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The Factors affecting quality assurance of pharmaceutical distributors in Nairobi County

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**THE FACTORS AFFECTING QUALITY ASSURANCE OF PHARMACEUTICAL
DISTRIBUTORS IN NAIROBI COUNTY**

PERIS KIBANDI
MBA/ 99733/17

Dissertation Submitted to Strathmore Business School in the partial fulfillment of the requirements for the award of a Master of Business Administration (MBA) Degree



JUNE, 2019

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I, Peris Wanjiku Kibandi declare that this research study is my original work and has not been submitted prior or approved by any University or Institution of learning for the award of a degree. To the best of my knowledge and belief, the dissertation contains no material that have been previously published or written by any other person except where due reference has been made in the dissertation itself.

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ABSTRACT

Quality assurance of pharmaceutical distributors is essential in the pharmaceutical product handling from the manufacturer to the patient as the end user. The Health Authority being the Pharmacy and Poisons Board has been instrumental in ensuring that the pharmaceutical distributor is well regulated through issuance of licenses for operation after an assessment. However, the distribution system in Kenya remains exposed to the risk of poor-quality medicines if the quality assurance is not observed or maintained. The study sought to determine the factors affecting quality assurance of pharmaceutical distributors in the county of Nairobi. The specific objectives were to determine the role of management commitment, customer focus and continuous improvement on quality assurance of pharmaceutical distributors in Nairobi County. A descriptive research design was adopted and the targeted population was the quality assurance managers of the 186 registered pharmaceutical distributors in Nairobi County. The analyst utilized a stratified random sampling strategy to come up with 74 respondents, which constituted the sample size. The research utilized primary data in form of questionnaires and comprised of both close and open-ended questions. The research chose 18 persons as the pilot group from the population of target. Analysis of data was carried out by employing Microsoft Excel and SPSS by the use of means, percentages and frequencies. A multivariate regression model assisted in establishing the relationship amongst the studied factors. In Conclusion, the pharmaceutical distributors had codes of practice in place regarding employees involved in the distribution of pharmaceutical products and budget for quality assurance aspects. The pharmaceutical distributors had enhanced customer satisfaction through timely delivery of customer products and responding to product quality defects. The pharmaceutical distributors had made innovations and improvements to their facilities and processes to ensure quality assurance was achieved. More funds should be allocated towards enhancing management commitment as a recommendation. Pharmaceutical distributors should continue ensuring customer satisfaction through timely delivery of customer products, timely response to customer complaints, offering quality services and quick response to product quality defects. Pharmaceutical distributors should improve the quality assurance by allocating more funds, developing well elaborate procedures, automation of processes, putting in place checks and balances and implementing recommendations of the Pharmacy and Poisons Board.

Key words: Quality Assurance, Distribution system, Pharmaceutical Distributors, Pharmacy and Poisons Board

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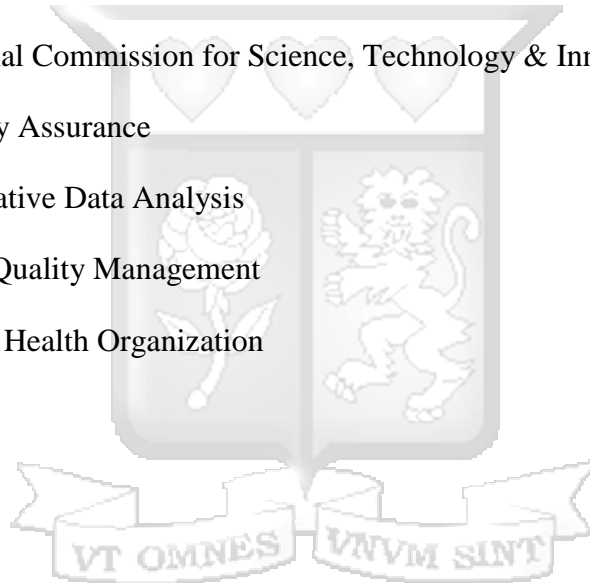
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LIST OF ABBREVIATIONS

GMP	Good Manufacturing Practices
GMP	Good Manufacturing Practices
GSK	GlaxoSmithKline
KEMSA	Kenya Medical Supplies Authority
KPPB	Kenya Pharmacy and Poisons Board
KPPB	Kenya Pharmacy and Poisons Board
MC	Management Commitment
NACOSTI	National Commission for Science, Technology & Innovation
QA	Quality Assurance
QDA	Qualitative Data Analysis
TQM	Total Quality Management
WHO	World Health Organization

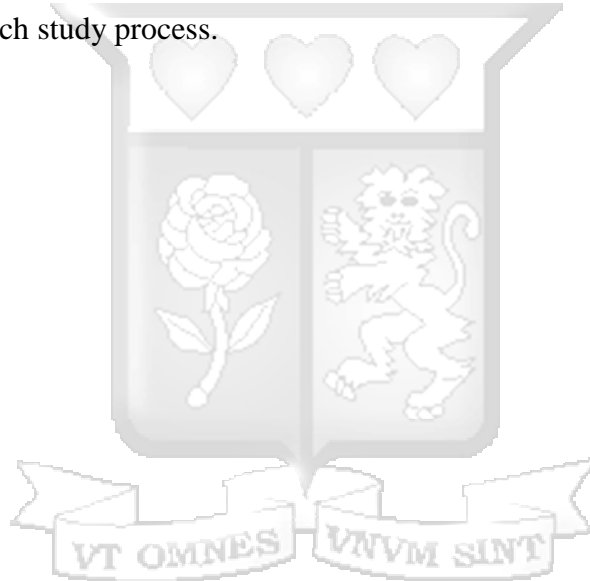


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DEDICATION

I dedicate this work to my loving parents, Eng. Peter Kibandi Ngugi and Florence Wamburu Ngugi including my siblings Anthony Ngugi, Charles Kibandi and Maureen Kibandi. As well as my good friends- Sheila Onyango and Joseph Boro. Thank you all for the full time support during my MBA program.



CHAPTER ONE: INTRODUCTION

1.1 Introduction

The overriding theme of this study is establishing factors affecting quality assurance of pharmaceutical distributors in Nairobi County. This chapter outlines the background to the study, definition of the problem, objectives of this research, research questions, scope of the research study and significance of this study.

1.2 Background to the Study

Clients are becoming more aware of the increasing standards in the quality of pharmaceutical products, having exposure to a broad range of alternatives. There happens to be an ever rising quality demand on services or products where the international revolution makes firms to make investments in resources that are substantial in implementation of whole quality management (Joshi and Shekhar in 2011). To better a firm's competitiveness, firms are searching for top level success in all processes and functions and the firms happen to be making quality assurance an approach to sustain themselves in the business (Christos & Evangelos, 2010). Dale in 2010 accentuated that constant advancement in overall activities of a business with the target on a client accentuates on the quality and the flexibility through which firms encounter threat are competitive. That is the reason the management, quality and linked constant improvement happen to be searched by a big number of firms as a way of surviving and maintaining competitiveness over competitors (Ustadh, 2012).

Quality is achieved when customers implied and articulated needs are met fully. This statement happens to be core from where other well-known quality definitions are obtained. They consist: the entirety of characteristics and attributes of a service or a product which stands on its potential in meeting an implied or articulated want, conforming to the need and suitability for usage (Sharma & Kodali, 2008). Its key to point out that meeting the expectations and the wants of a client is the major element in every of the descriptions. Thus, it is vital for a firm to recognize such like wants in advance in the service or the product cycle of development. The potential to accurately describe the wants associated with design, delivery, performance, safety, price and some more business operations will put an organization above their rivals in the same market. Quality happens to be an integrated system of strategy aimed at attaining the

satisfaction of clients, which consists of employees and their managers and applied quantitative approaches to consistently improve the processes of an organization (Ugboro & Obeng, 2010).

World Health Organization (WHO) describes QA as being a widespread idea sheltering all concerns, which collectively or individually affect the product's quality. It is the total sum of every plan with a goal to make sure of quality pharmaceutical products as needed for the desired use. QA thus adopts Good Manufacturing Practices (GMP) as well as other components, counting the ones that are not within this scope like product development and designing (WHO, 2017). Concerning the pharmaceuticals, QA could be categorized into 4 main areas; quality production, control, inspections and distribution. The guidelines, norms and standards development to enhance QA is a key section of the constitution of WHO and is supported and endorsed by many resolutions of World Health Assembly. Making sure that manufacturing, packaging, storing of pharmaceuticals in an environment that is not contaminated is a key necessity in the process of QA. The World Health Assembly incorporated numerous solutions and most currently in the Medicines Strategy of WHO from 2008 to 2013 requiring the firm to establish global standards, instruments and recommendations to guarantee the medicine's quality whether nationally or globally produced and sold (WHO, 2017).

WHO describes best practices of distribution as being a portion of QA which makes sure that pharmaceutical product's quality is paid attention to within sufficient ways of sufficient control of many operations happening in the course of the process of distribution and also offering an instrument to keep safe the system of distribution from unapproved, unlawfully imported, counterfeit, misbranded, adulterated and substandard products (WHO, 2017). WHO pointed out that pharmaceutical products that are counterfeit exist and are a threat to the health and the safety of the public. Therefore, it is key to guard the chain of supply of the pharmaceutical products to prevent entry of those bad products into the market. Weak distribution points of the products aid for entrance of counterfeit, stolen, unlawfully imported as well as substandard pharmaceutical products in the chain of supply through which those products are entering the chain of supply happen to increase day by day and results to establishment of successful grey and secondary markets in the entire world. The participation of entities that do not have authority to sell and distribute pharmaceutical products happens to be a major concern. Just a

mutual methodology consisting all players comprised in the chain of supply may be effective in the war against pharmaceutical products that are counterfeit and, thus, all players who are acting in that market are supposed to play actively in cooperative activities (WHO, 2015).

WHO recommends that every player concerned in distributing the pharmaceutical products is responsible of ensuring maintenance of integrity in the chain of distribution as well as distributing quality products. National legislation is supposed to be in place to control the operations of firms or persons partaking in the distribution of pharmaceutical products. All workers that are in the activity of distribution are supposed to be qualified and well trained on the needs of best practices of distribution. Rules are supposed to enhance a secure, transparent and safe system of distribution that comprises traceability of products in the whole chain of supply. There is supposed to be best practices in the storing and distribution of pharmaceutical products. The storing and distribution of Pharmaceutical products is supposed to be shipped in containers that have no hostile impacts on product quality. Selling and distribution of Pharmaceutical products is supposed to be done by authorized individuals or firms to get those products (WHO, 2015).

The Kenyan Pharmaceutical sector comprises of 4 sections namely retailers, hospitals, distributors and the manufacturers, that play a key function to support the sector of health in the nation. The Kenyan Pharmaceutical sector is mainly by Distributor Imports although there are local manufacturing sites. Asoko Visions has recognized forty-five registered manufacturers on pharmaceutical manufacturers by KPPB (Kenya Pharmacy and Poisons Board, 2017). Kenya has a substantial number of multinationals such as Astra Zeneca, GlaxoSmithKline and Novartis amongst others who import pharmaceutical products into the market. Amongst the top local manufacturers are Lab & Allied Limited, Universal Corporation Limited, Dawa Limited and Cosmos Limited. In 2016, there were 186 registered pharmaceutical distributors and approximately 700 registered wholesalers in Kenya, operated by pharmaceutical technologists and pharmacists who are registered, based on the medical directory Kenya Pharm Tech. The biggest distributor of the pharmaceutical products happens to be Kenya Medical Supplies Authority (Kenya Pharmacy and Poisons Board, 2017).

Pharmaceutical distributors therefore, mainly stock products from local manufacturers such as Cosmos, Regal, Beta Ltd and/or import from generic manufacturers such Getz Pharma, Cipla,

Intas and/or original/ branded manufacturers/ multinationals such as Novartis, Roche, Astra Zeneca, GSK. The Distributors store and distribute pharmaceutical products as per the Good Storage Practices and Good Distribution Practices as dictated by the WHO guidelines on Good Manufacturing Practices. Essentially the WHO Guidelines provides standards to ensure product integrity from the manufacturer right to the pharmacy level before the patient who in this case is the end user is prescribed the drug. WHO Guidelines therefore, has the GxP practices which guides handling of pharmaceutical products. The x can be replaced with M in case of manufacturing such that it becomes GMP- Good Manufacturing Practices which included Good Storage Practices and Good Distribution Practices Authority (Kenya Pharmacy and Poisons Board, 2017).

As a requirement by the KPPB, the Pharmaceutical Distributors should be licensed in order to operate. Before obtaining the license, the company should be assessed/ inspected by a member of KPPB to ascertain that they meet the minimum required standards of maintaining product integrity during storage and distribution of pharmaceutical products. The same assessment is also performed by branded companies such as Novartis before a commercial contract or agreement is signed in order to supply their pharmaceutical products. Quality Assurance is therefore essential from a Health Authority and Multinational perspective (Kenya Pharmacy and Poisons Board, 2017).

The Pharmacy and Poisons Board is committed to its mission to ensure the availability of pharmaceutical services in Kenya which satisfy the needs of all for the prevention, diagnosis and treatment of diseases using safe, efficacious, high quality and cost-effective pharmaceutical products. Pursuant to this mission, it is imperative that pharmaceuticals are distributed by highly qualified personnel through outlets that are duly licensed and professionally run. The operations in those premises should at all times be supervised by qualified personnel and the risk of exposing the public to unsafe medicines avoided at all cost. Guidelines have been prepared to provide distributors of pharmaceutical fraternity with a method of assessing eligibility and the process of lawfully operating drug distribution outlets (Kenya Pharmacy and Poisons Board, 2017).

1.3 Problem Definition

Quality assurance of pharmaceutical distributors is essential in the pharmaceutical product handling from the manufacturer to the patient as the end user. However, the distribution system in Kenya remains exposed to the risk of poor-quality medicines if the quality assurance is not observed or maintained (Wangai, 2015). The major distributors in Kenya such as Kenya Medical Supplies Authority (KEMSA) employ good distribution practices to enhance quality assurance of their products. Lack of quality assurance implementation amongst Pharmaceutical Distributors may lead to poor-quality medicines in the market. The pharmaceutical distributors rarely use a strict criterion in the selection of suppliers and products. Thus, product quality may not be reliably assured as it depends on the requirements of suppliers (Kenya Pharmacy and Poisons Board, 2017).

The suppliers perform QA audits according to certain aspects that need to be implemented such as capital intensive items: refrigeration, generators as power back up, temperature mapping, installation of Air Conditioning units to maintain temperature in the warehouse, owning refrigerated vehicles, monitoring temperature of products to the customer during transport etc but these quality aspects do not directly translate to a return on investment as the generic companies and local manufacturers do not perform QA audits on the same distributors who equally store and distribute their products. These Quality aspects are emphasized by multinationals before they accept to supply the distributor with their products for sale (Wangai, 2015).

Enhancement of quality assurance in the pharmaceutical drug distribution system could translate into return on its investment and customer satisfaction. Ndjama (2012) studied quality assurance and issues of safety of the pharmaceutical products advertised in developing nations and noted that the distribution of medicines that are substandard continues to be a critical problem in Africa's Sub-Saharan region whereby numerous drugs accessible happen to be imported. Locally, Cheroigin (2014) focused on total quality management and performance of multinational pharmaceutical firms in Nairobi, Kenya and it was noted that if TQM is well implemented it can meet the customers' needs, improve internal communication and better problem-solving capacity of the firm. The above studies focused on the total quality management which is different from quality assurance thus our study was different as it

focused on the factors affecting quality assurance in pharmaceutical distributors in Nairobi so as to fill the gap.

1.4 Research objectives

1.4.1 General Objective

The general objective of the study was to determine the factors affecting quality assurance of pharmaceutical distributors in the county of Nairobi.

1.4.2 Specific Objective

The following objectives of this research guided the study:

- i. To determine the role of management commitment on quality assurance of pharmaceutical distributors in Nairobi County.
- ii. To evaluate the effect of customer focus on quality assurance of pharmaceutical distributors in Nairobi County.
- iii. To assess the effect of continuous improvement on quality assurance of pharmaceutical distributors in Nairobi County.

1.5 Research Questions

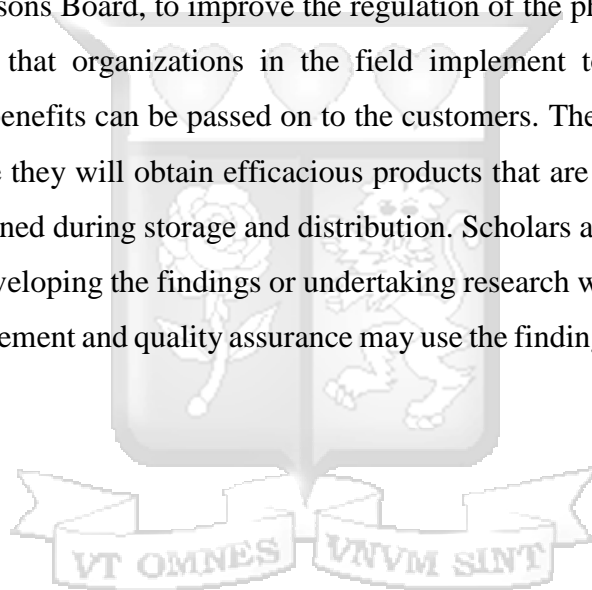
- i. What is the effect of management commitment on quality assurance of pharmaceutical distributors in Nairobi County?
- ii. To what extent does customer focus affect quality assurance of pharmaceutical distributors in Nairobi County?
- iii. What is the effect of continuous improvement on quality assurance of pharmaceutical distributors in Nairobi County?

1.6 Scope of the study

This study focused on the factors affecting quality assurance in pharmaceutical distributors in Nairobi County. The primary data was collected from the quality assurance managers of the 186 registered pharmaceutical distributors in Nairobi County and the study covered a period of five months.

1.7 Significance of the study

The study may have significant value for policy makers and development partners who lend a hand in the growth of distribution pharmaceutical companies. Regarding, total quality management and quality assurance, policies and regulations can be implemented to boost and stimulate both factors. The study sets to benefit the owners and managers of distribution pharmaceutical companies as they may appreciate the benefit of adopting various total quality management practices that may enable them improve the quality assurance of their processes. This may enable them continuously improve their products quality and standards in order to meet customers' expectations and thus enhance their competitiveness. The study maybe used by Pharmacy and Poisons Board, to improve the regulation of the pharmaceutical distributing industry in ensuring that organizations in the field implement total quality management practices so that the benefits can be passed on to the customers. The patients will also benefit as the end users since they will obtain efficacious products that are safe in that the quality of the product is maintained during storage and distribution. Scholars and researchers who might have an interest in developing the findings or undertaking research work in other related fields of total quality management and quality assurance may use the findings of this study as a source of reference.



CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

This chapter looks at the literature that focuses on factors affecting quality assurance in pharmaceutical distributors in Nairobi County. It also entails conceptual framework and theoretical framework. The empirical review also addresses on the different studies conducted under this field.

2.2 Theoretical Review

The section discusses and explains the role of total quality management on quality assurance of pharmaceutical distributors in Kenya. The theories discussed are the theory of Quality Improvement, Constraints theory and Resource-Based View.

2.2.1 Quality Improvement Theory

This theory suggests that a component of quality management places duty concerning fabricating associations decisively at the door of the highest administration (Deming, 1986). This hypothesis gives an expression that an administration is in charge of the frameworks, and the framework yields 80% of the firm issues (Hill & Wilkinson 1995). Deming in 1986 identified there would be no essence of quality framework of the administration in absence of duty of the highest; the administration places procedures on resources, makes corporate culture, chooses providers and grows long haul connections. Deming's theory of Quality Improvement gives enterprises a plan of taking out low issues on quality control by effective systems of administration.

Hubert in 2000 brought forward the theoretical approach by Deming in 1986 regarding substantial administration framework and it envisages production of a hierarchical framework which encourages taking part and thinking of ways of encouraging the process implementation that the administration rehearses. This, therefore, encourages the determined change in items, procedures as well as administration effects on the fulfilment of a worker. These happen to be typical to bettering the center of clients and then aiding in existence of associations. The hypothetical quintessence of the theory on Quality Improvement paid attention in the worries of quality in coming up with an influential framework that encourages learning and

participation for heartening the use of process administration rehearses, that, thus, encourages implementation (Anderson, Daly & Johnson, 1994). Oakland (2004) focused on that obligations of highest administration ought to control the pack in the frameworks and procedures of changes. Administration shoulders a critical section in assuring the achievement of value administration because the highest administration's duty of making and imparting the dream to move the entity toward change execution. The quality improvement theory advocates that for there to be quality assurance there must be continuous improvement of the processes and distribution systems in the organization and thus supports the objective of the study on the role of management commitment and continuous improvement on quality assurance of pharmaceutical distributors in Nairobi County.

2.2.2 Resource-Based View

This emphasizes on the assets of the association as being the important determining factors of implementation and competitive advantage. It incorporates 2 beliefs in flouting down competitive advantage (Barney in 2001). The model agrees that firms within an industry could be heterogeneous concerning assets controlled by the firm. Secondly, it agrees that heterogeneity of assets can hold on after a duration on the basis that assets applied in executing schemes of a firm happen not to be mobile across organizations. Asset heterogeneity is viewed as an important condition for an asset package to add to competitive advantage. The Resource-Based View Theory is to a great extent in light of behavioral and sociological worldview and considers organizational variables and their fit with the world as the significant determinants of progress (Barney, 2001).

Because assets reflect various capable components, this research similarly focuses on ramifications of performance of other internal characteristics of firms (Barney, 2001), for this instance organization's capacities, tireless change and customer centeredness. Dissimilarly, the typical argument of this theory is the fact that non-substitutable, matchless and uncommon assets brings about a firm's heterogeneity, and the fact that productive entities happen to be the ones that obtain and shield important and incredible assets to miss which result to a firms decent implementation resulting from the sustainable upper hand which develops (DiMaggio and Powell, 1991). The readiness of a firm discovers the kind of value frameworks to be searched for, because the assets which a certain association possesses will greatly affect the

functions or non-functions of the entity. The main objective of RBV stems from generating competitive advantage that enables companies to obtain quality assurance levels based upon their respective combination of resources and capacities which focuses on the need of the customers and thus supports the objective of the study on the effect of customer focus on quality assurance of pharmaceutical distributors in Nairobi County.

2.3 Empirical Literature

The section gives an insight on literature from previous scholars concerning the factors affecting quality assurance.

2.3.1 Management Commitment

Bhaskar, Sanjib and Abhishek (2016) focused on management commitment in pharmaceuticals in India. Purposive sampling was used and the self-administered questionnaire, semi-structured interviews and focus group discussion guide were used. It was noted that execution of a successful policy on quality assurance happens to be a key significant goal in the pharmaceutical sector. The concept of quality assurance and quality control together develops towards assuring the quality, effectiveness and safety of the pharmaceutical products. Therefore, quality happens to be a vital component towards the effectiveness of a firm in the recent world that may be attained by management commitment, a firm's methodology which aims at quality as being an over-arching objective, focused at mitigating effects as compared to detecting them.

Sudhanshu (2015) evaluated the impacts of management commitment on how Indian Pharmaceutical sectors performed. This survey got carried out through the issue of a self-designed questionnaire and distributed to choose Indian pharmaceutical firms. Management commitment operates as a shelter where everybody in a firm may work towards satisfaction of the needs of a client, cut down the wastage and expenses and raise services efficiency. It then was pointed out that the highest management leadership, commitment, quality management, customer focus, employee training and best relationships with the vendors and suppliers were discovered to be a major important element influencing execution of management commitment.

Adza (2016) focused on examining practices of management commitment on performance of an organization in Intravenous Infusions Limited Koforidua. Collection of primary data was carried out by the use of a structured and properly designed questionnaire that included close and open-end questions. The management commitment execution is at the level of quality assurance. It then got discovered that the indecisions of the management lowered the commitment of leadership towards quality and made practices of management commitment unsuccessful. A conclusion was then arrived at that there had a need to obtain modern tools for boosting production. Management should work at building trust between the members of staff to better the team work.

Monirei in 2016 focused on management commitment and organizational performance of manufacturing firms in Nairobi County. The research design used was descriptive and inferential statistics method. It was noted the effective execution of the substantial programs relied on the workers. If the industry of manufacturing could have more training, participating and empowering the workers it's quite probable to get more benefit over technique on quality management. Further implementation and adoption of other practices on quality management for instance ISO 9000 and contrast challenges and benefits of the practices of quality management.

2.3.2 Customer Focus

Sadik (2018) focused on the impact of customer focus on customer satisfaction (e-services) a descriptive research was undertaken and questionnaires were used as the instruments for the study. It was noted that implementation of customer focus would change the market and organizations in future. It would help in achieving organizational goals. It would also help the customers to achieve customer satisfaction and understanding. There would be management commitment of the employees with the organization. If all the system of the organization work in a quality management and in a systematic way then this all will ultimately result in better customer and supplier relationship.

Cheroigin (2014) examined customer focus an element of TQM and how multinational pharmaceutical companies based in Nairobi performed. This study incorporated a descriptive research design. Collection of data was done by the use of self-administered questionnaires. It got discovered that in the case where there was customer focus; it yields a number of benefits

like satisfying the wants of clients, advanced communication and increased capacity of the company to solve problems. It was also found that effectiveness of customer focus program rises where its execution is cascaded down the whole employee's cadre since it needs the improvement of the culture of corporates and infusion of fresh philosophy of business in the firm.

In determining customer focus and TQM and the performance of pharmaceutical manufacturing and distributing in terms of quality assurance in entities situated in Kenya, Wangai (2015) adopted a cross sectional survey and systematic random sampling method was used. The measures of performance were both financial and non-financial and included stock turns, equipment effectiveness, people productivity, delivery schedule achievement, value added per person and profitability. Data collected was analyzed by use of descriptive statistics using SPSS. The study found that customer focus greatly affected performance of pharmaceutical manufacturing and distribution firms in Kenya. Results established the existence of a positive association amongst customer focus and performance of Kenyan pharmaceutical distribution and manufacturing firms.

2.3.3 Continuous Improvement

Esin and Hilal (2014) focused on the effects of continuous improvement and performance of firms in Turkey where a cross-sectional survey methodology was used and the unit of the sample was at the plant level. It was noted that firms should give necessary continue to improve through offering training to all their employees so as to improve their proficiencies in their tasks. Effective continuous improvement in quality bring success for the firms. Employees' effective knowledge and learning capability will provide sustainability of quality management in the firm. Furthermore, learning organizations adapt rapidly to the changes and develop unique behavior, which distinguishes them from other firms and enables them to obtain better results. Quality does not begin in one department or function; it is the responsibility of the whole firm. Training should be given to all employees based on the results of the training needs assessment.

Kaziliunas (2010) focused on the effect of continuous improvement on quality assurance of firms in Malaysia, the study noted that success factors for continuous improvement of processes include top management improvement, improvement in reward systems, team,

motivational factors and education and training. The study findings deduced that there was a relationship between the values and requirements stated above, thus underpinning the quality assurance standard and organizations' strategic dimensions. The study concluded that education and training of employees is another way of providing employees with the knowledge and skills to meet their overall work and personal objective. If carried out consistently and reinforced in the workplace by real-time updating, education and training, it can form a solid base for continuous improvement and hence quality assurance.

Prajogo and Sohal (2014) conducted an empirical study on the multi-dimensionality of ISO practices in determining quality assurance of Australian firms. The basic proposition was whether ISO embodied two models of practices, mechanistic and organic, with each indicating a different impact in the association and with two different kinds of continuous improvement, on quality and on innovation. The researchers used some empirical data gathered from Australian firms and reported some evidence on the proposition upon pairing the mechanistic elements of ISO with quality assurance. The results of the implementation on Pearson Correlation Ratio had indicated that there were some positive and meaningful relationship between continuous improvement of ISO standard components and quality assurance.

2.4 Summary of Research Gap

From the evidence, many studies have been conducted on the effects of the factors affecting quality assurance but few have focused on the pharmaceutical distributors. Bhaskar, Sanjib and Abhishek (2016) focused on management commitment in pharmaceuticals in India and noted that execution of a successful policy on quality assurance happens to be a key significant goal in the pharmaceutical sector. This study was done in India which is a different context from Kenya in terms of development in technologies and innovations relating to the medical field. Monirei in 2016 focused on management commitment and organizational performance of manufacturing firms in Nairobi County and noted the organizational performance of the substantial programs relied on the management commitment. This study focused on manufacturing firms and it was broad in terms of organizational performance as quality assurance is a part of organizational performance.

Sadik (2018) focused on the impact of customer focus on customer satisfaction and noted that implementation of customer focus would also help the customers to achieve customer

satisfaction and understanding. The above study focused on customer satisfaction and customer focus while this study seeks to focus on the role of customer focus in enhancing quality assurance. Taking into consideration that quality assurance of pharmaceutical distributors is essential in the pharmaceutical product handling from the manufacturer to the patient as the end user in order to preserve product integrity. This study thus seeks to fill the gap that exist by focusing on the factors affecting quality assurance of pharmaceutical distributors in Nairobi County.

2.4 Conceptual Framework

This alludes to the level by which a research is able to conceptualize as relationship amongst contextual variables during the research and illustrates that relationship in a diagram or a graph. This relationship gives a description of the link between independent and the dependent variables.

Independent Variables

Dependent Variables

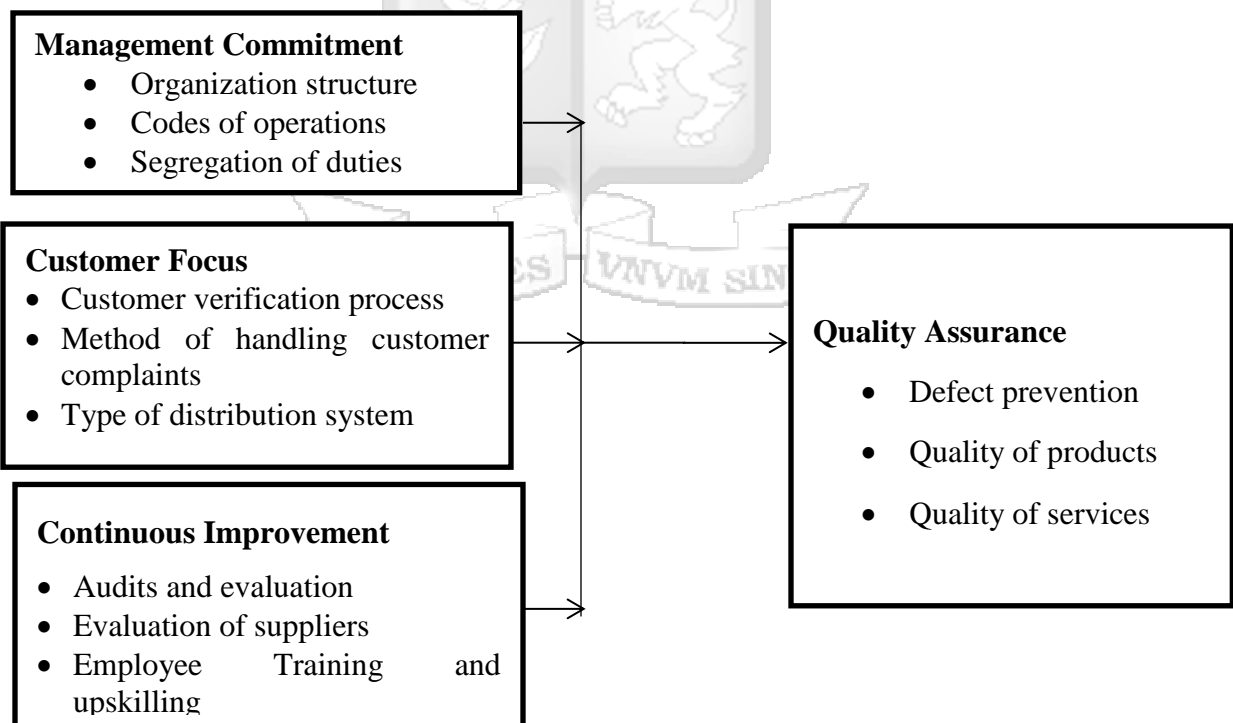


Figure 2.1: Conceptual Framework

Source: Author (2018)

2.4.1 Management Commitment

Management commitment for it to be successful change in the culture of an organization and this may only be attainable having a deep attention or participation of the management towards the strategy of the organization concerning constant advancements, coordination and transparent communication in the entire firm. Implementation of MC better the performance of a firm through the influence of other dimensions of MC (Kaynak in 2013). Evans and Lindsay in 2013 suggest that being successful in the promotion of success and efficiency of a business, MC should begin from the top, that is the CEO. Ellram and Cooper in 2013 regarded leadership being important towards implementing change in the organization most particularly in sectors of bettering the relations with the people who supply to them and the rest in the delivery chain. The leadership commitment of the strategy of MC as indicated in everyday work disposition is likely to take long to motivate workers to submit services of good quality which are beyond the clients' anticipation. Oakland in 2013 pointed out that MC implementation needs a transparent long-term commitment of leadership. Oakland in 2013 accentuated the management essence in offering a client targeted system of support like the recognition, measurements and awards for meeting clients with a goal to build a significant relation with clients.

2.4.2 Customer Focus

Happens to be a concept aimed at meeting the needs of clients. Therefore, a big number of firms will do their best to satisfy or even go beyond the expectation of clients in the root of their day to day operations and in the long-run (Andrle, 2014). TQM needs firms to grow a client targeted process of operations while obligating resources which position clients and satisfy their anticipation being an asset to the firm's betterment of their financial performance. Forza and Filippini in 2015 gave an explanation that its key for a firm to keep a close relation with the clients so as to be aware of what they need and evaluate how effective it has been in satisfying the needs of clients.

2.4.3 Continuous Improvement

This alludes to continuous assessment of administrative and technical processes while searching better approaches (Fuentes-Fuentes in 2014). TQM consists of the design in the production process, a constant improvement system. Oakland in 2013 suggested that the attention on constant betterment will result to quality assurance by information of a difficult team whereby membership is measured by their job on the comprehensive comprehension of the procedure, and their ability to take improvement action'. TQM has concerns in every production process, from planning levels and making decisions to work execution by the staff at the front line. The belief underlying constant betterment is typically the concept that errors may be mitigated and also having to prevent defects from occurring. Stahl in 2015, suggests that constant advancement alludes to constant improvement and refinement of the system of the organization, the services and goods of the firm to produce better value for clients. Then he outlined explained that the continuous look for ways in improving quality of product or service in the absence of customers complain may prevent a future problem. The constant process of improvement focuses on identifying and eliminating the roots of errors so as to curb them from occurring again.

2.4.4 Quality Assurance

Oakland in 2015 described quality assurance widely as avoidance of heavy problems by use of systematic and planned operations that involves documentation. This happens to be a belief underlying designing the production process of an enterprise with the goal to cut down the opportunities of yielding goods that are substandard. Cooper and Dale in 2014 suggest that quality assurance refers to a system that is prevention grounded that betters the quality of a service or a product with a rise in yields through accentuating on process redesigning, service and product. It stresses prevention of defects, as compared to quality controls that aims at detecting defects after production of an item. Quality assurance targets on preventing yielding of products that are non-consistent and places much stress on operations concerning the production process. Therefore, it is the design of the management focused on quality controls at every production stage to stop the emergence of superior problems. The philosophy of quality assurance ranted that creation of quality is done at the stage of designing, not at the stage of control and the fact that problems linked to quality are as a result of improper designing

process. Lockwood in 2016 suggests that quality assurance that is effective, should consist of establishment of a fresh approach and philosophy to operate which seems practical as compared to responsive, which involves motivation and participation of people in the course of the process from every department.



CHAPTER THREE: RESEARCH METHODOLOGY

3.1 Introduction

This research methodology chapter gives a description of the different methodologies applied in data collection, procedures incorporated in carrying out this study, the methods applied in analyzing and interpreting the collected data. Particularly, it identified the research design, population of target, the sample design, the instrument of collecting data, pilot testing and data analysis methods.

3.2 Research Design

A descriptive research design was adopted that aim at determining the factors affecting quality assurance in pharmaceutical distributors in Nairobi. It was preferred for this research because it allowed the analysis of various variables at a go and allowed the researcher to give a description of conditions, variables and situations (Erik & Marko, 2011). The method selected allowed the researcher give a general view of the outcomes to a larger population.

3.3 Population

Garg and Kothari in 2014 points out that population is a group of properly defined classes of elements, individuals, events, households or a set of things under investigation. This description makes sure that the targeted population is homogeneous. Conversely, the population of target is the particular population over which the information intended will be gained from (Kothari & Garg, 2014). The targeted population was the quality assurance managers of the 186 registered pharmaceutical distributors in Nairobi County. The quality assurance managers were selected based on their awareness of the quality practices and the standards used by the pharmaceutical distributors.

Table 3.1: Target Population

Population Category	Population Frequency	Percentage (%)
Local companies	80	43.0
Multinational companies	106	57.0
Total	186	100.0

3.4 Sampling

Marko and Erick (2011) states that sampling alludes the selection process of various individuals for the research in a manner that an individual mirrors a bigger group from where the individuals are selected. A sample alludes to a small class derived from the population available. Sampling method is the procedure used by a researcher in gathering things, places or people for study (Kombo & Tromp, 2006). As per Mugenda and Mugenda (2008) for descriptive studies 10% - 20% of the total target population is adequate for the study. A 40% sample of the total population is considered sufficient and was therefore used to come up with 74 respondents which constituted the sample from the target population of the 186 respondents.

The analyst utilized a stratified random sampling strategy since the study population is not homogenous and, in this way, it is conceivable to isolate this population into strata for inducing a sample that is representative. Marko and Erik in 2011, pointed out that stratified random sampling methods is preferred as they are able to give an estimate of the population under study with better precision and provides a sample which mirrors the population the most.

Table 3.2: Sample Size

Population Category	Sample Size	Percentage (%)
Local companies	32	43.0
Multinational companies	42	57.0
Total	74	100.0

3.5 Data Collection Methods

The research utilized primary data in form of questionnaires. Questionnaires in descriptive statistics need few resources (cost, time and staff) and are fit to best produce primary information (Cooper & Schindler, 2011). The researcher had a letter of introduction from Strathmore University to guarantee respondents confidentiality of the information provided and will only be applied for purposes of research when performing actual data collection. Administration of self-administered questionnaires was carried out by use of the drop and pick method. The researcher also used email and made phone calls to reach the respondents to ensure a high response rate.

The questionnaires comprised of both close and open-ended questions. Open-ended questions were employed in this research for purposes of enabling respondents respond to questions on their own terms. This also gave the researcher room to explore ideas that may not have been discussed, yet are important (Cooper & Schindler, 2011). The questions need to be well thought- out as well as contemplated from the respondent's side and may consume more time to provide answers (Cooper & Schindler, 2011).

Questions that were close-ended entailed mainly the likert scales and based on Schindler and Cooper in 2011, likert scales happen to very reliable and give increased data volumes as compared to the rest of the scales. They as well happen to be good in approximating the curve for normal curve of responses.

3.6 Pilot Test

The essence of pilot testing is establishing appropriateness and the accuracy of the instruments of research and the design. Schindler and Cooper (2011) agree that the essence of pilot testing is detecting the weaknesses existing in the design and incorporating and providing proxy for collection of data of a probability sample. The research conducted a pilot study to test the validity and reliability of the questionnaire. The research chose 18 persons as the pilot group from the population of target. Kothari in 2014 gave a recommendation that at least 10 per cent of the population in the pilot test is supposed to be represented therefore the selection of 18 persons is regarded as a representative pilot.

3.6.1 Reliability of Instruments

The methodology of Cronbach alpha, that is grounded on the internal consistency, was employed in measuring data reliability. Cronbach's alpha tests the mean of items measurable and their correlation. Total reliability of the scales of the current condition and the intended condition was measured by the Cronbach's alpha, that is supposed to be beyond 0.7 which is the level of reliability that is acceptable (Bryman & Bell, 2007).

3.6.2 Validity of Instruments

With regard to Johnson and Gill in 2008, validity refers to the level of representativeness of the items sampled to the content designed to be measured by the test. Content validity used in

this research is an examination of the level at which the collected data by use of specific instruments mirrors a specific content or domain of a specific concept. The pilot study allowed for familiarity of the study and the procedure of its administration and identification of items requiring modification. The outcomes assisted the research to find solution of inconsistencies resulting from instruments that ensured what is desired, is measured.

3.7 Data Analysis and Presentation

The collected data was both qualitative and quantitative. Descriptive statistics were used in analyzing the data both qualitatively and quantitatively. These consisted of median, modes, mode, percentages, tables and frequency distributions. Additionally, advance statistical approaches were taken into consideration (inferential statistics). Analysis of data was carried out by employing Microsoft Excel and SPSS by the use of means, percentages and frequencies. This produced quantitative reports. Tables were used in summarizing feedbacks for future analysis and enable comparison.

Qualitative data analysis (QDA) alludes to procedures and processes which are employed to do data analysis and give some degree of description, interpretation or understanding. Typically, qualitative data happens in a simultaneous manner with the collection of data. For qualitative analysis of data was carried out by the application of content analysis and presentation of outcomes in pros form. Content Analysis was used in the analysis and interpretation of behavioral or verbal data.

A multivariate regression model assisted in establishing the relationship amongst the studied factors. The study terms the method of regression as being important as a result of its potential in testing the kind of influence generated by the independent variables on dependent ones. Regression as well is capable of estimating the linear equation's coefficients, comprising one or many independent variables, that best estimates the dependent variable's value (Cooper & Schindler, 2011). The linear regression model was applied in assessment of the combined impact of 4 dependent and the independent variables.

The regression model was as follows:

$$Y = \beta_0 + \beta_1X_1 + \beta_2X_2 + \beta_3X_3 + \varepsilon$$

Where:

Y = Quality Assurance

X_1 = Management Commitment

X_2 = Customer Focus

X_3 = Continuous Improvement

β_0 = Constant Term; β_1 , β_2 and β_3 = Beta coefficients which was employed for measuring dependent variable's sensitivity (Y) to a change in a unit of predictor variables.

ε = Error term

3.8 Ethical Considerations

The consideration was offered to ethical concerns which might result in the course of addressing the objectives of the research. Participants' rights on handling the questionnaires were respected. Accuracy and Integrity of collection of data was observed while handling respondents and as well as in the analysis and reporting of outcomes. Ethics clearance was provided by the Strathmore Review Ethics Committee on the Informed consent form issued to participants ahead of responding to the questionnaires. Thereafter, consent was obtained from the Education ministry to collect data through National Commission for Science, Technology & Innovation (NACOSTI). There was guarantee of participants' confidentiality, Voluntary participation and anonymity.

3.9 Dissemination of Study Results

After finalizing the report, it was presented to Strathmore University where the thesis will be available on the Strathmore University online library portal. The thesis may assist other future researchers who wish to participate in the area of quality assurance get empirical data. The result findings were also given to the pharmaceutical distributors through email. Finally, it was published, printed and used as resource material for other researchers.

CHAPTER FOUR: PRESENTATION OF RESEARCH FINDINGS

4.1 Introduction

The chapter gives a presentation of research outcomes according to the set objectives. The presentation of analyzed data was done in tables.

4.1.1 Response Rate

The research focused on 74 individuals as the samples. Based on those 74 sampled, 64 participated in the research making a general rate of response of 86.5%. Table 4.3 gives a presentation of the rates of response.

Table 4.1: Response Rate

Response rate	Frequency	Percentage
Questionnaires Distributed	74	100%
Questionnaires completed	64	86.5%

4.2 Demographic Information

4.2.1 Age

The study requested respondents to give an indication of their categories of age that were as given below

Table 4.2: Age of Respondents

Age category	Frequency	Percent
Below 30 years	4	6.3
31-40 years	33	51.6
Above 40 years	27	42.2
Total	64	100.0

The outcomes reveal that a huge number of respondents (51.6%) were between 31 to 40 years, 42.2% were above 40 years of age while 6.3% were below 30 years. Based on Kothari (2014) it is important to have all ages represented in order to have an overall view of every generation in the place of work as age comes with experience.

4.2.2 Gender of the Respondents

The study sought the gender of the respondents. The findings are presented in Table 4.3

Table 4.3: Gender of the Respondents

Gender	Frequency	Percent
Male	37	57.8
Female	27	42.2
Total	64	100.0

The outcomes reveal that a number of respondents were male whereas 42.2% were female. The findings reveal that there was no gender bias. The above results would be due to there being a higher percentage of male pharmacists compared to female in Africa compared to a higher percentage of female pharmacists in the European and Eastern Mediterranean region. A higher percentage of male pharmacists is also seen in the Pan American region (Global Pharmacy Workforce and Migration Report, 2015).

4.2.3 Highest Level of Education

Table 4.4: Highest Level of education

Level of education	Frequency	Percent
Postgraduate	24	37.5
Degree	40	62.5
Total	64	100.0

The outcomes reveal that a number of respondents (62.5%) were degree holders while 37.5% were postgraduates. The findings imply that respondents were well educated to respond to the study questions regarding quality assurance. The level of education plays a significant role in enhancing the competence of employees. In Kenya, pharmacists are required to have a minimum of diploma (Kenya Pharmacy and Poisons Board, 2017). However, the pharmacists are in managerial roles thus important for them to have either a degree or be post graduate which confirms the above results.

4.2.4 Period Worked in The Organization

The research aimed at finding out the respondents experience in their organizations.

Table 4.5: Period Worked

Period	Frequency	Percent
Less than 5	8	12.5
5-10 years	38	59.4
Over 10 years	18	28.1
Total	64	100.0

The outcomes reveal that a number of respondents had worked in the facility for a period of 5-10 years, 28.1% for a duration above 10 years and 12.5% had an experience of below 5 years in the facility. The outcomes show that respondents had adequate experience in the respective organization to understand the status of quality assurance in their organization. Wangai (2015) noted that duration of existence in the pharmaceutical firm enhance the implementation of quality assurance. Employees who have been in operation for a longer period tend to gain greater benefits from understanding quality assurance practices.

4.3 Management Commitment and Quality Assurance

The study requested the respondents to indicate the challenges faced by the top management in enhancing the quality assurance of the products and services. From the findings, the respondents indicated that some employees are resistant, some employees lack the necessary skills, there are delays and shortages, financial constraints, poor implementation of the recommendations made and poor coordination within the management. The respondents, were then requested to give an indication of how much they agree with the statements that relate to effect of management commitment on quality assurance. The outcomes are as illustrated below

Table 4.6: Influence of Management Commitment on Quality Assurance

Statements	N	Min	Max	Mean	Std. Deviation
There is an organizational structure regarding the distribution of our pharmaceutical products	64	1.00	4.00	1.906	0.526
The employees' responsibility participating in distribution of pharmaceutical products is clearly stated in a job description	64	1.00	4.00	2.031	0.666

The authority of all personnel participating in distribution of pharmaceutical products is clearly stated	64	1.00	3.00	2.266	0.718
The interrelationships of all personnel participating in distribution of pharmaceutical products is clearly stated	64	1.00	4.00	2.016	0.630
There is a business continuity plan to mitigate contingencies and natural disasters such as fire	64	1.00	3.00	1.938	0.302
The distributor has a budget for Quality Assurance aspects such as redesigning the warehouse or investing in refrigerated vehicles	64	1.00	3.00	1.875	0.766
There is a code of practice in place regarding employees involved in the distribution of pharmaceutical products	64	1.00	2.00	1.563	0.500
The distributor conducts risk assessments for measuring the probable risks towards the quality and integrity of the pharmaceutical products	64	1.00	4.00	1.891	0.475

Based on the outcomes, majority of the respondents strongly agreed that a code of practice was in place regarding employees involved in the distribution of pharmaceutical products as indicated by a mean of 1.563 while the variation was small as indicated by standard deviation of 0.500. It was agreed that the distributor had a budget for quality assurance aspects such as redesigning the warehouse or investing in refrigerated vehicles as indicated by a mean of 1.875 while the variation was small as indicated by standard deviation of 0.766. It was agreed that the distributor conducts risk assessments for measuring the probable risks towards the quality and integrity of the pharmaceutical products as indicated by a mean of 1.891 while the variation was small as indicated by standard deviation of 0.475. It was finally agreed that there was an organizational structure regarding the distribution of their pharmaceutical products as indicated by a mean of 1.906 while the variation was small as indicated by standard deviation of 0.526. Oakland (2013) earlier pointed out that MC implementation needs a transparent long-term commitment of leadership. The interrelationships of all personnel participating in distribution of pharmaceutical products is clearly stated.

The respondents further agreed that there was a business continuity plan to mitigate contingencies and natural disasters such as fire as indicated by a mean of 1.938 while the variation was small as indicated by standard deviation of 0.302. It was agreed that the interrelationships of all personnel participating in distribution of pharmaceutical products was

clearly stated as indicated by a mean of 2.016 while the variation was small as indicated by standard deviation of 0.630. It was agreed that the employees' responsibility participating in distribution of pharmaceutical products was clearly stated in a job description as indicated by a mean of 2.031 while the variation was small as indicated by standard deviation of 0.666. The respondents also agreed that the authority of all personnel participating in distribution of pharmaceutical products is clearly stated as indicated by a mean of 2.266 while the variation was small as indicated by standard deviation of 0.718. Consistent to the study findings, Sudhanshu (2015) found that management commitment, leadership, quality management and good supplier and vendor relationship were the most significant factors affecting quality assurance. Similarly, Rania and Samir (2015) found that there was significance influence of effective leadership on quality assurance.

4.4 Customer Focus and Quality Assurance

The study sought to find out in what ways the Pharmaceutical Distributors has enhanced customer satisfaction and met their expectation based on the services offered by the facilities. Based on the outcomes, respondents gave an indication that; they ensure timely delivery of customer products, timely response to customer complains, offering quality services, utilizing customer suggestion box, quick response to product quality defects and ensuring there are no counterfeits products.

The respondents got a request to give an indication of how much they agreed with the statements below concerning how quality assurance was influenced by customer focus. The responses are as illustrated below

Table 4.7: Influence of Customer Focus on Quality Assurance

Statements	N	Min	Max	Mean	Std. Deviation
There is an existing documented procedure for handling complaints by customers	64	1.00	2.00	1.922	0.270
There is a customer suggestion box at the facility	64	1.00	3.00	2.109	0.567
The is no supply or selling of pharmaceutical products ahead of authorization	64	1.00	3.00	2.156	0.672
There's a process for quality auditing or self-inspection which frequently assesses the success of the distribution system	64	1.00	3.00	1.875	0.630

There exists a system that approves changes which might be having an effect on the quality of pharmaceutical products	64	1.00	2.00	1.688	0.467
There is a system present for recalling a batch of pharmaceutical products from supply or sale	64	1.00	2.00	1.734	0.445
We always examine the causes of substantial defects on pharmaceutical products	64	1.00	2.00	1.766	0.427
All measures and decisions made arising from a complaint are documented and then references made to the conforming batch numbers	64	1.00	3.00	1.797	0.568

Based on the outcomes, it was strongly agreed that there exists a system that approves changes which might be having an effect on the quality of pharmaceutical products as indicated by a mean of 1.688 while the variation was small as indicated by standard deviation of 0.467. It was strongly agreed that there was a system present for recalling a batch of pharmaceutical products from supply or sale as indicated by a mean of 1.734 while the variation was small as indicated by standard deviation of 0.445. It was strongly agreed that distributors always investigate the causes of quality defects on the pharmaceutical products as indicated by a mean of 1.766 while the variation was small as indicated by standard deviation of 0.427. It was strongly agreed that all measures and decisions made arising from a complaint were documented and then references made to the conforming batch numbers as indicated by a mean of 1.797 while the variation was small as indicated by standard deviation of 0.568. Stahl (2015) earlier revealed that the constant of ways of bettering service or product quality can curb the occurrence of a problem in future.

The respondents further agreed that there's was process for quality auditing or self-inspection which frequently assesses the success of the distribution system as shown by the mean 1.875 while the variation was small as indicated by standard deviation of 0.630. It was agreed that there was an existing documented procedure for handling complaints by customers as shown by the mean 1.922 while the variation was small as indicated by standard deviation of 0.270. It was agreed that there was a customer suggestion box at the facility as shown by the mean 2.109 while the variation was small as indicated by standard deviation of 0.567. It was agreed that there was no supply or selling of pharmaceutical products ahead of authorization as given by the mean of 2.156 while the variation was small as indicated by standard deviation of 0.672. Cheroigin (2014) found that performance and total quality management of the multinational

pharmaceutical entities is determined by customer focus through meeting the customers' needs.

4.5 Continuous Improvement and Quality Assurance

The respondents were requested to indicate the innovations and improvements made to their facility and processes to ensure quality assurance is achieved. The respondents' indicated they have adopted E-business, automated stock control, implemented electronic procurement system, regular employee training, technology adoption., have diverse designating systems and distribution control systems. The study made a request to respondents to give an indication of how much they agreed with statements that relate to influence of continuous improvement on quality assurance.

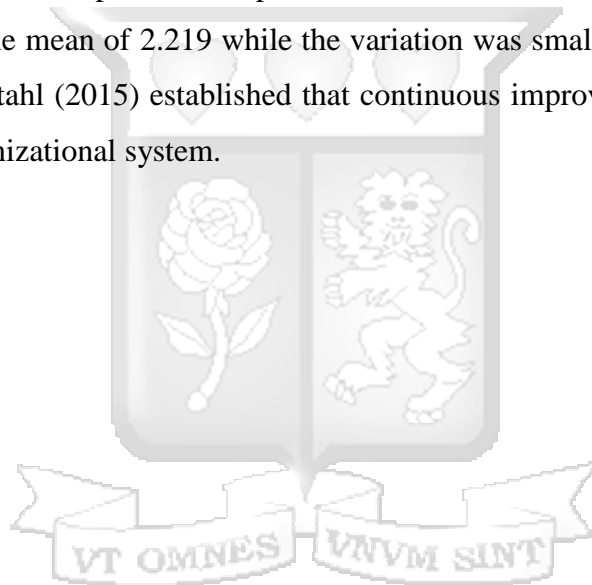
Table 4.8: Influence of Continuous Improvement on Quality Assurance

Statements	N	Min	Max	Mean	Std. Deviation
The Distributor undertakes quality audits and evaluation so as to enhance its quality assurance	64	1.00	3.00	1.844	0.541
There is a sectional department in place to assess the effectiveness of your distribution system	64	1.00	4.00	2.219	0.701
The Distributor evaluates the performance of suppliers so as to enhance its quality assurance	64	1.00	3.00	2.203	0.622
The Distributor undertakes regular trainings on employees so as to improve their skills and competences	64	1.00	2.00	1.734	0.445
Regular departmental and employee appraisals are carried out to measure employee performance	64	1.00	3.00	2.016	0.488
There is a system in place to reduce the number of quality defects resulting from transportation	64	1.00	3.00	1.875	0.519

Based on the outcomes, it was strongly agreed that a distributor undertakes regular trainings on employees so as to improve their skills and competences as given by the mean of 1.734 while the variation was small as indicated by standard deviation of 0.445. It was agreed that the distributor undertakes quality audits and evaluation so as to enhance its quality assurance as given by the mean of 1.844 while the variation was small as indicated by standard deviation of 0.541. It was agreed that there was a system in place to reduce the number of quality defects resulting from transportation as given by the mean of 1.875 while the variation was small as

indicated by standard deviation of 0.519. Consistent to the findings Oakland (2013) found that the attention on constant improvement will result to quality assurance by information of a difficult team whereby membership is measured by their job on the comprehensive comprehension of the procedure.

Further, it was agreed that regular departmental and employee appraisals were carried out to measure employee performance as given by the mean of 2.016 while the variation was small as indicated by standard deviation of 0.488. It was agreed that the distributor evaluates the performance of suppliers so as to enhance its quality assurance as given by the mean of 2.203 while the variation was small as indicated by standard deviation of 0.622. Finally, it was agreed that there was a sectional department in place to assess the effectiveness of the distribution system as given by the mean of 2.219 while the variation was small as indicated by standard deviation of 0.701. Stahl (2015) established that continuous improvement was done through innovations and organizational system.



4.6 Quality Assurance

The respondents, were then requested to give an indication of ways in which they can enhance the quality assurance of the services and products offered at their facility. The respondents, indicated that that quality assurance of the services and products offered at their facility can be enhanced by allocating more funds, encourage top management support, employee training, development of well elaborate procedures, automation of processes, putting in place checks and balances, implementing recommendations of Pharmacy and Poisons Board, enhancing staff commitment having clear and direct procedures and improving quality of QA manual.

The study made a request to respondents to give an indication of the relation of some aspect of quality assurance relate to their facility. The respondents' levels of agreement were as in Table 4.9

Table 4.9: Aspect of Quality Assurance

Aspects	N	Minimum	Maximum	Mean	Std. Deviation
Our company has a quality assurance manager	64	1.00	2.00	1.922	0.270
Our company has a quality manual for implementing the QA programmes	64	1.00	3.00	2.156	0.541
Our company has developed the standard operating procedures (SOPs)	64	1.00	4.00	2.031	0.470
Management commitment is the key factor in enhancing quality assurance at the Distributor	64	1.00	3.00	1.859	0.687
Customer focus is the key factor in enhancing quality assurance at the Distributor	64	1.00	2.00	1.750	0.436
Continuous improvement is the key factor in enhancing quality assurance at the Distributor.	64	1.00	4.00	1.938	0.560

Based on the outcomes, it was strongly agreed that customer focus is the key element in enhancing quality assurance at the distributor as given by the mean of 1.750 while the variation was small as indicated by standard deviation of 0.436. It was agreed that the management commitment is the key factor in enhancing quality assurance at the distributor as given by the mean of 1.859 while the variation was small as indicated by standard deviation of 0.687. It was agreed that the companies had a quality assurance manager as given by the mean of 1.922

while the variation was small as indicated by standard deviation of 0.270. It was agreed that continuous improvement was the key factor in enhancing quality assurance at the distributor as given by the mean of 1.938 while the variation was small as indicated by standard deviation of 0.560. It was agreed that companies had developed the standard operating procedures (SOPs) as given by the mean of 2.031 while the variation was small as indicated by standard deviation of 0.470. Finally, it was agreed companies had a quality manual for implementing the QA programmes as given by the mean of 2.156 while the variation was small as indicated by standard deviation of 0.541.

4.7 Inferential Statistics

4.7.1 Model Summary

The model summary sought to determine if the significance of the correlation coefficient at 5% significance level as well as the extent that each independent variable explained the dependent variable through the coefficient of determination.

Table 4.10: Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.583 ^a	.340	.307	1.40864

a. Predictors: (Constant), total management commitment, customer focus, continuous improvement

Adjusted R squared refers to a coefficient of determination that explains the dependent variable's variation as a result of changes arising from the variables that are independent: Based on the outcomes above, the adjusted R squared value; 0.307 was an implication of presence of 30.7% variation on the quality assurance as a result of changes in continuous improvement, customer focus and overall management commitment at 95% level of confidence. This implies, 30.7% of changes in the quality assurance may be explained by the changes in continuous improvement, customer focus and overall management commitment. R refers to correlation coefficient that illustrates how the variables under study relate, based on the outcomes indicated in the above table there existed a positive relationship amongst the variables under study as illustrated by the value 0.583.

4.7.2 Analysis of Variance

This was tested so as to determine whether the model was significant at a 95% level of confidence.

Table 4.11: ANOVA

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	61.382	3	20.461	10.312	.000 ^b
	Residual	119.055	60	1.984		
	Total	180.438	63			
a. Dependent Variable: quality assurance						
b. Predictors: (Constant), total management commitment, customer focus, continuous improvement						

Based on the analysis of ANOVA shown above, the data processed, that is the parameters of population, had a level of significance of 0.000 that implies the suitability of the data in coming up with a conclusion concerning the parameters of population as the significance value is below 5%. The value of F critical was 2.758 at 5% significance level and three degrees of freedom whereas F calculated value was 10.312, because the value of F calculated was bigger than that of F critical, the entire model was deemed significant.

4.7.3 Multiple Regression

It was carried out in order to measure the level at which independent variables influenced the dependent ones.

Table 4.12: Multiple Regression

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	1.351	0.331		4.082	0.000
	X1	0.574	0.181	0.556	3.171	0.002
	X2	0.598	0.1701	0.571	3.514	0.001
	X3	0.552	0.178	0.526	3.101	0.002
a. Dependent Variable: Quality assurance						

$$Y=1.351+ 0.574 X1 + 0.598X2 + 0.552 X3+ \varepsilon$$

Based on the above equation it got discovered that holding total management commitment, customer focus and continuous improvement to a constant zero, quality assurance of pharmaceutical distributors in Nairobi County could be 1.351. An increase by one unit in management commitment would result to a rise in the quality assurance by 0.574 units. A unit increase in customer focus would lead to an increase in quality assurance by 0.598 units. A increase by one unit in continuous improvement would lead to an increase in quality assurance by 0.552 units. At 5% significance level and a 95% confidence level, every variable was significant ($p<0.05$).



CHAPTER FIVE: DISCUSSIONS, CONCLUSION AND RECOMMENDATIONS

5.1 Introduction

This chapter presents a summary of outcomes, the conclusion and study recommendations. The presentation is discussed as per the study objectives.

5.2 Discussions

5.2.1 Management Commitment and Quality Assurance

The study's first objective was to determine the function of management commitment on quality assurance of pharmaceutical distributors in Nairobi County. The findings revealed that there is a code of practice in place regarding employees participating in pharmaceutical products distribution, the distributor has a budget for quality assurance aspects such as redesigning the warehouse or investing in refrigerated vehicles and conducts assessments of risks for measuring the probable risks towards the integrity and quality of the pharmaceutical products. Oakland (2013) earlier pointed out that MC implementation needs a transparent long-term commitment of leadership. The interrelationships of all personnel participating in distribution of pharmaceutical products is clearly stated. Consistent to the study findings, Sudhanshu (2015) found that management commitment, leadership, quality management and good supplier and vendor relationship were the most significant factors affecting quality assurance.

The research revealed that there are organizational structures regarding the distribution of pharmaceutical products and business continuity plans to mitigate contingencies and natural disasters such as fire. Cheroigin (2014) noted where there is proper implementation of TQM; it yields a number of benefits like satisfying the wants of clients, advanced communication and increased capacity of the company to solve problems. The employees' responsibility participating in distribution of pharmaceutical products is clearly stated in a job description as well. The authority of all personnel participating in distribution of pharmaceutical products is clearly stated. Similarly, Rania and Samir (2015) found that there was significance influence of effective leadership on quality assurance.

The research found that challenges faced by the top management in enhancing the quality assurance of the products and services are employees are resistant, lack the necessary skills,

delays and shortages, financial constraints, poor implementation of the recommendations made and poor coordination within the management. The above findings relate to quality improvement theory put across by (Deming, 1986) which suggest that continuous improvement gives an organization a plan of taking out low issues on quality control by effective systems of administration. Hence management commitment in terms of providing the resources necessary for enhancing quality assurance is key. The leadership commitment of the strategy of MC as indicated in everyday work disposition is likely to take long to motivate workers to submit services of good quality.

5.2.2 Customer Focus and Quality Assurance

The second study objective was evaluating the effect of customer focus on quality assurance of pharmaceutical distributors in the county of Nairobi. The study outcomes portrayed that the presence of systems for approval of changes which might be of effect on the quality of pharmaceutical products. Similarly, Stahl (2015) revealed that the constant of ways of bettering service or product quality can curb the occurrence of a problem in future. There is a system present for recalling a batch of pharmaceutical products from supply or sale. The pharmaceutical distributors always examine the causes of quality defects on the pharmaceutical products and that all measures and decisions made arising from a complaint are documented and then references made to the conforming batch numbers. Consistent to the findings, Cheroigin (2014) found that performance and total quality management of the multinational pharmaceutical entities is determined by customer focus through meeting the customers' needs.

The pharmaceutical distributors have procedures for self-inspection and/or quality audit that regularly appraises the effectiveness of distribution system and written procedures are in place for the handling of customer complaints. Customer suggestion box are also available at the facilities. The Pharmaceutical Distributors has enhanced customer satisfaction and met their expectation based on the services offered by the facilities by ensuring timely delivery of customer products, timely response to customer complains, offering quality services, utilizing customer suggestion box, quick response to product quality defects and ensuring there are no counterfeits products. Forza and Filippini (2015) gave an explanation that its key for a firm to keep a close relation with the clients so as to be aware of what they need and evaluate how

effective it has been in satisfying the needs of clients. The above findings also relate to Resource-Based View theory which explores the role of key resources, identified as intangible assets and capabilities, in creating competitive advantage and superior performance. It emphasizes on the assets of the organization as being the important determining factors of implementation and enhancement of quality assurance. The theory relates to customer focus since customers are viewed as a significant component of an organization's asset. The main objective of RBV stems from generating competitive advantage that enables companies to obtain quality assurance levels based upon their respective combination of resources and capacities which focuses on the need of the customers.

5.2.3 Continuous Improvement and Quality Assurance

The third objective was to assess the effect of continuous improvement on quality assurance of pharmaceutical distributors in Nairobi County. The study established that the Pharmaceutical Distributors undertakes regular trainings on employees to improve their skills and competences. They undertake quality audits and evaluation to enhance its quality assurance. There is a system in place to reduce the number of quality defects resulting from transportation. Regular departmental and employee appraisals are performed to measure employee performance. Consistent to the findings Oakland (2013) found that the attention on constant improvement will result to quality assurance by information of a difficult team whereby membership is measured by their job on the comprehensive comprehension of the procedure. The pharmaceutical distributors evaluate the performance of suppliers to enhance its quality assurance while a sectional department is in place to assess the effectiveness of the distribution system.

The findings determined that the pharmaceutical distributors have made innovations and improvements to their facilities and processes to ensure quality assurance are achieved. The innovations and improvements made were; adoption of E-business, automation of stock control, implementation of electronic procurement system, regular employee training, technology adoption as well as having diverse designating systems and distribution control systems. Consistent to the findings Stahl (2015) established that continuous improvements done thought innovations and organizational system. The above findings relate to quality improvement theory put across by (Deming, 1986) which suggest that continuous

improvement gives an organization a plan of taking out low issues on quality control by effective systems of administration. The quality improvement theory advocates that for there to be quality assurance there must be continuous improvement of the processes and distribution systems in the organization. Quality Improvement theory alludes to constant improvement and refinement of the system of the organization, the services and goods of the firm to produce better value for clients.

5.3 Conclusion

The research established that management commitment took a significant role on quality assurance of pharmaceutical distributors in Nairobi County. The pharmaceutical distributors had codes of practice in place regarding employees involved in the distribution of pharmaceutical products and budget for quality assurance aspects. The interrelationships of all personnel participating in distribution of pharmaceutical products is clearly stated and their responsibilities are clearly stated.

Customer focus, impacted significantly on quality assurance of pharmaceutical distributors in Nairobi County. Systems for change approval which could be of impact over the quality of pharmaceutical products and recalling a batch of pharmaceutical products from sale or supply are put in place. The pharmaceutical distributors had enhanced customer satisfaction and met their expectation based on the services offered by the facilities by ensuring timely delivery of customer products and responding to product quality defects and ensuring there are no counterfeit products.

The pharmaceutical distributors undertook regular trainings on employees to improve their skills and competences and quality audits and evaluation to enhance its quality assurance. Systems are put in place to reduce the number of quality defects resulting from transportation. The pharmaceutical distributors have made innovations and improvements to their facilities and processes to ensure quality assurance are achieved.

5.4 Recommendations

The recommendations that follow are discussed according to the outcomes of the study;

The study concludes that management commitment had a significant role on quality assurance of pharmaceutical distributors in Nairobi County. The research therefore recommends that

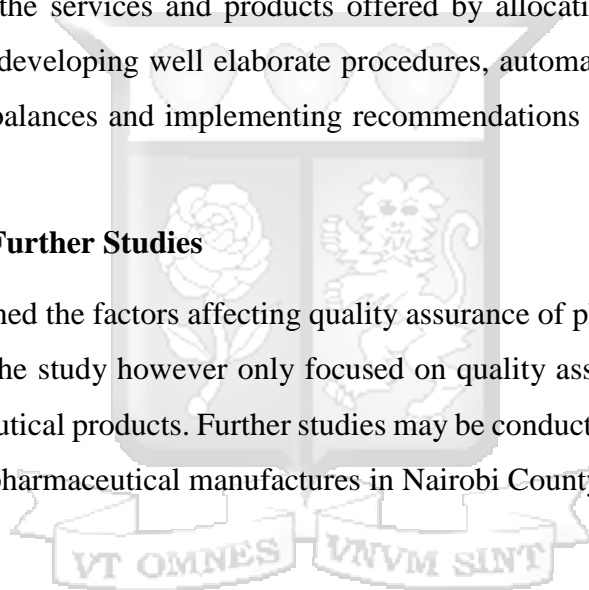
more funds should be allocated towards enhancing management commitment. The management should as well involve the employees in formulating and implementing the quality assurance strategies to overcome their resistance.

Customer focus was discovered as having a significant impact over quality assurance of pharmaceutical distributors and as such, the study recommends that pharmaceutical distributors should continue ensuring customer satisfaction by ensuring timely delivery of customer products, timely response to customer complaints, offering quality services and quick response to product quality defects.

The research gives a recommendation that pharmaceutical distributors should improve the quality assurance of the services and products offered by allocating more funds to quality assurance processes, developing well elaborate procedures, automation of processes, putting in place checks and balances and implementing recommendations of Pharmacy and Poisons Board.

5.5 Suggestions for Further Studies

The research determined the factors affecting quality assurance of pharmaceutical distributors in Nairobi County. The study however only focused on quality assurance at the distribution level of the pharmaceutical products. Further studies may be conducted on the factors affecting quality assurance of pharmaceutical manufactures in Nairobi County.



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APPENDICES

Appendix I: Introduction Letter

Dear Respondent,

RE: Research Proposal

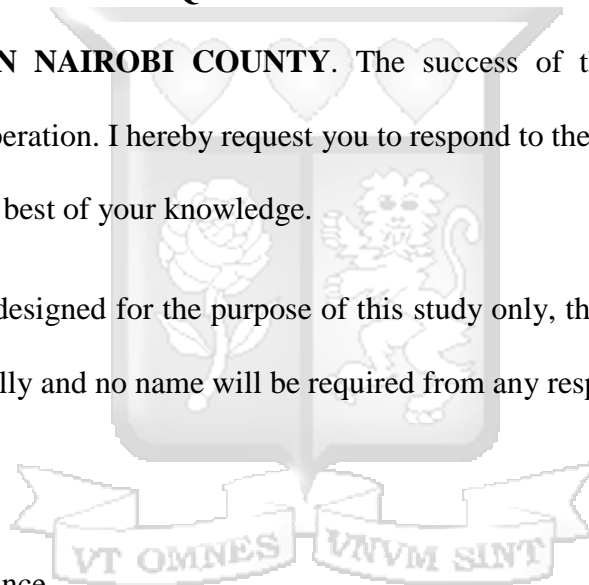
I am a postgraduate student at Strathmore University pursuing a master of Business Administration Degree. I am carrying out a management research project aimed at determining **THE FACTORS AFFECTING QUALITY ASSURANCE OF PHARMACEUTICAL DISTRIBUTORS IN NAIROBI COUNTY**. The success of the research substantially depends on your cooperation. I hereby request you to respond to the questionnaire as honestly as possible and to the best of your knowledge.

The questionnaire is designed for the purpose of this study only, therefore the responses will be treated confidentially and no name will be required from any respondent.

Thanking you in advance

Yours sincerely,

Peris Kibandi



Appendix II: Sample Questionnaire

Kindly ticks in the space provided the correct answer or supply the required information where, required, please specify and elaborate.

Part A: Respondents Information

1 Name..... (Optional)

2 Age of the respondent ()

3 Gender of the respondent?

Male []

Female []

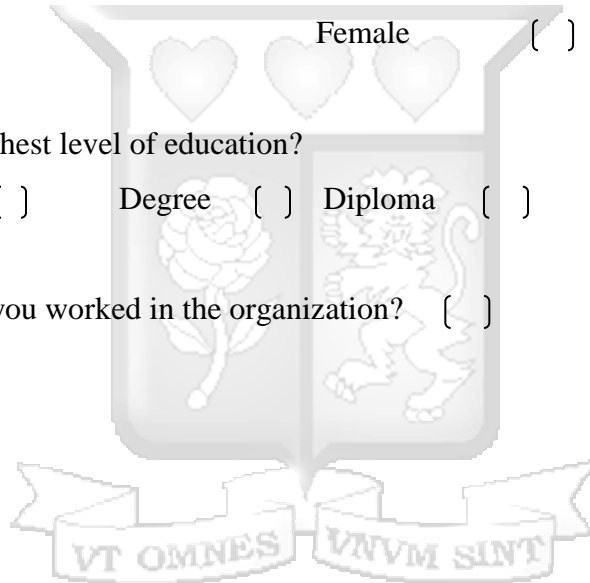
4 What is your highest level of education?

Postgraduate []

Degree []

Diploma []

5 How long have you worked in the organization? []



Part B: Management Commitment and Quality Assurance

6 Please indicate the challenges faced by the top management in enhancing the quality assurance of the products and services?

.....

7 Indicate your level of agreement with the following statements that relate to influence of management commitment on quality assurance? Where: 1= Strongly agree; 2= Agree; 3= Neutral; 4= Disagree; 5= Strongly disagree

Statement	Strongly agree (1)	Agree (2)	Neutral (3)	Disagree (4)	Strongly disagree (5)
There is an organizational structure regarding the distribution of our pharmaceutical products					
The employees' responsibility participating in distribution of pharmaceutical products is clearly stated in a job description					
The authority of all personnel participating in distribution of pharmaceutical products is clearly stated					
The interrelationships of all personnel participating in distribution of pharmaceutical products is clearly stated					
There is a business continuity plan to mitigate contingencies and natural disasters such as fire					
The distributor has a budget for Quality Assurance aspects such as redesigning the warehouse or investing in refrigerated vehicles					

There is a code of practice in place regarding employees involved in the distribution of pharmaceutical products					
The distributor conducts risk assessments for measuring the probable risks towards the quality and integrity of the pharmaceutical products					

Part C: Customer Focus and Quality Assurance

8 Please indicate in what ways your facility has enhanced customer satisfaction and met their expectation based on the services offered as a Pharmaceutical Distributor.

.....
.....
.....

9 Indicate your level of agreement with the following statements that relate to influence of customer focus on quality assurance. Where: 1= Strongly agree; 2= Agree; 3= Neutral; 4= Disagree; 5= Strongly disagree

Statement	Strongly agree (1)	Agree (2)	Neutral (3)	Disagree (4)	Strongly disagree (5)
There is an existing documented procedure for handling complaints by customers					
There is a customer suggestion box at the facility					
The is no supply or selling of pharmaceutical products ahead of authorization					
There's a process for quality auditing or self-inspection which frequently assesses the success of the distribution system					

There exists a system that approves changes which might be having an effect on the quality of pharmaceutical products					
There is a system present for recalling a batch of pharmaceutical products from supply or sale					
We always investigate the causes of quality defects on the pharmaceutical products					
All measures and decisions made arising from a complaint are documented and then references made to the conforming batch numbers.					

Part D: Continuous Improvement and Quality Assurance

10 Please indicate the innovations and improvements made to your facility and processes to ensure Quality Assurance is achieved.

.....
.....
.....

11 Indicate your level of agreement with the following statements that relate to influence of continuous improvement on quality assurance? Where: 1= Strongly agree; 2= Agree; 3= Neutral; 4= Disagree; 5= Strongly disagree

Statement	Strongly agree (1)	Agree (2)	Neutral (3)	Disagree (4)	Strongly disagree (5)
The Distributor undertakes quality audits and evaluation so as to enhance its quality assurance					
There is a sectional department in place to assess the effectiveness of your distribution system					

The Distributor evaluates the performance of suppliers so as to enhance its quality assurance					
The Distributor undertakes regular trainings on employees so as to improve their skills and competences					
Regular departmental and employee appraisals are carried out to measure employee performance					
There is a system in place to reduce the number of quality defects resulting from transportation					



Part E: Quality Assurance

12 Please indicate ways in which you can enhance the quality assurance of the services and products offered at your facility?

.....

13 Indicate your level of agreement with the following statements that relate to quality assurance in your facility? Where: 1= Strongly agree; 2= Agree; 3= Neutral; 4= Disagree; 5= Strongly disagree

Statement	Strongly agree (1)	Agree (2)	Neutral (3)	Disagree (4)	Strongly disagree (5)
Our company has a quality assurance manager					
Our company has a quality manual for implementing the QA programmes					
Our company has developed the standard operating procedures (SOPs)					
Management commitment is the key factor in enhancing quality assurance at the Distributor					
Customer focus is the key factor in enhancing quality assurance at the Distributor					
Continuous improvement is the key factor in enhancing quality assurance at the Distributor.					

THANK YOU