focus, Supplier Quality Management, People Management, Process Management, and Continuous Improvement.

After exhaustive literature reviews, the researcher identified seven critical success factors for this study. To select these factors the researcher considered the importance & relevance of these factors to the manufacturing industry in general and the pharmaceutical industry in particular. More over the researcher considered the frequency of TQM factors as they appear in the various related researches.

Accordingly the following critical success factors will be used in this study: Top Management Support, Supplier Quality Management, Customer Focus, People Management, Process flow management, Product Design and Continuous Improvement. Table 1 below shows the summary of supported studies to the seven factors identified in this study.

Table 1: Summary of Supported Studies of CSFS

Critical Success Factors	Supportive Literature
Top Management Support	Flynn et al. (1995); Fuzi & Gibson(2013); Lewis W.G. , Pun K.F. , Lalla T.R.M.,(2006); Powell (1995), Demirbag et al (2006), Salaheldin (2009), Cua et al (2001), Kumar et al (2016), Evangelos et al (2010), Zhang et al (1999)
Process Management	Flynn et al. (1995); Cua et al (2001), (1995), Lewis et al. (2006) , Demirbag et al (2006), Fuzi & Gibson(2013), Evangelos et al (2010), Powell (1995),
People Management	Salaheldin (2009, Cua et al (2001), Tummala et al (1995), Powell (1995), Fuzi & Gibson(2013), Zhang et al (1999), Demirbag et al (2006),
Supplier Quality Management	Salaheldin (2009), Cua et al (2001), Fuzi & Gibson(2013), Zhang et al (1999), Demirbag et al (2006),
Customer Focus	Black and Porter (1996); Tummala et al (1995) Dean and Bowen (1994); Salaheldin (2009), Cua et al (2001), Fuzi & Gibson(2013),Evangelos et al (2010),
Continuous Improvement	Lewis et al. (2006); Salaheldin (2009), Tummala et al (1995), Fuzi & Gibson(2013), Powell (1995),
Product Design	Salaheldin (2009), Cua et al (2001), Zhang et al (1999), Flynn et al. (1995);Munizu(2011)

Source: Literature Survey 2019

2.7 TQM Constructs

The TQM dimensions that are emphasized in this study are Top Management Support, Supplier Quality Management, Customer Focus, People Management, Process Flow Management, Product Design and Continuous Improvement. Therefore in this study these dimensions are used as TQM constructs. The following section further discusses these TQM constructs.

2.7.1 Top Management Support

Sadikoglu & Oclay (2014) pointed out that top management commitment and participation are the most important factors for the success of TQM practices. To be successful in promoting business efficiency and effectiveness, TQM must be truly organization-wide, and it must start at the top with the chief executive or equivalent (Oakland, 2003 p.31)

According to Anderson et al (1994), leadership is the ability of top management to establish practice a long term vision of the organization or firm driven by changing customer requirement. Dale et al (2016, p. 21) further discussed that leaders at all levels establish unity of purpose and direction and create conditions in which people are engaged in achieving the quality objectives of the organization. Flynn et al (1995) indicated the necessity of top management commitment, as top management has a large influence on the overall attitude and strategic direction of the organization.

The involvement of managers in TQM process is believed to give companies more opportunities to organize the quality system according to the company's requirements. The top management should support the TQM implementation by providing all the necessary resources, giving strategic direction and creating conducive environment so that all people in the organization are motivated and involve in quality management activities. This particularly important in the pharmaceutical industry where business environment is very dynamic & manufacturers face with fierce competition globally.

2.7.2 Supplier Quality Management

Supplier quality management is another important aspect of TQM as the quality of the finished product depends on the quality of the raw materials used. Dale et al (2016, p. 141) stated that the quality of purchased supplies is crucial to an organization's products and services and consequently to its success in the marketplace since materials and purchased parts are often a major source of quality problems.

Effective supply management practices enable the suppliers to adopt quality management and deliver reliable and high quality products and/or services timely (Sadikoglu & Oclay, 2014).

Supplier management includes emphasis on supplier quality and service performance, supplier capabilities, supplier involvement and integration (supplier partnerships), such as joint quality improvement, and participation in new product development, technology development and planning, and even strategic planning (Easton and Jarrell, 1998)

Haile & Raju (2016) suggested that organization that pursues good supplier quality management will be able to reduce total quality costs and improve product quality in the long run.

Review of the above studies revealed that firms need to have detailed information about supplier quality & periodic supplier audit should be done. Moreover, quality has to be number one criterion in selecting suppliers. It is also very important to establish a supplier information feedback system, to give information to suppliers about their product performance.

2.7.3 Customer Focus

Chin K.S., Tummala V.M. Rao, Chan K.M. (2002) emphasized that well satisfied customer is the ultimate aim in TQM implementation and customer focus is generally regarded as the most important TQM principle.

Dean and Bowen (1994) also stated that the goal of satisfying customers is fundamental to TQM and is expressed by the organization's attempt to design and deliver products and services that fulfill customer needs.

As Sadikoglu & Oclay (2014) pointed out in their study, using successful customer focus efforts, production can be arranged considering the customers' needs, expectations, and complaints. This will help firms to produce better quality and reliable products/ services timely with increased efficiency and productivity. Firms should understand and determine customer needs by meeting their requirements and striving to exceed their expectations (Lewis et al, 2006).

Therefore, customer satisfaction can be considered as important requirement for long-term organizational success and to achieve this entire organization need to focus on customers' needs.

2.7.4 People Management

Employees at all levels must be recognized as the essence of the organization, and strategies must be put in place to ensure their full involvement, so that the organization can derive maximum benefits from their abilities (Lewis et al, 2006).

Flynn et al (1995) argued that successful implementation of a TQM environment requires a committed and skilled workforce to fully participate in the activities carried out to improve the quality. All the

employees at all levels within the organization should be encouraged to take responsibility and communicate effectively toward improving the quality at all production stages. The employees from the top management to the labor-force must understand the philosophies of TQM. Teamwork, which is collaboration between managers and non-managers, between functions, and between customers and suppliers is another important TQM principle (Dean & Bowen, 1994).

Demirbag et al (2006) pointed out the most important quality practices were found to be training, employee relations, and quality data and reporting. Hence, companies should be suggested to develop formal reward and recognition systems to encourage employee involvement and participation, support teamwork and provide feedback to the employees.

2.7.5 Process Management

Anderson et al (1994) described process management as a set of practices that combine methodological approaches with human resource management, and these are implemented in order to manage and improve processes that produce products and services.

It includes preventive and proactive approaches to quality management to reduce variations in the process and improve the quality (Sadikoglu & Oclay, 2014). According to Jorgensen and Nielsen (2013), within TQM philosophy having a process based approach confirms the necessity of having processes designed to meet company's quality requirements. It is important that the core processes are identified and supported to assure appropriate resources are available to inspect and improve these processes.

Pharmaceutical companies therefore need to focus in their process management in order to align with the changing business environment.

2.7.6 Product Design

Focus on product design is also perceived to be a very important factor for TQM implementation. Product Design is one of the most important TQM factors which determine the success of a product (Lakshmi Jagannathan, 2008).

Sound product design meets or exceeds the requirements and expectations of customers better than the competitors, leading to an increased market share (Zhang et al, 1999).

One part of the product design that seeks special attention is packaging & labeling of the product. According to Gopinathar et al (2016) packaging & labeling can provide information to a consumer regarding the product contents. Packages and labels communicate how to use, transport, recycle, or dispose of the package or product. With pharmaceuticals, food, medical, and chemical products, some

types of information are required by government legislation. WHO (2002) emphasized packaging as an essential source of information on medicinal products. Such information is provided by labels and package inserts for patients. According to WHO (2002) all finished drug products should be identified by labeling, as required by the national legislation, bearing information such as the name of the drug product, a list of the active ingredients showing the amount of each present, and a statement of the net contents, the batch number assigned by the manufacturer; the expiry date in an un-coded form; any special storage conditions or handling precautions that may be necessary; the directions for use, and any warnings and precautions that may be necessary; the name and address of the manufacturer or the company or person responsible for placing the product on the market.

Labels perform several functions such as identifying the product or brand, describing and promoting the product through attractive graphics (Kotler, 2002 p. 192).

According to the USA Food & Drug Administration (FDA, 2013), all labels printed for use in the pharmaceutical and healthcare industry are required to be designed and applied so they can remain in place and be read in different environments through distribution, storage, and use. Poor label design can contribute to medication errors by making it difficult for healthcare professionals, caregivers, and/or patients to readily locate and understand critical safety information.

2.7.7 Continuous Improvement

Fryer Karen J. Antony Jiju and Douglas Alex (2007) see continuous improvement as where all members of the organization work together on an ongoing basis improving processes and reducing errors to improve overall performance for the customer. Continuous improvement consists of data collection, business process improvement, benchmarking, job analysis and open communication system (Zelalem & Getachew, 2002).

It has become increasingly essential to continuously improve the processes in the manufacturing industry to reduce cost, increase production efficiency without affecting the quality of products.

One of the most common ways of implementation of continuous improvement as cited by many researchers is through Japanese continuous improvement system known as Kaizen (Nzair, 2013). According to Nazir (2013), Kaizen is a philosophy which gives emphasis on continuous improvement of processes in manufacturing, engineering and business management. In simple terms Kaizen is the process of incremental, systematic, gradual, orderly and continuous improvement that uses the best of all techniques, tools, systems and concepts (Dale et al 2016, p58).

2.8 Conceptual Frame work

The objective of this study is to analyze the impact of implementation of TQM on operational performance of the Ethiopian Pharmaceutical manufacturing plants. The following conceptual model is proposed based on the studies of Haile & Raju (2016); Salaheldin (2009), Fuzi & Gibson (2013) and Cua et al (2001). The conceptual framework demonstrates the relationship between TQM practices and operational performance through exploring the combined direct effects of seven TQM practices identified in the literature on operational performance. The TQM dimensions that are emphasized in this study are Top Management Support, Supplier Quality Management, Customer Focus, People Management, Process Management, Product Design and Continuous Improvement. Therefore in this study these dimensions are used as TQM constructs.

Slack et al (2010, p. 46) explained that there are five operation performance objectives which are cost, quality, speed, reliability and flexibility. Excelling at one or more of these operation performance objectives can enable an organization to pursue a business strategy based on corresponding competitive factor. Salaheldin (2009) indicated that operational performance reflects the company's internal operating performance in terms of cost and reducing waste, improving product quality, new product development, improves delivery performance, and increased productivity. These indicators and variables are considered as the main factor because they follow directly from the action taken in the company's operating activities. According to Cua et al, (2001) there are many ways of measuring manufacturing performance. The most predominant approach in the literature is to use cost, quality, delivery, and flexibility as the four basic dimensions of manufacturing performance. This study therefore follows the performance measurements as mentioned in Cua et al (2001), Boyer and Lewis (2000) & Flynn Barbara B. Picasso Fernando G.; Paiva Ely Laureano (2014).

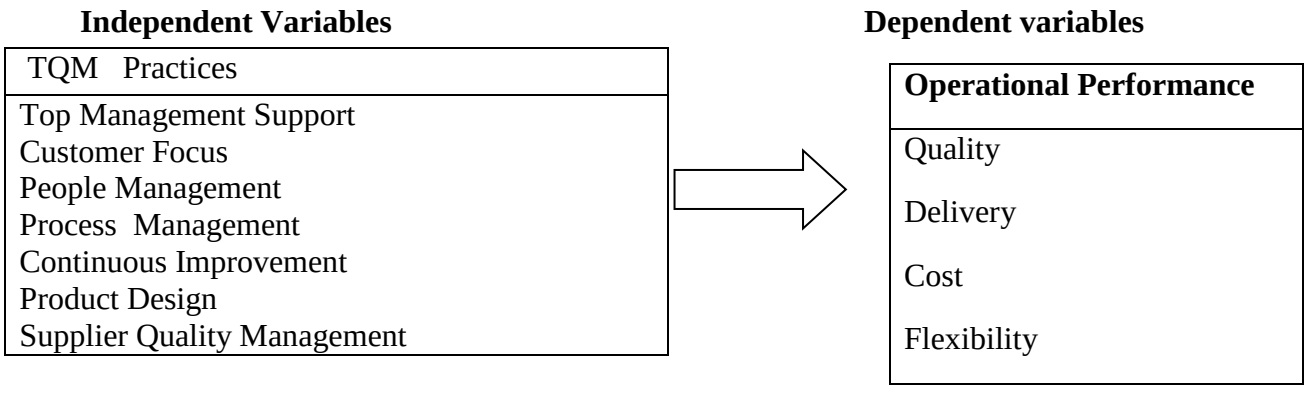

Figure 1: Conceptual Frame Work

2.9 Research Hypothesis

As indicated above in the literature review, it is supposed that TQM implementation will improve operational performance of manufacturing firms. Hence, from the theoretical and practical evidences it can be expected that effective implementation of TQM practices will have positive relationship with Operational performance measures: Cost Performance, Quality Performance, Delivery performance & Flexibility to Volume Performance.

The variables that belong to the construct of the Total Quality Management were operationalized using a five-point Likert type scale (strongly agree (5) to strongly disagree (1)). Respondents were asked to indicate how strongly they agree with each of the TQM statements.

Based on theoretical and practical evidences, the following hypotheses are proposed:

Proposition:

TQM Practices are positively associated with the level of operational performance. It is expected that the relationship of TQM practices with operational performance to be positive.

Above proposition can be validated through empirical tests of following hypotheses:

Hypothesis H1:

TQM Success factors are positively associated with Cost Performance

Hypothesis H2:

TQM Success factors are positively associated with Quality Performance

Hypothesis H3

TQM Success factors are positively associated with improved Delivery Performance

Hypothesis H4

TQM Success factors are positively associated with Flexibility to Volume performance.

Chapter 3 - Research Methodology

3.1 Introduction

This chapter presents the methodology used in this study and describes how the research problem has been solved. It includes research design, sources of data, target population, sampling methods, data collection techniques & method of data analysis.

3.2 Research Approach

The purpose of this study is to examine the relationship of TQM practices and operational performance of the Ethiopian pharmaceutical manufacturing companies. This study uses cross-sectional field survey. In the cross sectional field survey, independent and dependent variables were measured at particular time. Besides, explanatory research is suitable for this study as explanatory study establishes causal relationships between variables and explains the relationships between variables. This study is conducted using quantitative research approach since it is an appropriate method to create quantifiable cause and effect relationship between the variables of the study.

3.3 Population of the Study

The main focus of this study is the existing pharmaceutical manufacturing companies in Ethiopia which are engaged in manufacturing of medicine. There are about 13 pharmaceutical companies in Ethiopia which produce medicinal products according to the Ministry of Industry. The companies are categorized as medium & large enterprises (MOFED, 2010). Census was carried out due to the relatively small number of Ethiopian pharmaceutical manufacturing companies. This can give a good appreciation of the TQM practices that are applied in pharmaceutical industries in Ethiopia. The target population for study is plant technical managers, operational managers (production managers), quality control & assurance managers and other senior experts who are assumed to provide the most relevant information of the respective companies. 65 managers are considered as population of study taking in to account the potential respondents in each company. The following table (Table 2) shows the distribution of potential participants according to their positions in the companies.

Table 2: Distribution of potential Participants according to their positions in the companies

Job Position	Number of Companies	Possible number of Participants in each company	Total Number of Participants
Technical plant managers & above	13	1	13
Quality control/Quality assurance mangers	13	1	13
Production(Operation) managers	13	1	13
Research & Development managers/experts	13	1	13
Senior quality experts /technicians& others	13	1	13
		Total	**65**

Source: own survey, 2019

3.4 Source of Data and Data Collection Instrument

The study is mainly dependent on primary data. The primary data is collected directly from respondents through self-designed questionnaire. The targeted respondents will be managers who are working in quality control, quality assurance, production, research & development, technical plant managers and other quality experts of each respective company who are assumed to have the required knowledge of the study & provide the most relevant information of the respective companies.

The main advantage of this type of data is to collect the research's purpose in mind. The information resulting from the primary data is more consistent with the research questions and objectives. Data collected from questionnaire will be used in the survey. The use of questionnaire was chosen because it will enable the researcher to reach a number of respondents within a limited period of time and it is convenient to ensure the privacy of respondents.

The Survey instrument (questionnaire) is adapted from similar studies of Sila & Ebrahimpour (2005), Phan & Matsui (2006), Sadikoglu & Oclay (2014), Powell (1995), Cua et al (2001), Seth & Tripathi (2005).

The survey questions applicable to this study are five point Likert scale.

The survey questionnaire has three sections: 1) General information about the plant 2) Extent of practicing the elements of TQM 3) the operational performance of the firm. The informants were asked to indicate their agreement or disagreement with the statements provided using five point Likert scales

where a value of 5 indicates strong agreement and 1 indicates strong disagreement. For the performance measures, the informants were asked to evaluate plant previous years' performance.

3.5 Methods of Analysis

The study being descriptive in nature, the quantitative method of data analysis and inferential analysis are used as analysis techniques. Descriptive analysis enables to describe relevant aspects of TQM practices and operational performance of pharmaceutical manufacturing firms in Ethiopia and to provide detailed information about each relevant variable.

Correlation analysis is conducted to explore the strength and direction of the linear relationship between the seven CSFs of TQM (independent variables) and the four operational performance measures (dependent variables).

Multiple Regression analysis is used to examine the relationship between TQM practices and operational performance of Ethiopian pharmaceutical manufacturing firms and to know the effect and magnitude of TQM practices on operational performance of Ethiopian pharmaceutical manufacturing firms. This will be done by developing regression models. In each regression model, the seven quality measurement scales are considered as independent variables, and each of the four operational performance measures are considered as dependent variable.

3.6 Measurement of Variables

As it was discussed above in the literature review section, the critical success factors of TQM which are identified in this study are Top Management Support, Supplier Quality Management, Customer focus, People Management, Process Management, Product Design and Continuous Improvement. These variables are considered as independent variables. The measures for each factor is adapted from similar studies such as Sila & Ebrahimpour (2005), Phan & Matsui (2006), Sadikoglu & Oclay (2014), Powell (1995), Cua et al (2001),Seth & Tripathi (2005).

The operational performance measures which are considered in this study are cost performance, quality performance, delivery performance, and flexibility to volume performance. These variables are considered as dependent variables.

Neely et al (2005) define performance measurement as "the process of quantifying the efficiency and effectiveness of action." Thus, the performance of the operations function serves as a measure of whether an organization has realized its intended operations strategy or not. Consequently, operational performance is crucial for assessing how well operations support the overall business goals (Flynn et al, 2014). Operational performance is measured by the quality, delivery, flexibility and cost scales as

developed by Boyer and Pagell (2000), Flynn et al (2014) & Cua et al (2001), which assessed opinion of managers on the level of operational performance. According to these researchers, quality performance is measured with conformance to product specifications, performance and consentient & reliable product quality. Delivery performance is measured with providing fast deliveries, meeting delivery promises and reducing production lead time. Flexibility to volume performance is measured by making rapid design changes, adjusting capacity quickly, making rapid volume changes, & adjusting product mix quickly. Cost performance is measured through reduction in inventory, increase in capacity utilization, reduction in production costs and increase in labor productivity.

The following table (Table 3) shows measurements of the constructs (dependent & Independent Variables) and the sources from which questionnaires are developed:

Table 3: Sources of Measurement of Constructs

	Variables	Measurements	Source
Independent Variables	Top Management Support	Question number 1 up to 6	Fuzi & Gibson (2013); Cua et al (2001), Seth & Tripathi (2005), Powell (1995),
	Process Management	Question number 7 up to 13	Fuzi & Gibson (2013); Saraph et al as cited in Sila & Ebrahimpour (2005), Phan & Matsui (2006)
	People Management	Question number 14 up to 22	Fuzi & Gibson (2013); Saraph et al as cited in Sila & Ebrahimpour (2005), Cua et al (2001), Seth & Tripathi (2005), Phan & Matsui (2006)
	Continuous Improvement	Question number 23 up to 27	Fuzi & Gibson (2013);Anderson et al (1995) as cited in Sila & Ebrahimpour (2005),, Zhang et al (1999)
	Supplier Quality Management	Question number 28 up to 34	Fuzi & Gibson (20130; Cua et al (2001);Flynn et al (1995), Powell (1995
	Customer Focus	Question number 35 up to 42	Fuzi & Gibson (2013), Cua et al (2001), Flynn et al (1995),Sadikoglu & Oclay (2014)
	Product Design	Question number 42 up to 48	Cua et al (2001);Flynn et al (1995), Phan & Matsui (2006); Zhang et al (1999)
Dependent Variables	Quality Performance	Question number 49 up to 51	Cua et al (2001);Flynn et al (1995); Boyer & Lewis (2000), Phan & Matsui (2006)
	Cost Performance	Question number 52 up to 55	Cua et al (2001);Flynn et al (1995); Boyer & Lewis (2000), Phan & Matsui (2006)
	Delivery Performance	Question number 56 up to 58	Cua et al (2001);Flynn et al (1995);Boyer & Lewis (2000), Phan & Matsui (2006)
	Flexibility Performance	Question number 59 up to 61	Cua et al (2001);Flynn et al (1995); Boyer & Lewis (2000), Phan & Matsui (2006)

Source: Adapted from literature survey, 2019

3.7 Reliability & Validity of the Instrument

3.7.1 Reliability Test

According to Hair Jr Joseph F, William C. Black, Barry J. Babin & Rolph E. Anderson (2014, p. 91-92), reliability refers to the extent to which a variable or set of variables is consistent in what it is intended to measure. If multiple measurements are taken, reliable measures will all be consistent in their values. It suggests that the same thing is repeated or recurs under the identical or very similar conditions. The opposite of reliability is an erratic, unstable, or inconsistent result that happens because of the measurement itself (Neuman, 2014 p.212)

The internal consistency of a set of two or more construct indicators is commonly measured by Cronbach's alpha. This measure is expected to be more than 0.7 to say that the test is internally consistent (Mujis, 2004 p. 73). The following tables (Table 4) shows the Cronbach's alpha coefficient of the TQM constructs & operational performance measures.

Table 4: Reliability Test of Variables

TQM Construct	Cronbach's Alpha	Number of Items
Top Management Support	0.805	6
Process Management	0.788	7
People Management	0.859	9
Continuous Improvement	0.754	5
Supplier Quality Management	0.725	7
Customer Focus	0.748	8
Product Design	0.778	6
Over all Cronbach's α (independent Variables)	**0.882**	**7**
Quality Performance	0.778	3
Cost Performance	0.781	4
Delivery Performance	0.728	3
Flexibility to Volume Performance	0.708	3
Over all Cronbach's α (dependent variables)	**0.909**	**4**

Source: Own Survey, 2019

Cronbach's alpha coefficient was applied in order to determine the internal consistency of reliability of the questionnaire. The above table shows that reliability test result ranges from 0.708 to 0.859 for each variable of the study. This indicates the internal consistency of the questionnaire and each scale represents a reliable construct. The overall Cronbach's α for the seven independent variables was found

to be 0.881 and for performance measures was 0.909. The Cronbach's α values for each dependent & independent variables and over all values are found to be above the minimum acceptable limit of 0.7 as suggested by Mujis (2004,p.73). Accordingly the seven TQM constructs & the four operational performance measures in this study are judged to be reliable.

3.7.2 Validity

Validity is the extent to which a scale or set of measures accurately represents the concept of interest. According to Mujis (2004, p.82), validity basically concerns whether we are measuring what we want to measure and is probably the single most important aspect of measurement. Content validity represents assessment of the degree of correspondence between the items selected to constitute a summated scale and its conceptual definition (Hair et al, 2014, p. 90). In this study extensive review of the literature on the empirical study of quality management practices and operational performance was conducted to develop a content-valid constructs. The researcher adapted instruments from previous researches to carefully select the variables & their measurements (Cua et al ,2001;Seth & Tripathi ,2005;Phan & Matsui,2011; Powell,1995; Sadikoglu & Oclay,2014; Boyer & Pagell,2000; Boyer & Lewis ,2000; Flynn et al ,2014; Phan & Matsui ,2006).

Moreover two experienced professionals in the pharmaceutical industry were consulted about the content of the questionnaire and their opinion is taken.

Chapter 4 - Data Presentation & Analysis

4.1 Introduction

This chapter presents the analysis of data and findings from the primary data that was gathered from the respondents. The questionnaire was collected from 57 participants of 13 companies which are engaged in manufacturing of medicinal products. The targeted respondents are managers who are working in quality control, quality assurance, production, research & development, technical plant managers and other quality experts who are assumed to provide the required information according to the proposed study. All completed questionnaires were edited for completeness and consistency. Statistical Package for Social Sciences (SPSS) V 25 was used in statistical analysis. This section includes back ground information of surveyed companies & respondents, descriptive analysis, correlation & regression analysis and finally summary of findings & hypothesis testing results.

4.2 Background Information of the Surveyed Companies & Respondents

A total number of 65 questionnaires were distributed to the pharmaceutical industries which are engaged in the manufacture of medicines in Ethiopia. According to the information obtained from the Food, Beverages & Pharmaceutical Development Institute of the Ministry of Industry of Ethiopia, there are currently about 12 pharmaceutical companies which are actively engaged in the production of pharmaceutical products (medicines). One company which is producing gelatin capsule is also included in the survey as its product is considered as pharmaceutical product related to Capsule dosage form. Accordingly a total of 13 companies were considered in this study. Five questionnaires were distributed for each company considering the number of above –mentioned managers in respective companies. Out of the total questionnaires distributed, 8 questionnaires (three are incomplete & five are non-responded) were rejected which makes the response rate 87.7%. The response rate was quiet reasonable to reflect the views of the current pharmaceutical manufacturing companies.

4.2.1 Background of Surveyed Companies

The questionnaires targeted key personnel of each company: Quality control & or Quality Assurance managers, Production Managers, Technical Plant managers (General Managers), quality experts of respective companies who are believed to have the required knowledge of the study & provide the most relevant information of the respective companies.

The following table (Table 5) shows the general information about surveyed companies.

Table 5: General Information about Surveyed Companies

Description	Measure	Frequency	Percentage	Cumulative Percentage
Years of Company's establishment	Less than 5 years	2	15.4%	15.4%
	Between 5 years & 10 Years	1	7.7%	23.1%
	More than 10 years	10	76.9%	100%
Company ownership	Ethiopian Owned	5	38.5%	38.5%
	Foreign owned	3	23.0%	61.5%
	Joint venture	5	38.5%	100%
Number of full time employees	Less than 75 workers	2	15.4	15.4%
	Between 75 to 200 workers	6	46.1%	61.5%
	More than 200 workers	5	38.5%	100.0%
Certificate of Local or international Quality Award	Certified	10	76.9%	76.9%
	Not certified	3	23.1%	100%
Planning to have quality certificates in short term	Have short term plan	11	84.6%	84.6%
	No short term plan	2	15.4%	100%

Source: Own survey, 2019

The respondents were asked to indicate the duration of existence in terms of number of years, and the size of company in terms of the number of workers as these factors may determine the level of investment in TQM initiative (Fuzi & Gibson, 2013). From the findings in table 5 above, it was found that 10 companies (76.9%) had been in existence for more than 10 years, 1 company (7.7%) had been in existence for 5-10 years while 2 companies (15.4%) had operated for a period of less than 5 years. These results indicate that most of the firms in this study have been operated for considerable period of time to implement TQM.

With regard to number of employees, it was found that 5 companies (38.5%) had 200 and above employees, 6 companies (46.1%) had 75-200 employees, while 2 companies (15.4%) had less than 75 employees. The result shows that most of the companies have enough number of employees to practice Total Quality Management. The respondents were also asked to indicate the company ownership, according to the result, 38.5 % of the companies are owned by Ethiopians and 38.5% are joint venture companies between Ethiopian & foreigners and the rest 23 % of companies are owned by foreigners.

The above result shows that majority of the companies (61.5 %) are either joint venture companies or foreign owned companies indicating the possibility that companies may have adopted quality management principles & technology from abroad.

Finally respondents were asked whether their companies obtained quality certificate and their intentions of obtaining this certificate in short term basis. The survey analysis indicates that among the surveyed companies 76.9 % had local or international quality certificate, the rest don't have the certificates so far. Nearly 85 % of surveyed companies expressed their intention that they have a plan to obtain quality certificates in short term while 2 companies showed no interest to obtain any quality certificate in the short run.

4.2.2 Background Information about Respondents

The following table presents the demographic profile of respondents.

Table 6: Back ground Information about Respondents

Description	Measure	Frequency	Percentage	Cumulative Percentage
Educational Level	Diploma & lower	0	0	0
	Bachelor degree	45	78.9%	78.9%
	Master degree	12	21.1%	100%
	PhD degree	0	0	0
Current Job Position of respondents	Plant technical managers or higher	11	19.3%	19.3%
	Quality Assurance Manager	13	22.8%	42.1%
	Quality Control Manager	11	19.3%	61.4%
	Production Manager	13	22.8%	84.2%
	Research & Development experts & others	9	15.8%	100%
Work Experience in Current Job Position	Less than 5 years	14	24.6%	24.6%
	Between 5 years & 10 Years	21	36.8%	61.4%
	More than 10 years	22	38.6%	100%

Source: Own survey, 2019

The majority of individuals who participated in this research were having position within the company as plant technical, quality assurance, quality control & production managers (84.2%) with a minimum educational qualification of bachelor degree. Most of the respondents had work experiences on their

current position more than 5 years (75.4%). This indicates that the questionnaires were completed by experienced persons who have better knowledge about the situation in their company.

4.3 Descriptive Statics of Study Variables

One statistical approach for determining equivalence between groups is to use simple analyses of means and standard deviations for the variables of interest for each group in the study.

The mean and standard deviation of the TQM constructs which were identified in this study were analyzed using SPSS V 25 software and the outcomes are provided below in table 7.

Table 7: Mean Value of Constructs

TQM Variables	Item Number	The mean score of each item	The mean score of each construct	Standard Deviation
Top Management Support	1	4.1930	3.6481	0.46024
	2	3.9649		
	3	3.7719		
	4	3.5965		
	5	3.4561		
	6	3.1228		
Process Management	1	4.2632	3.7994	0.43016
	2	4.1404		
	3	3.0000		
	4	3.9649		
	5	3.5965		
	6	4.1579		
	7	3.5088		
People Management	1	4.1754	3.7192	0.36402
	2	3.4035		
	3	3.6316		
	4	3.6842		
	5	3.6667		
	6	3.5614		
	7	3.6140		
	8	3.5789		
	9	4.1404		
Continues Improvement	1	3.7544	3.4702	0.40619
	2	2.9298		
	3	3.2632		
	4	3.3333		
	5	4.0702		

Supplier Quality Management	1	4.2807	3.9474	0.32129
	2	4.1228		
	3	3.5439		
	4	3.6316		
	5	4.0877		
	6	4.0175		
	7	3.8772		
Customer Focus	1	4.0351	3.5022	0.35786
	2	3.6842		
	3	3.5879		
	4	3.4035		
	5	3.1228		
	6	3.3333		
	7	3.6140		
	8	3.2456		
Product Design	1	4.1404	3.4591	0.36226
	2	3.6491		
	3	3.5263		
	4	3.7018		
	5	2.8596		
	6	2.8772		
Quality Performance	1	3.4211	3.6665	0.46394
	2	3.9474		
	3	3.6316		
Cost Performance	1	3.4211	3.5088	0.39519
	2	3.9474		
	3	3.6316		
	4	3.0551		
Delivery Performance	1	3.7895	3.5096	0.43232
	2	3.1993		
	3	3.5439		
Flexibility To Volume Performance	1	4.2456	3.7953	0.47873
	2	3.789		
	3	3.3509		

Source: Own survey, 2019

Analysis of summary mean scores indicate that the overall mean score ranges from 3.46 to 3.95 with minimum standard deviation of 0.32129 and maximum standard deviation of 0.47873 for all variables as stated in the above table. The mean value shows the average response of respondents on a certain dimension. While, standard deviation shows that how diverse are the respondents for a given variable.

Among the seven TQM elements, supplier quality management scored the highest responses mean rating of 3.95 with standard deviation 0.32129 followed by Process Management with mean 3.80 and standard deviation 0.43016. According to the result, the respondents believed that product design is the least TQM element practiced in the industry with a minimum overall mean rating of 3.46 with standard deviation of 0.36226.

Similarly analysis of the mean of operational performance measures showed that flexibility performance scored the highest mean rating of 3.79 with Standard deviation of 0.47873 and cost performance showed the relatively least mean with 3.51 and standard deviation of 0.39519.

According to Lai kee-hang et al (2002), a company achieving a level of quality management implementation above the mean value of 3 is regarded as having "positive" level of implementation. Whereas a company with a level of quality management implementation below the mean value of 3 would indicate that it lacks the efforts to practice quality management or to implement quality management systems. As the overall mean rating of all the TQM constructs is above the midpoint in the likert scale, the majority of respondents believed that TQM practices are being implemented in the surveyed pharmaceutical industries to some extent. It is not surprising that supplier quality management & process management practices scored the highest responses as pharmaceutical industries are highly involved in these activities to maintain their quality of products. The results are in agreement with the findings of Fuzi & Gibson (2013) who studied the effect of TQM implementation in Libyan industries.

4.4 Correlation Analysis

Correlations are perhaps the most basic and most useful measure of association between two or more variables (Marczyk Geoffrey, De Matteo David & Festinger David, 2005 p.216). Pearson's r gives us information the direction of the relationship: a positive sign indicates a positive direction, a negative sign indicates a negative direction, a value of 0 represents lack of correlation; the strength of the relationship: the closer to 1 (+ or –) the stronger the relationship (Mujis, 2004 p.144). Correlation analysis was conducted in this study to explore the strength and direction of the linear relationship between the seven CSFs of TQM (independent variables) and the four operational performance measures (dependent variables). As the table below (Table 8) showed, most of TQM variables are positively & significantly correlated with each other at significant level of $p < 0.01$. The bivariate correlations among the TQM factors range from 0.333 to 0.768. These results are similar to findings of Hailu & Raju (2016) with a correlation result that ranges from 0.266 to 0.796 and that of Hassan et al (2012) which ranges from 0.216 to 0.829.

The significant correlation among the measurement scales proves the assumption that Total Quality Management activities strongly support and depend on each other. The highest correlation was observed between process management & people management (r=.768), this was expected since a process oriented companies requires high involvement of qualified staff to achieve the required process improvements. The second highest correlation was between customer focus & product design (r=.709), this was also anticipated as customer oriented companies pay a greater attention on their product developments to increase quality of their products. This is evident especially in pharmaceutical industries.

Table 8: Correlation between TQM Variables

		TMS	PRM	PEM	CI	SQM	CF	PD
TMS	Pearson Correlation	1	.465**	.508**	.431**	.532**	.590**	.477**
	Sig. (2-tailed)		.000	.000	.001	.000	.000	.000
	N	57	57	57	57	57	57	57
PRM	Pearson Correlation	.465**	1	.768**	.505**	.463**	.599**	.585**
	Sig. (2-tailed)	.000		.000	.000	.000	.000	.000
	N	57	57	57	57	57	57	57
PEM	Pearson Correlation	.508**	.768**	1	.446**	.421**	.648**	.608**
	Sig. (2-tailed)	.000	.000		.001	.001	.000	.000
	N	57	57	57	57	57	57	57
CI	Pearson Correlation	.431**	.505**	.446**	1	.334*	.618**	.526**
	Sig. (2-tailed)	.001	.000	.001		.011	.000	.000
	N	57	57	57	57	57	57	57
SQM	Pearson Correlation	.532**	.463**	.421**	.334*	1	.333*	.401**
	Sig. (2-tailed)	.000	.000	.001	.011		.011	.002
	N	57	57	57	57	57	57	57
CF	Pearson Correlation	.590**	.599**	.648**	.618**	.333*	1	.709**
	Sig. (2-tailed)	.000	.000	.000	.000	.011		.000
	N	57	57	57	57	57	57	57
PD	Pearson Correlation	.477**	.585**	.608**	.526**	.401**	.709**	1
	Sig. (2-tailed)	.000	.000	.000	.000	.002	.000	
	N	57	57	57	57	57	57	57

**. Correlation is significant at the 0.01 level (2-tailed). Source: Own Survey,2019

*. Correlation is significant at the 0.05 level (2-tailed).

Key: TMS =Top Management Support, PRM= Process Management, CI=Continuous improvement, SQM= Supplier quality Management, CF= Customer Focus, PD= Product Design,

Table 9 below revealed that there was a strong positive relationship between individual TQM elements & each operational performance measures at $p < 0.01$ for most of the variables. The correlations between the TQM practices and performance measures range from 0.317 to 0.780. All TQM variables are significantly & positively correlated with all performance measures.

Highest correlation was observed between Customer Focus & Cost Performance (r=.780) followed by Product Design & Quality Performance(r=.763). The above correlation result is in agreement with the previous studies such as Salaheldin (2009), Hassan et al (2012), Demirbag et al (2006) & Musran (2011) & several others who indicated that there is strong relationship between TQM factors and operational performance.

Table 9: Correlation between TQM Variables & Performance Measures

		TMS	PRM	PEM	CI	SQM	CF	PD
QP	Pearson Correlation	.520**	.755**	.674**	.518**	.413**	.746**	.763**
	Sig. (2-tailed)	.000	.000	.000	.000	.001	.000	.000
	N	57	57	57	57	57	57	57
CP	Pearson Correlation	.527**	.753**	.686**	.536**	.385**	.780**	.756**
	Sig. (2-tailed)	.000	.000	.000	.000	.003	.000	.000
	N	57	57	57	57	57	57	57
DP	Pearson Correlation	.473**	.525**	.646**	.423**	.317*	.701**	.623**
	Sig. (2-tailed)	.000	.000	.000	.001	.016	.000	.000
	N	57	57	57	57	57	57	57
FP	Pearson Correlation	.460**	.722**	.642**	.504**	.448**	.746**	.654**
	Sig. (2-tailed)	.000	.000	.000	.000	.000	.000	.000
	N	57	57	57	57	57	57	57

**. Correlation is significant at the 0.01 level (2-tailed). Source: Own Survey,2019

*. Correlation is significant at the 0.05 level (2-tailed).

Key: QP= Quality performance, CP=Cost Performance, DP= Delivery performance, FP= Flexibility to Volume performance

4.5 Regression Analysis

The purpose of this study is to analyze how the independent variables are related to the independent variables (operational) performance measures. The results of correlations indicated the existence of the relationship between the variables but did not identify the most crucial variables for this relationship. To achieve this objective, multiple regressions were conducted to analyze the combined effect of predictor variables (independent) on dependent variables and to test the research model and to predict operational

performance measures from the TQM constructs identified in this study. The researcher used the statistical package for social sciences (SPSS v 25) to code, enter and compute the measurements of the multiple regressions for the study. Before the regression analysis was performed, the general statistical assumptions were checked as presented in the following section.

4.5.1 Testing Statistical Assumptions

Meeting the assumptions of regression analysis is essential to ensure that the results obtained are truly representative of the sample and that we obtain the best results possible. Any serious violations of the assumptions must be detected and corrected if at all possible (Hair et al, 2014 p.204).

This study employs the regression analysis method to analyze the data and test the hypotheses. Thus, before regression analyses take place, the assumptions of Normality, Linearity, Multicollinearity, and Independent of Observation were checked (Hair et al., 2014; Pallant, 2007 p.189). The minimum acceptable sample size for independent variables ratio is 5:1 (Hair et al., 2014, p.171).

4.5.1.1 Normality Test

According to Hair et al (2014, p.73), the most fundamental assumption in multivariate analysis is Normality, referring to the shape of the data distribution for an individual metric variable and its correspondence to the normal distribution, the benchmark for statistical methods. The skewness value provides an indication of the symmetry of the distribution. On the other hand kurtosis provides information about the peak of the distribution (Pallant, 2007 P.56.)

Table 10 below shows the result of normality test. The result indicates that skewness value ranges from -0.604 to 0.665 and Kurtosis value ranges from -1.166 to 0.973.

According to George & Mallery (2010) as cited in Bushera (2016), the acceptable range for the skewness and kurtosis values for research variables are in between ±2.00, accordingly the assumption of normality is achieved for all the variables under this study.

More over the histogram & P-P plot of the model illustrates that the normality assumption is achieved since the bars make a normal curve and the normal P-P plot –points lie closer to the diagonal line. The results are presented in Appendix 1: Assumption of Normality & Linearity.

Table 10: Normality Test

	N	Skewness		Kurtosis	
	Statistic	Statistic	Std. Error	Statistic	Std. Error
TMS	57	.391	.316	-1.118	.623
PRM	57	.144	.316	.094	.623
PEM	57	-.111	.316	-1.166	.623
CI	57	-.061	.316	-1.012	.623
SQM	57	.665	.316	.488	.623
CF	57	-.604	.316	.332	.623
PD	57	-.127	.316	-.340	.623
QP	57	.173	.316	-.037	.623
CP	57	.081	.316	.973	.623
DP	57	.132	.316	-.767	.623
FP	57	-.194	.316	-.386	.623
Valid N (listwise)	57				

Source: Own survey, 2019

4.5.1.2 Linearity Checking

Standard multiple regression can only accurately estimate the relationship between dependent and independent variables, if the relationships are linear in nature. If the relationship between independent variables and the dependent variable is not linear, the results of the regression analysis will under-estimate the true relationship. The most common way to assess linearity is to examine scatter plots of the variables and to identify any nonlinear patterns in the data (Hair et al, 2014 p.74). This assumption was assessed through the investigation of the scatter plot of residuals against predicted values and the normal plot of regression standardized residuals for the dependent variables. As it can be shown in Appendix 1 the standardized residual plots did not exhibit any nonlinear pattern to the residuals, thus ensuring that there was no violation of linearity. Hence the assumption of linearity was met.

4.5.1.3 Multicollinearity

Multicollinearity which refers to the relationship among the independent variables is another issue in assumption testing. Multicollinearity problem exists when the independent variables are too highly correlated. The presence of high correlations (generally .90 and higher) is the first indication of substantial collinearity (Pallant, 2007 p.149 and Hair et al, 2004 p.196). The two most common measures for assessing both pairwise and multiple variable collinearity are tolerance and its inverse, the

variance inflation factor (VIF). A direct measure of multicollinearity is tolerance, which is defined as the amount of variability of the selected independent variable not explained by the other independent variables. A second measure of multicollinearity is the variance inflation factor (VIF), which is calculated simply as the inverse of the tolerance value (Hair et al, 2014 p. 196).

According to Hair et al, the suggested cut off VIF is 10 which means that tolerance value less than 0.1 and VIF value greater than 10 indicates there is sever multicollinearity & violets the assumption of linear regression. The following table (table 11) depicts the tolerance & VIF values

Table 11: Collinearity Statistics

		Tolerance	VIF
1	TMS	.519	1.927
	PRM	.356	2.807
	PEM	.341	2.936
	CI	.572	1.749
	SQM	.628	1.591
	CF	.323	3.098

Source: Own survey,2019

The above table indicates that tolerance value is above 0.1 and VIF value is less than 5 which confirms that there is no sever multicollinearity among the independent variables.

4.5.1.4 Independence of Observation

Independence of observation requires that the dependent measures for each respondent be totally uncorrelated with the response from other respondents in the sample**.** Durbin-Watson statistic uses to test the assumption that residuals are independent (or uncorrelated). The Durbin-Watson statistic ranges in value from zero to four. A value of two indicates no autocorrelation. A value towards zero indicates positive autocorrelation. Conversely, a value towards four indicates negative autocorrelation (Saunders, M., Lewis, P. & Thornhill, A., 2009 p.467). The Durbin-Watson values in this study are found to be in the range of 1.587 to 2.181 based on the output from SPSS & thus the general rule of thumb was met which ensures that the assumption of independence of error terms is not violated.

In summary since the general assumptions of the data are satisfied, it is eligible to perform multiple regression.

4.5.2 Regression Results of TQM Variables and Quality Performance

Table 10: Regression Results of TQM Constructs & Quality Performance

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.872[a]	.761	.727	.24248

a. Predictors: (Constant), PD, SQM, CI, TMS, PEM, PRM, CF

ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	9.173	7	1.310	22.286	.000[b]
	Residual	2.881	49	.059		
	Total	12.054	56			

a. Dependent Variable: QP

b. Predictors: (Constant), PD, SQM, CI, TMS, PEM, PRM, CF

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	-.609	.462		-1.320	.193
	TMS	.032	.098	.032	.332	.741
	PRM	.457	.126	.423	3.618	.001
	PEM	-.053	.153	-.042	-.349	.729
	CI	-.057	.105	-.050	-.541	.591
	SQM	-.001	.127	-.001	-.010	.992
	CF	.361	.157	.283	2.298	.026
	PD	.450	.136	.351	3.315	.002

a. Dependent Variable: QP Source: Own survey,2019

The regression result in the table 12 above shows that the model is statistically significant at $p < 0.05$ level. The multiple correlation coefficient value (r=.872) indicates that there is positive relationship between independent & dependent variables. The R^2 value (0.761) indicates the independent variables together accounted for 76.1% of the variance in quality performance (dependent variable).The adjusted R^2 value (.727) indicates the generalizability of this model in another population. Analysis of variance result with F-ratio of 22.286 and a significance level of 0.000 indicate that the quality performance of the pharmaceutical manufacturing industries depends, to a significant degree, on the use of TQM practices.

Further analysis of the parameters of the model as shown in the coefficients' table indicates that process management (β =0.457), Product design (β =0.45) & customer focus (β =.361) was found statistically significant at $p < 0.05$. The variation in the above model significantly comes from the three independent variables. These findings indicate that process management, product design and customer focus are important TQM variables that significantly impact on the quality performance of Ethiopian Pharmaceutical manufacturing companies.

4.5.3 Regression results of TQM Variables and Cost Performance

Table 11: Regression Results of TQM Constructs & Cost Performance

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.881[a]	.776	.744	.19992

a. Predictors: (Constant), PD, SQM, CI, TMS, PEM, PRM, CF

ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	6.787	7	.970	24.259	.000[b]
	Residual	1.958	49	.040		
	Total	8.746	56			

a. Dependent Variable: CP b. Predictors: (Constant), PD, SQM, CI, TMS, PEM, PRM, CF

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients		
		B	Std. Error	Beta	t	Sig.
1	(Constant)	-.104	.381		-.274	.785
	TMS	.029	.081	.033	.354	.725
	PRM	.366	.104	.399	3.520	.001
	PEM	-.021	.126	-.019	-.164	.870
	CI	-.037	.087	-.038	-.427	.671
	SQM	-.043	.105	-.035	-.414	.681
	CF	.388	.129	.357	2.997	.004
	PD	.328	.112	.300	2.927	.005

a. Dependent Variable: CP Source: Own survey,2019

The regression model as it is depicted in table 13 is statistically significant at $p < 0.05$ level. The multiple correlation coefficient value (r=.881) indicates that there is positive relationship between independent & dependent variables. The R^2 value (0.776) indicates the independent variables together explain 77.6 % of the variance in cost performance (dependent variable).

The significant F-test in the ANOVA table indicated that the relationship between the dependent variable and the independent variables was linear and the model significantly predicted the dependent variable (cost performance).

Further analysis of the coefficients showed that out of the seven variables, customer focus (β =3.88), process management (β =0.366) and product design (β =0.328) are statistically significant at $P < 0.05$ significance level.

The regression result thus indicated that customer focus, process management and product design are the most predominant factors that are responsible for the variation on cost performance of the pharmaceutical industries in Ethiopia.

4.5.4 Regression Results of TQM Variables and Delivery Performance

The multiple correlation coefficient value as shown in the table 14 below (r=.756) indicates that there is positive relationship between independent & dependent variables. The R^2 value (0.572) indicates the independent variables together accounted for 57.2 % of the variance in delivery performance (dependent variable).The adjusted R^2 value (.511) indicates the generalizability of this model in another population.

The significant F-test in the ANOVA table confirms that the relationship between the dependent variable and the independent variables was linear and the model significantly predicted the Delivery performance. Further analysis of the parameters of the model confirmed out of the seven variables customer focus and people management are statistically significant at $p < 0.05$ level. The variation in the above model significantly comes from these independent variables.

Table 12: Regression Results of TQM Variables and Delivery Performance

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.756[a]	.572	.511	.30241

a. Predictors: (Constant), PD, SQM, CI, TMS, PEM, PRM, CF

ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	5.985	7	.855	9.349	.000[b]
	Residual	4.481	49	.091		
	Total	10.466	56			

a. Dependent Variable: DP

b. Predictors: (Constant), PD, SQM, CI, TMS, PEM, PRM, CF

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients		
		B	Std. Error	Beta	t	Sig.
1	(Constant)	-.075	.576		-.129	.898
	TMS	.026	.122	.028	.212	.833
	PRM	-.068	.157	-.068	-.433	.667
	PEM	.386	.190	.325	2.027	.048
	CI	-.059	.132	-.055	-.446	.658
	SQM	.004	.159	.003	.022	.982
	CF	.495	.196	.417	2.533	.015
	PD	.221	.169	.185	1.305	.198

a. Dependent Variable: DP Source: Own survey,2019

4.5.5 Regression Results of TQM Constructs & Flexibility to Volume Performance

The regression result in the table 15 below shows that the model is statistically significant at $p < 0.05$ level. The multiple correlation coefficient value (r=.835) indicates that there is positive relationship between independent & dependent variables. The R^2 value (0.697) indicates the independent variables together accounted for 69.7 % of the variance in flexibility performance (dependent variable).The adjusted R^2 value (.654) indicates the generalizability of this model in another population.

The significant F-test in the ANOVA table revealed that the relationship between the dependent variable and the independent variables was linear and the model significantly predicted the Flexibility to Volume performance. Analysis of the individual parameters of the model result in customer focus (β =0.661) and process management (β = 0.436) are statistically significant. These two independent parameters accounts for 69.7 % of the variance in flexibility to volume performance.

Table 13: Regression Results of TQM Variables & Flexibility to Volume Performance

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.835[a]	.697	.654	.28156

a. Predictors: (Constant), PD, SQM, CI, TMS, PEM, PRM, CF

ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	8.950	7	1.279	16.128	.000[b]
	Residual	3.884	49	.079		
	Total	12.834	56			

a. Dependent Variable: FP b. Predictors: (Constant), PD, SQM, CI, TMS, PEM, PRM, CF

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients		
		B	Std. Error	Beta	t	Sig.
1	(Constant)	-.755	.536		-1.408	.165
	TMS	-.114	.113	-.110	-1.008	.318
	PRM	.436	.147	.391	2.973	.005
	PEM	-.045	.177	-.034	-.256	.799
	CI	-.056	.122	-.048	-.461	.647
	SQM	.216	.148	.145	1.460	.151
	CF	.661	.182	.502	3.627	.001
	PD	.146	.158	.111	.927	.359

a. Dependent Variable: FP Source: Own survey,2019

4.6 Summary of Result Analysis & Hypothesis Testing

4.6.1 Results of Hypothesis H1:

Hypothesis H1 proposes that TQM Success factors are positively associated with Quality Performance. To examine the effect of TQM success factors on Quality performance, the correlation & the regression analysis of the model was carefully examined. Based on the outcomes of the correlation analysis (Table 9), all TQM variables in the model showed a significant positive relationship with quality performance at P< 0.01 level. Among the variables Product Design is highly correlated with Quality Performance (r=.763) followed by Process Management (r=.755). Moreover as it was depicted in table 12, regression coefficient R = .872 confirms that there is a very strong positive correlation between the dependent variable (Quality Performance) and the TQM practices. The independent variables accounts for 76.1% of the variation in Quality performance of the industries. The proposed model is statistically significant at $p < 0.05$ level as the ANOVA table indicated. Therefore the hypothesis that TQM success factors are positively associated with quality performance is accepted. Among the individual parameters process management (β =0.457), Product design (β =0.45) & customer focus (β =.361) are the predominant factors that are statistically significant at $p < 0.05$ level. These variables are responsible for 76.1% of the variation in quality performance. The remaining variation (23.9%) in quality performance could be attributed to other variables which are not included in this study.

4.6.2 Results of Hypothesis H2:

Hypothesis H2 proposes that TQM Success factors are positively associated with Cost Performance. Correlation analysis showed that all the TQM variables under this study are positively and significantly correlated with Cost performance at significance level of 0.01 (Table 9). Customer focus (r=.780), product design(r=.756) and process management (r=.753) are strongly correlated. TQM factors that impacts the cost performance of the pharmaceutical industries. Similarly the regression analysis of the model (Table 13) indicated that with regression coefficient (r=.881) and Coefficient of determination (R^2=.776), there is a strong & positive relationship between independent variables with dependent variable. The independent variables accounted for 77.6 % of the variation in the cost performance of the surveyed industries. Among the variables customer focus (β =.386), process management (β =.366) and product design (β =.328) are statistically significant level of 0.05. Accordingly, the Hypothesis H2 which proposes TQM success factors are positively associated with cost performance is accepted**.**

4.6.3 Results of Hypothesis H3:

Hypothesis H3 states that TQM Success factors are positively associated with Delivery Performance. The correlation analysis (table 9) confirms that all of the TQM factors are positively correlated with cost performance. Strong correlation was observed with customer focus(r=.701) and with people management (r=.646). Again the regression analysis (Table 14) resulted in the proposed model significantly predicts the dependent variable (Delivery performance). The R^2 value (0.572) indicates the independent variables together accounted for 57.2 % of the variance in delivery performance (dependent variable).Further analysis of the individual parameters indicated that the significance contribution of the variation comes from customer focus(β =.495) and People Management (β =0.386).

Therefore Hypothesis H3 which states that TQM success factors are positively associated with Delivery performance is accepted.

4.6.4 Results of Hypothesis H4:

Hypothesis H4 postulates that there is positive relationship between TQM factors and Flexibility to volume performance. In order to test this hypothesis results of correlation analysis (Table 9) and regression analysis (Table 15) were investigated. Correlation analysis results showed that there is strong positive relationship between the variable TQM variables and Flexibility to volume performance at $p<0.01$ level. Among the variables Customer Focus showed the highest positive correlation(r=.722) followed by process management (r= .722). The regression analysis also showed that the model is found to be significant at $p< 0.05$ level to predict the dependent variable (Flexibility to volume performance).The R^2 value (0.697) indicates the TQM success factors together accounted for 69.7 % of the variance in Flexibility to volume performance. Analysis of the individual parameters of the model result in customer focus (β =.661) and process management (β = 0.436) are significant factors the impact the flexibility to volume performance most. Therefore H4 is accepted.

Table 14: Summary of Hypothesis & Test Results

	Hypothesis	**Result**
H1	TQM Success factors are positively associated with Cost Performance	Accept
H2	TQM Success factors are positively associated with Cost Performance	Accept
H3	TQM Success factors are positively associated with Cost Performance	Accept
H4	TQM Success factors are positively associated with Cost Performance	Accept

Chapter 5 -Summary of Findings, Conclusion & Recommendations

5.1 Summary of Findings

This study attempted to examine the impact of TQM practices on operational performance of Ethiopian pharmaceutical manufacturing companies. To achieve this objective, first the critical success factors of TQM that are most relevant to Ethiopian pharmaceutical industries were identified. Then the conceptual model was proposed. This was achieved through a comprehensive literature review. Accordingly seven TQM success factors: Top Management Support, Process management, People Management, Continuous Improvement, Supplier Quality Management, Customer Focus & Product Design were identified. Next the research instrument was checked for reliability and validity. It was concluded that the instruments used for measuring TQM implementation & operational performance measures are reliable & valid. Data from 13 companies were used to test the conceptual model proposed. Correlation analysis was done to examine the relationship between TQM variables & operational performance measures. Finally regression analysis was performed for estimating the overall model fit & to identify the most predominate TQM success factors that impact on the operational performance measures.

Based on comprehensive analysis of the questionnaire, it was found out that the Ethiopian pharmaceutical manufacturing industries are practicing the identified TQM activities but not at highest level. Among the variables, Supplier Quality Management was the most highly practiced activity which is followed by Process Management. Product design was the least TQM variable that had been practiced among the surveyed companies. In contrast to these findings, Haile & Raju (2016) while studying the extent of TQM practices in Ethiopian manufacturing industries found that Process Management & People management are the two TQM elements which are highly practiced and Supplier quality management was least practiced activity. On another study on Libyan manufacturing industries, Fuzi & Gibson (2013) found that Process Management was highly practiced whereas people management was the least practiced TQM principles. On both studies pharmaceutical industries were not part of the studies. This implies that different industries adopt different TQM elements to realize their operational objectives.

The outcomes of correlation analysis support the hypothesis that there is positive relationship between TQM practices & operational performance of the pharmaceutical industries. All the identified TQM variables are positively correlated with Quality, Cost, Delivery & Flexibility to volume performances. Correlation analysis further revealed that Product Design, Process Management and Customer Focus are the most highly correlated variables with Quality performance, Cost performance & Flexibility to

Volume performances. Customer Focus and people management were found to be highly correlated with Delivery performance.

The findings of regression analysis indicated that Process Management, Product Design and Customer Focus are significant factors that influence the Quality & Cost performance of the surveyed pharmaceutical industries. It was observed that Customer Focus & People Management are the most important factors that impact on Delivery performance whereas Process Management and Customer Focus are the most TQM success factors that accounted for variation in Flexibility to volume performance of the surveyed companies.

In all regression models it is interesting to see that Customer Focus is the most important TQM variable that has significance contribution in all four operational measures. This is in agreement with the findings of Chin et al (2002) who identified that customer focus is the most important TQM element in Hong Kong manufacturing industries. Dean and Bowen (1994) also emphasized that the goal of satisfying customers is fundamental to TQM and is expressed by the organization's attempt to design and deliver products and services that fulfill customer needs.

Process management is also found to be important TQM element that impacts on Quality, Cost and Flexibility to volume performance significantly. This result is in agreement with study of Fuzi & Gibson (2013). It is important that pharmaceutical companies have to focus in their Process Management to avoid process variations, minimize defects & improve the quality of their products.

Another important TQM element which was found significant in two of dimension of performance measures was Product Design. According to Zhang et al (1999), sound product design meets or exceeds the requirements and expectations of customers better than the competitors, leading to an increased market share. Ethiopian pharmaceutical manufacturing plants need to focus on their products design to meet customer requirements. People Management was found to be a significant contributor on the delivery performance of the pharmaceutical industries.

In summary, the regression analysis found out that Customer Focus, Process Management, Product Design and People Management are found to be statistically significant on at least in one of the operational performance dimensions. However Top Management Support, Supplier Quality Management, and Continuous Improvement are not statistically significant to any of operational performance measures. The sample data used for the analysis is so small that it doesn’t have sufficient power to detect significant contribution of these variables. Despite the insignificant contribution of these three elements, it should not be concluded that these factors do not have impact on performance of the

organizations. As discussed earlier these 3 parameters were positively correlated to performance measures and to other TQM variables in the study. This implies that their contribution to operational performance of the industries might not be a direct one; they may have indirect relationship with performance measures in the study.

5.2 Conclusion

This paper investigates the relationship and impact that Total Quality Management practices have on common important measures of operational performances (i.e. quality, cost, delivery & flexibility) with respect to Ethiopian Pharmaceutical manufacturing companies. The study employs correlations and regressions analysis to justify the findings. The findings show that TQM can significantly improve the operational performance of Pharmaceutical manufacturing companies in Ethiopia. TQM practices that seem to play a major role in enhancing operational performance are found to be Customer Focus, Process Management, Product Design and People management. Top Management support, supplier quality management and continuous improvement do not appear to contribute to higher performance in the case of Ethiopian pharmaceutical industries. As these three factors are positively & significantly correlated to each of the performance measures & to other TQM elements, it can be argued that they could impact operational performances indirectly.

Customer focus was found to be the one which contributes to the highest impact on improvements in all four individual performance measures. This study confirms that operational performance of the pharmaceutical industries is highly dependent on the customer-focused activities of the companies. It was also identified that pharmaceutical industries should concentrate on process improvement & new product development activities to improve their operational performances. Pharmaceutical Manufacturing companies should be better than their competitors by responding rapidly to their customers' demands, manufacturing products that satisfy or exceed the expectation of their customers and anticipating future needs of their customers.

This study supports the importance and impact of TQM practices on performance of organizations as discussed in academic literature and other empirical researches. The findings suggest that effective TQM initiatives can significantly contribute towards operational performance improvements to compete in the highly dynamic business environment.

5.3 Recommendations

The pharmaceutical products requires a strong quality focus, efficient production & best customers services. The study indicates that TQM can play a significant role on operational performance of the pharmaceutical industries in terms of improving quality of products, minimizing production costs, improving delivery & volume flexibility performances.

On the basis of the findings and conclusions mentioned, the following points are recommended:

- This study has revealed that the predominant TQM dimensions in the surveyed Ethiopian pharmaceutical manufacturing industries are Customer Focus, Process Management and Product Design, thus the pharmaceutical companies are advised to focus on implementation of these TQM dimensions so that they can improve their operational performances significantly.
- This study further indicated that the operational performance of the Ethiopian pharmaceutical industries is highly dependent on customer focused activities. Therefore pharmaceutical companies should work closely with their customers to identify and meet their needs and expectations.
- The pharmaceutical companies should give strong attention in their process management to avoid possible process variations, to minimize defects & to improve the quality of their products
- This study has found that pharmaceutical manufacturing companies should give more emphasis to product design in order to meet customer requirements.
- It is advisable to consider all aspects of TQM dimensions in the manufacturing industries as this study investigated; each TQM construct improves different aspects of operational performance measures.
- In general the managers in the pharmaceutical industries should consider implementing the TQM dimensions on their operational activities as this study has indicated there is strong positive relationship of most of TQM dimensions & operational performance of the organizations.

5.4 Research Limitations and Future Research

This study has some limitations that should be addressed in future researches. First the sample data used in survey is so small and this may decrease the power of study and might limit generalization to other situations. The study also used cross-sectional data to test the research model based on the perception of respondents at a point in time. TQM activities & operational performance measures are dynamic in

nature that can be affected through changes of time and as a result cross-sectional data may not address this issue.

Due to time constraint, only pharmaceutical industries which are engaged in the production of medicine are included in the study, other similar industries such as food industries, medical device & supplies manufacturers were not part of the survey. Therefore the researcher suggests that future research can be carried out including these companies. The present study measured performance by the perception of managers in each company. For future research, it is better to use both objective and subjective performance measures to avoid risk of receiving biased responses. It is also recommended that future researches to consider longitudinal studies to investigate the effect of TQM elements across certain period of time.

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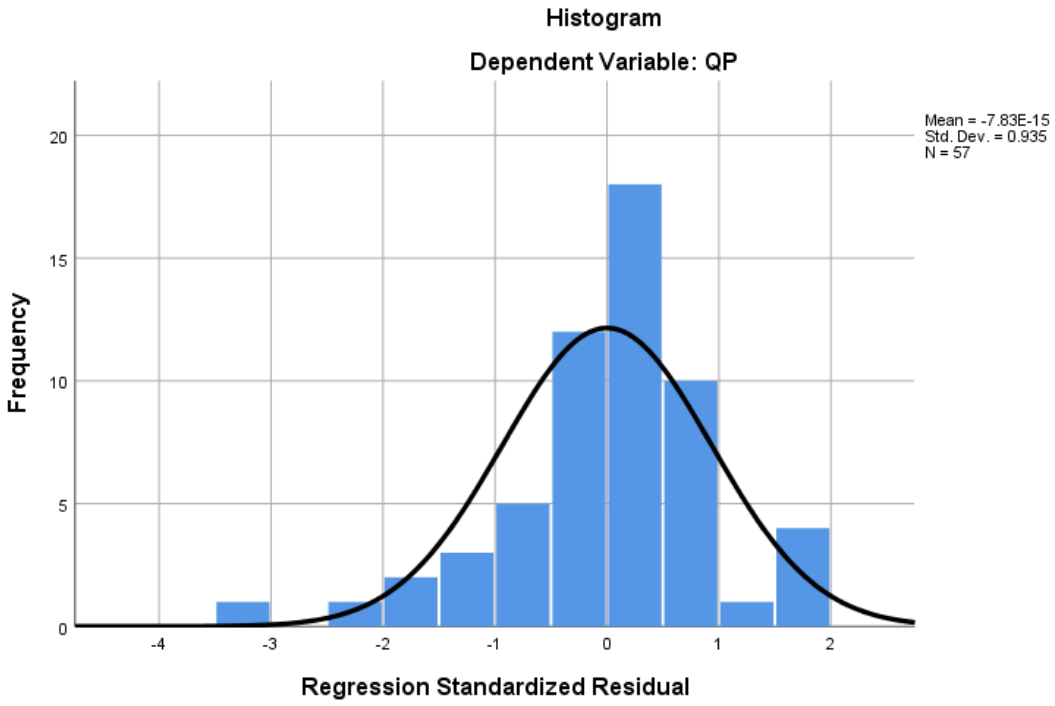
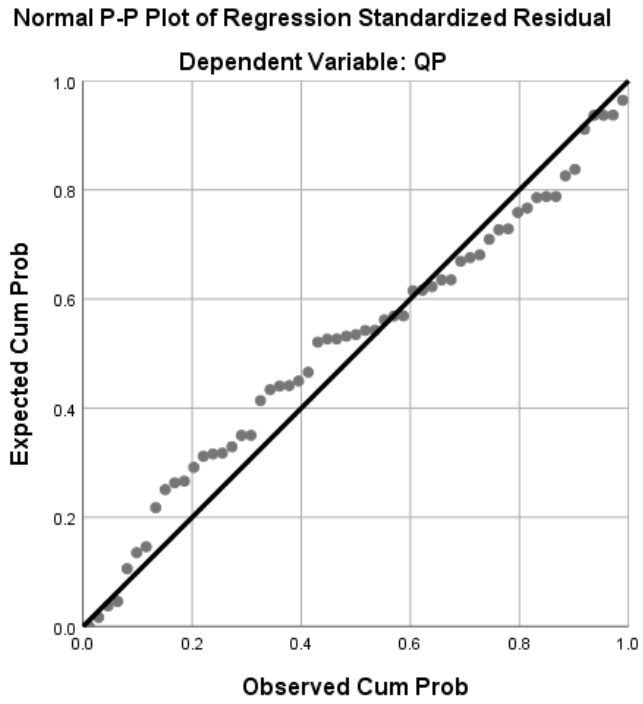
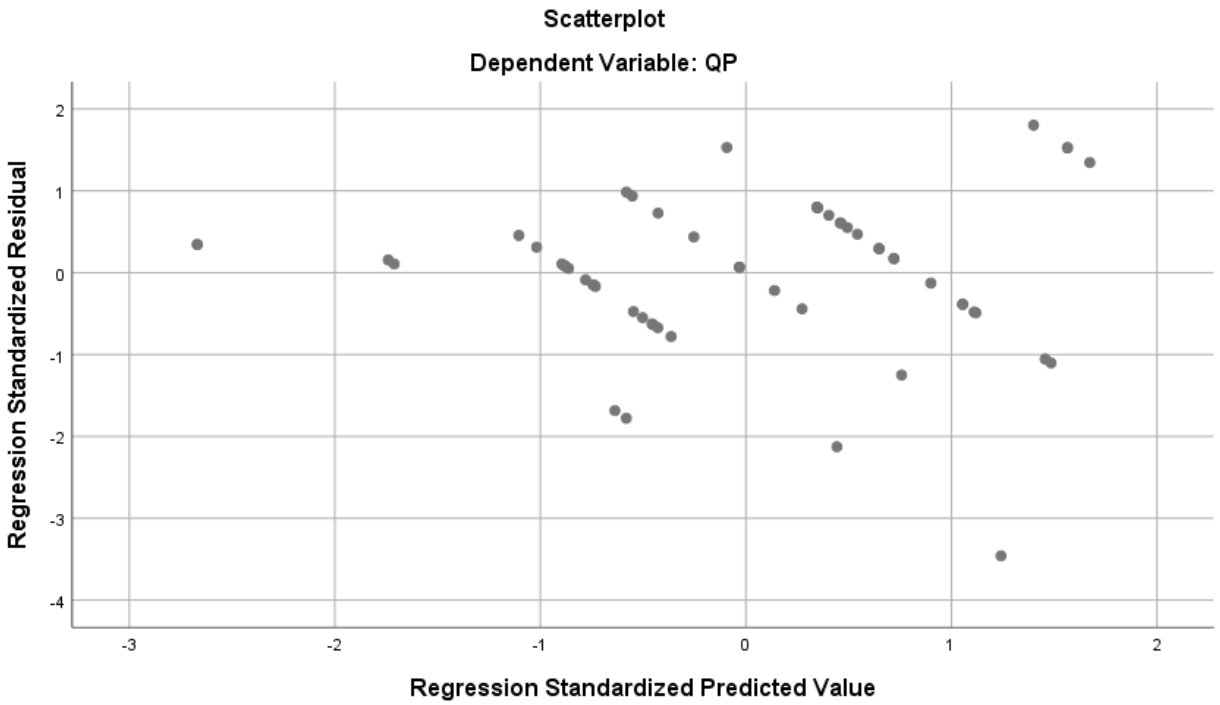
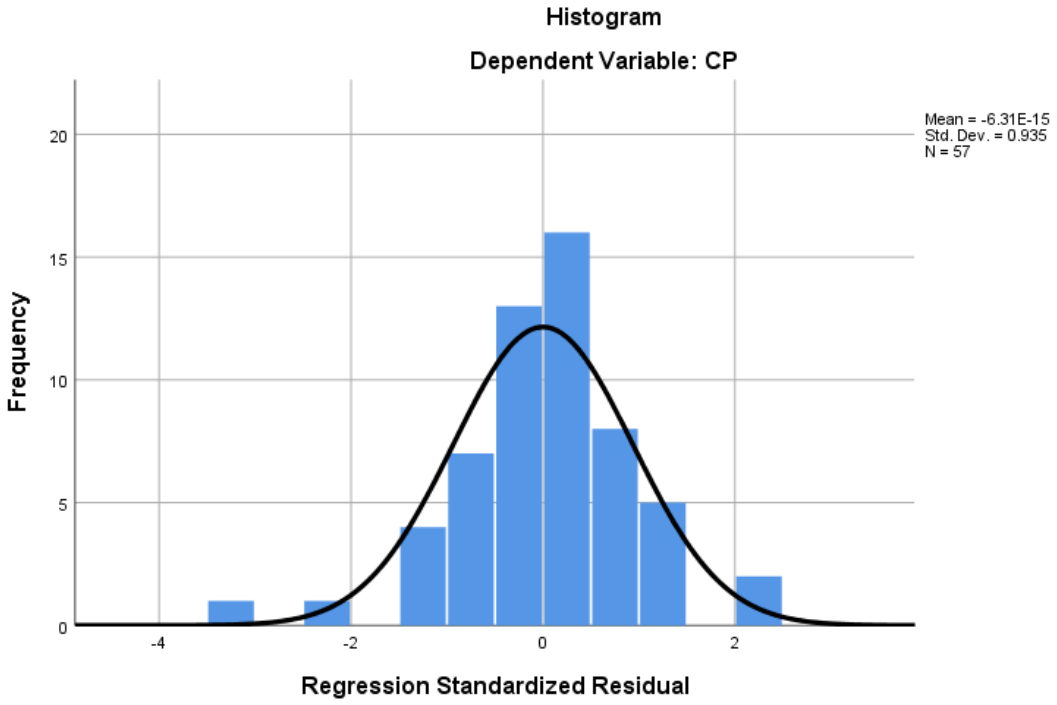
Appendix 1: Linearity & Normality Test results






Scatterplot
Dependent Variable: QP
Regression Standardized Residual
Regression Standardized Predicted Value
2
1
0
-1
-2
-3
-4
-3
-2
-1
0
1
2


Histogram
Dependent Variable: CP
Mean = -6.31E-15
Std. Dev. = 0.935
N = 57
Frequency
Regression Standardized Residual
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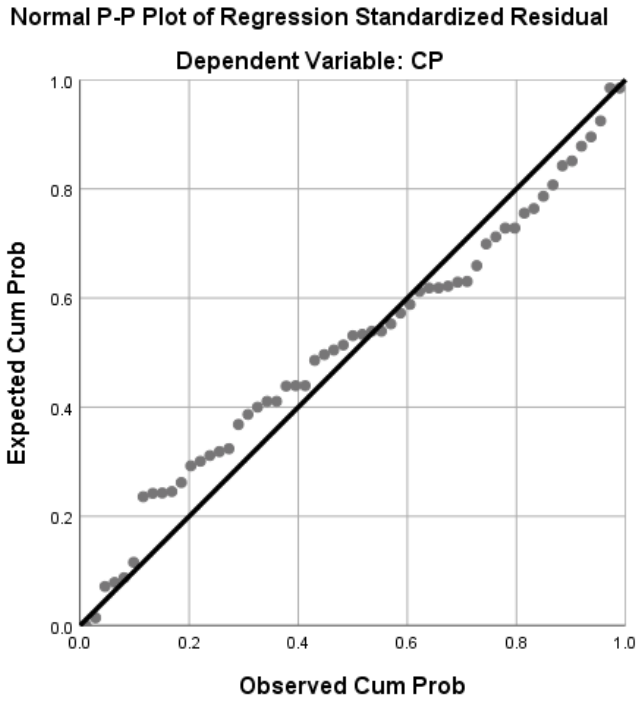
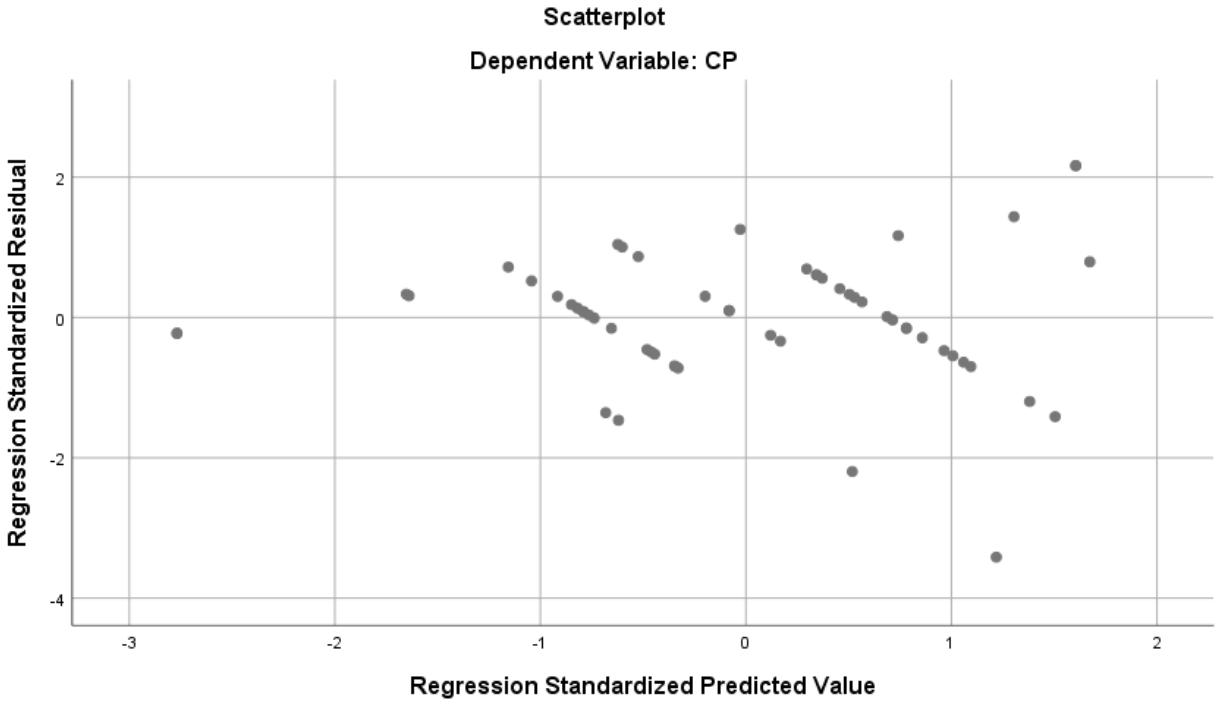
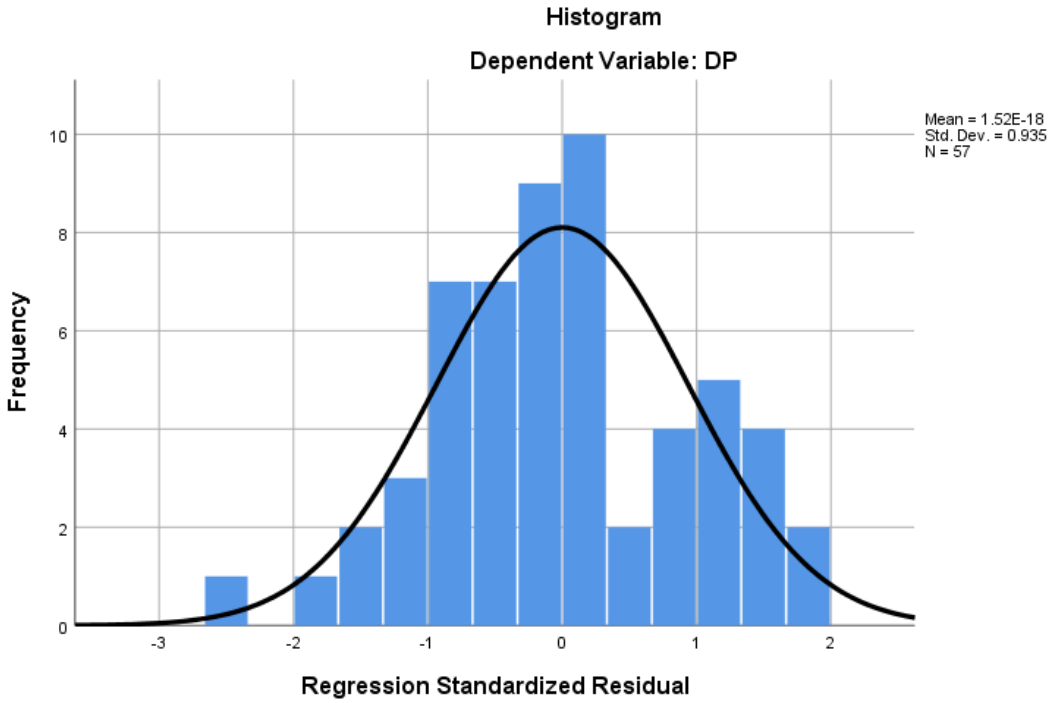
15
10
5
0
-4
-2
0
2


Normal P-P Plot of Regression Standardized Residual
Dependent Variable: CP
Expected Cum Prob
Observed Cum Prob
0.0
0.2
0.4
0.6
0.8
1.0


Scatterplot
Dependent Variable: CP
Regression Standardized Residual
Regression Standardized Predicted Value
2
0
-2
-4
-3
-2
-1
0
1
2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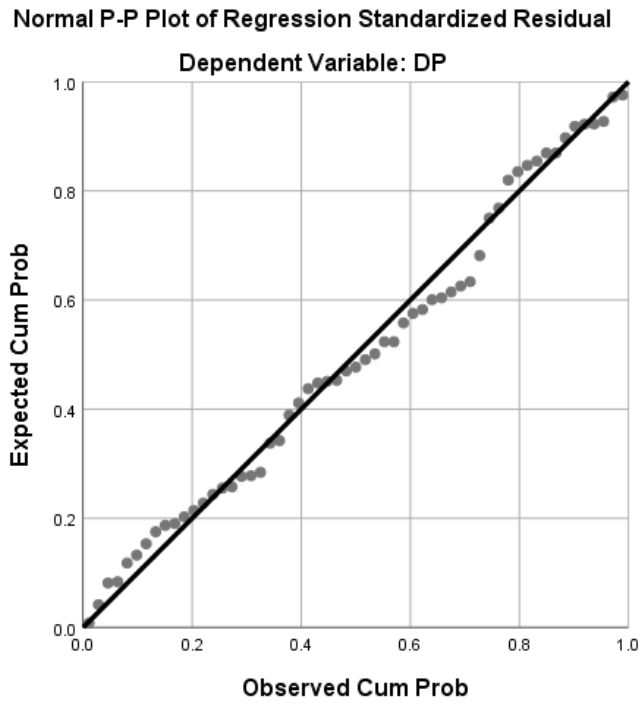
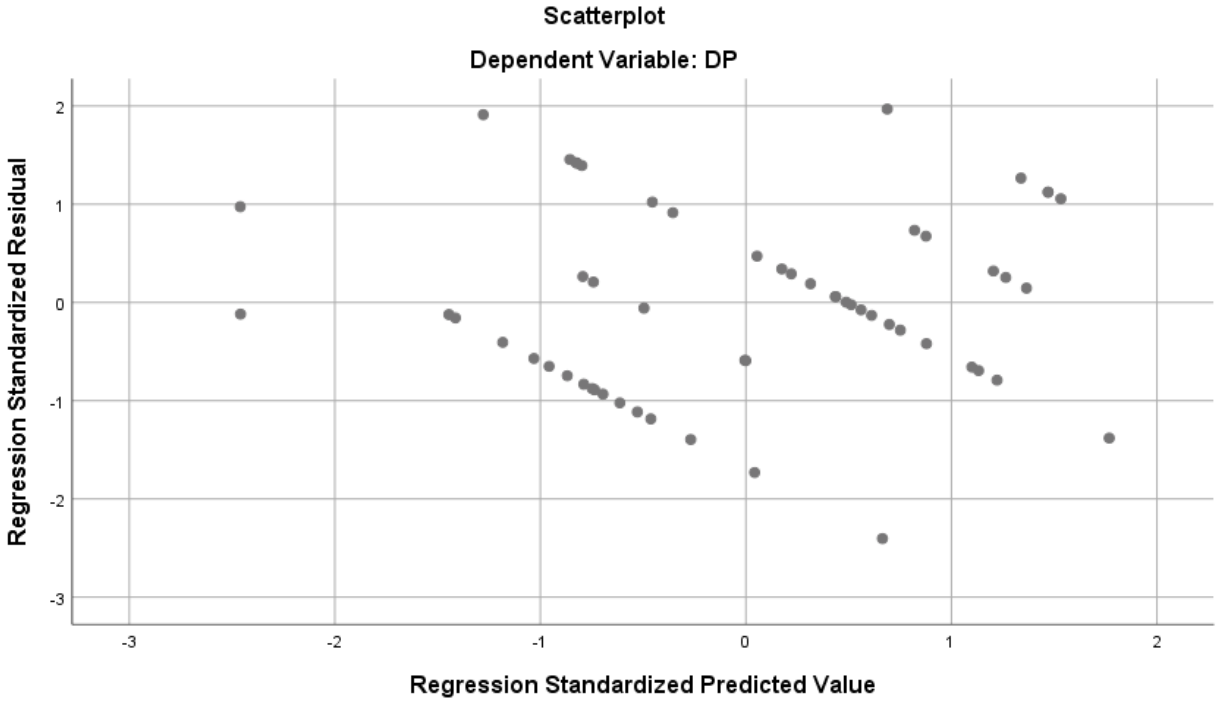
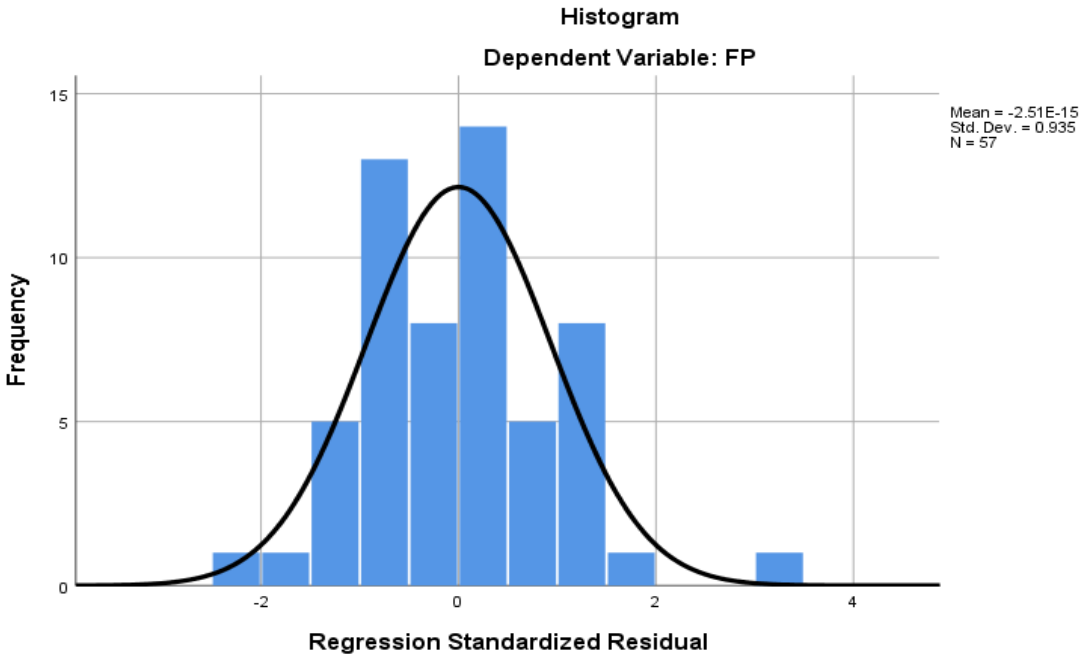
N = 57
Frequency
Regression Standardized Residual


Normal P-P Plot of Regression Standardized Residual
Dependent Variable: DP
Expected Cum Prob
Observed Cum Prob


Scatterplot
Dependent Variable: DP
Regression Standardized Residual
Regression Standardized Predicted Value
2
1
0
-1
-2
-3
-3
-2
-1
0
1
2


Histogram
Dependent Variable: FP
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Std. Dev. = 0.935
N = 57
Frequency
Regression Standardized Residual
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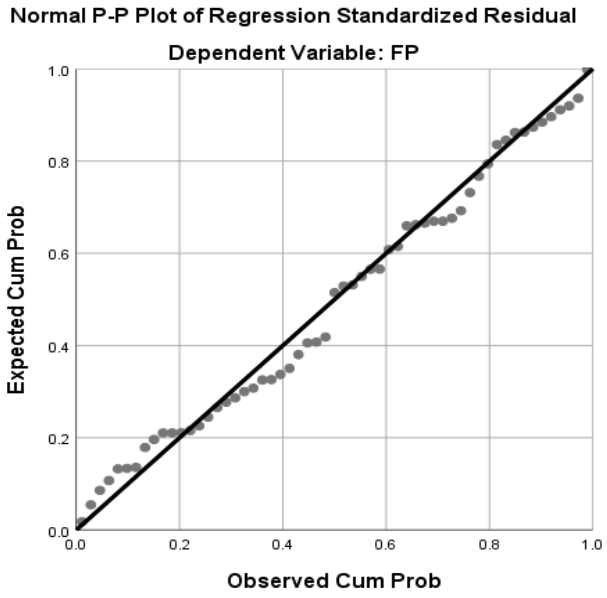
10
5
0
-2
0
2
4


Normal P-P Plot of Regression Standardized Residual
Dependent Variable: FP
Expected Cum Prob
Observed Cum Prob
0.0
0.2
0.4
0.6
0.8
1.0

Appendix 2: Questionnaire

ADDIS ABABA UNIVERSITY
COLLEGE OF BUSINESS AND ECONOMICS

RESEARCH PROJECT QUESTIONNAIRE FOR FULFILLMENT OF MBA

Dear Respondents,

Thank you for participating in this study

INTRODUCTION

The purpose of this survey is to determine how manufacturing practices such as Total Quality Management (TQM), influence the operational performance of Ethiopian Pharmaceutical industries. Your response will help to understand the extent of these practices being effectively practiced in the Ethiopian pharmaceutical manufacturing sector. In addition, this study aims to improve the company's competitive advantage and to sustain an advanced competitive strategy for the long run.

Dear Participants, this study is purely for academic purpose and for partial fulfillment of the requirements for the Degree of Masters of Business Administration (MBA) in Addis Ababa University. All responses will be kept confidential and will not be traceable to individual respondent.

For the successful accomplishment of the research, your genuine response will have an important role and the responses will be used as a valuable and primary input for the study. For this reason, you are kindly requested to spare few minutes of your busy schedule and genuinely fill this questionnaire.

If you have any question or enquiry, please don't hesitate to contact me at any time through the following address:

Shegaw Aderaw
MBA candidate, Addis Ababa University, College of Business & Economics, Addis Ababa
Tel: 0911649558
E mail: She_gaw@yahoo.com

I. GENERAL INFORMATION

Please provide us with some basic information about the company and yourself.

1. Please indicate your company ownership:

- ☐ Ethiopian owned
- ☐ Foreign owned (please indicate the country of origin): .....
- ☐ Joint Venture (please indicate the countries of origin): .....
- ☐ Others (please specify): .....

2. Age of company's establishment in Ethiopia (please specify):

- ☐ Less than 5 years
- ☐ Between 5 to 10 years
- ☐ More than 10 years

3. Number of full-time employees:

- ☐ Less than 75 workers
- ☐ Between 75 to 200 workers
- ☐ More than 200 workers

4. Please indicate your designation in the company:

- ☐ General Manager/ Managing director or above
- ☐ Plant Manger
- ☐ Quality Assurance/Control Manager
- ☐ Production Manager
- ☐ Senior executive
- ☐ Expert/Technician
- ☐ Other (please specify): .....

5. Number of years of experiences in your current job position:

- ☐ Less than 5 years
- ☐ Between 5 to 10 years
- ☐ More than 10 years

6. Please indicate your highest Educational Level:

☐ Diploma ☐ Bachelor Degree ☐ Master Degree ☐ PhD Degree

7. Has your company obtained a local or an International Quality award?

☐ Yes ☐ No

8. Is your company planning to obtain international quality certificates in short term?

☐ Yes ☐ No

II. TQM PRACTICES

Direction:

This section of questionnaire focuses on manufacturing practices implemented in the company. On the following scale, please tick (√) the appropriate number under the space provided that best represents your opinion.

Strongly disagree	Disagree	Neutral	Agree	Strongly Agree
1	2	3	4	5

Top Management Support	1	2	3	4	5
1. Top Management are actively involved in establishing and communicating the organization's vision ,goals, plan and values for quality program					
2. All Major department heads within our plant accept their responsibility for quality					
3. Top management provides personal leadership for quality products and quality improvement					
4. Top management is personally involved in quality improvement projects					
5. Top management strongly encourages employee involvement in the production process					
6. Top Management is evaluated in quality performance					
Process Management	1	2	3	4	5
7. Our process are well designed in order to minimize the chance of employee error					
8. We give clear, comprehensive, and standardized documentation about work methods and process instructions to employees					
9. We make extensive use of statistical techniques to reduce variance in processes					
10. We continually use internal or external audits to make sure we deliver quality products and services					
11. We monitor our processes using statistical process control.					
12. Corrective action is taken immediately when a Product or process quality problem is identified					
13. Key processes are identified & systematically improved to achieve better product or process quality					
People Management	1	2	3	4	5
14. We constantly ensure that employees are aware of quality issues in our company					
15. Promotions and Career development programs emphasize quality management in the organization					
16. Training programs are developed and implemented					
17. We have effective open communication in three directions: up ,down & across					
18. Employees participate in quality improvement activities					

19. The company uses a team approach that entails idea generation, alternative evaluation and consensus building to solve problems					
20. Employee satisfaction is formally and regularly measured.					
21. Employee flexibility, multi-skilling and training are actively used					
22. We have a transparent and effective appraisal system for recognizing and rewarding employees for their efforts					
Continuous Improvement	1	2	3	4	5
23. We emphasize the continuous improvement of quality in all work processes					
24. Our company uses PDCA (plan-do-check-act) cycle extensively for process control and improvement					
25. We frequently measure the product quality					
26. Our firm has an effective performance measurement system to track overall organizational performance					
27. We systematically benchmarking other companies to improve a systems or subsystems and implement & monitor programs					
Supplier Quality Management	1	2	3	4	5
28. Our company has established a long term co-operation with our suppliers					
29. Our company regards product quality as the most important factor for selecting suppliers					
30. Our company always participated in suppliers activities related to quality					
31. Our company always gives feedback on performance of suppliers' products					
32. Our key suppliers provide input into our product development projects					
33. Our suppliers are certified, or qualified for quality					
34. Our company regularly conducts supplier quality audit					
Customer Focus	1	2	3	4	5
35. Products or service designs are based on meeting the needs of the customer					
36. We frequently are in close contact with our customers					
37. We actively and regularly seek customer inputs to identify their needs and expectations					
38. A complaints process and guidelines are established, complaints are properly recorded					
39. Our customers give us feedback on quality and delivery performance					
40. We measure customer satisfaction systematically and regularly					
41. Customer complaints are used as input to improve our processes					
42. We inform customers' current and future needs and expectations to our employees effectively					

Product Design	1	2	3	4	5
43. Direct labor employees are involved to a great extent (on teams or consulted) before introducing new products or making product changes					
44. We work in teams, with members from a variety of areas (Research & development, marketing, production, engineering etc.) to introduce new products					
45. The customer requirements are thoroughly considered in new product design					
46. New product designs are thoroughly reviewed before the product is produced & sold					
47. Manufacturing engineers, process engineers and technical experts are involved to a great extent before the introduction of new product.					
48. Utilization of quality designing techniques in new product development					

III. Operational performance measures

Please tick (√) the number which indicates your opinion about the level of operational performance in your company in the last 3 years;

Strongly disagree	**Disagree**	**Neutral**	**Agree**	**Strongly Agree**
1	2	3	4	5

Quality	1	2	3	4	5
49. Improve high performance product features					
50. Offer consistence and reliable product quality					
51. Improve conformance to product specification					
Cost	1	2	3	4	5
52. Reduce inventory					
53. Increase capacity utilization					
54. Reduce production costs					
55. Increase labor productivity					
Delivery performance	1	2	3	4	5
56. Improve fast delivery					
57. Improve delivery on time					
58. Reduce production lead time					
Flexibility to change volume	1	2	3	4	5
59.Make rapid volume changes					
60. Adjust capacity quickly					
61. Adjust product mix quickly					

Thank you for your participation and the time contribution in answering the survey questionnaire. All responses will be treated with **utmost confidentiality** and no single set of responses will be readily identifiable.

Comments (optional):

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THANK YOU FOR YOUR PARTICIPATION

Appendix 3: List of Surveyed Companies

1. Ethiopian Pharmaceutical Manufacturing Company (Epharm)
2. Addis Pharmaceuticals Factory plc. (APF)
3. Addis Pharmaceuticals Factory plc.: Large Volume Parenteral Factory
4. Cadila Pharmaceuticals (Ethiopia) plc.
5. East Africa Pharmaceuticals Plc.
6. Sino-Ethiop Associate (Africa) plc.
7. National Veterinary Institute—Vaccine Factory
8. Fawes Pharmaceutical plc.
9. Pharmacure Plc.
10. Medsol Pharmaceuticals plc.
11. SANSHENG pharmaceuticals plc.(Ethiopia)
12. Human well pharmaceuticals (Ethiopia) plc.
13. Julphar pharmaceuticals (Ethiopia) plc.