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SCHOOL OF COMMERCE

DEPARTMENT OF LOGISTICS AND SUPPLY CHAIN MANAGEMENT

FACTORS AFFECTING QUALITY MANAGEMENT SYSTEM IN PHARMACEUTICAL TRANSPORTATION:

IN CASE OF ETHIOPIAN CARGO & LOGISTICS SERVICES

A THESIS SUBMITTED TO OFFICE OF GRADUATE STUDIES OF ADDIS ABABA UNIVERSITY SCHOOL OF COMMERCE IN THE PARTIAL FULFILLMENT OF THE REQUIREMENT FOR THE DEGREE OF MASTER OF LOGISTICS AND SUPPLY CHAIN MANAGEMENT

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DECLARATION

I, the undersigned, declare that this thesis entitled "Factors affecting Quality Management System in Pharmaceutical Transportation: In Case of Ethiopian Cargo & Logistics Services" is my original work and has not been presented for degree requirement in any other university, and all the sources used to support this particular study have been appropriately acknowledged.

Ermias Adera Bayuh

Signature: _____ Date: _____

CONFIRMATION

This is to certify that Ermias Adera has carried out this thesis on the topic entitled “Factors affecting Quality Management System in Pharmaceutical Transportation: In Case of Ethiopian Cargo & Logistics Services” under my supervision. Accordingly, I here assure that his work is appropriate and standard enough to be submitted for partial fulfillment of the requirements for the award of the degree of Master of Arts in logistics and supply chain management.

Busha Temesgen (PhD.)

Signature: _____ Date: _____

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LIST OF ACRONYMS AND ABBREVIATIONS

CEIV Pharma: Centre of Excellence for Independent Validators in Pharmaceutical Logistics

ECLS: Ethiopian Cargo & Logistics Services

ECPW: Ethiopian Cargo Pharma Wing

EU: European Union

GDP: Good Distribution Practices

IATA: International Air Transport Associations

QMS: Quality Management System

TCR: Temperature Control regulation

USP: U. S. Pharmacopeial Convention

WHO: World health organization

ABSTRACT

Transporting pharmaceutical and health care products via air desires the institution of complex logistical techniques to maintain pharmaceutical shipments integrity. It requires unique equipment storage facilities, harmonized handling procedures and, above all robust cooperation among bloodless chain partners. Strategically a predominant component in a retailer's choice for the stock a supplier's merchandise are come to and out of the country thru transportation and it represents a fundamental determinant of a supplier's grant chain and business success like air transportation as Ethiopian Cargo & Logistics Services and Ethiopian Mojo Dry Port Logistics Services Enterprise as water transportation. To assess the factors affecting of quality management system in Pharmaceutical Transportation in Ethiopian Cargo & Logistics Services and come up with the solution for the identified problems. The research has used quantitative approach on collecting and analysis of the data. Descriptive Statistics and inferential statistics were used for frequency and percentage for analysis purpose and also Microsoft Office Excel and SPSS that was used to generate data presentation using tables, charts, and graphs. In addition to descriptive method explanatory statistics used. The sampling technique was used probable sampling in which each sample has a known population. According to the effect of Quality Planning on Quality management system of pharmaceutical transportationabove half of them 127(54.74%)were strongly agree on their Our company has company manuals for implementing the QMS programme; again above half of them, 140(60.34%) strongly agree on their company has developed the standard operating procedures (SOPs) and most respondents 146(62.93%)agree on I believe there is adequate and appropriate resource are available.According to the effect of Quality Assurance on Quality management system of pharmaceutical transportation strongly agree on their Our company has company manuals for implementing the QMS programme, their company has developed the standard operating procedures (SOPs) and they believe there is adequate and appropriate resource are available. There is also effective quality improvement program by having training and PDCA tools. In overall pharmaceutical air transport having quality risk management as key elements during supply chain and establish risk mitigation tools during supply network.

Key words: Good Distribution Practice, Quality Management System, IATA CEIV pharma, QMS, Transportation

CHAPTER ONE
INTRODUCTION

1.1. Background of the study

The global pharmaceutical market has experienced significant growth in recent years. As of end-2020, the total global pharmaceutical market was valued at about 1.27 trillion U.S.dollars ,(Mikulic, 2021). Whereas the air cargo share has declined due to lack of compliance, standardization, accountability and transportation across the air transport supply chain per by IATA annually report in 2021. Generally speaking, prescription drugs need extraordinary cares and managing on transportation, due to the fact it's affected by means of surroundings such as temperature, humidity, pressure variance, sunlight exposure.

Transporting pharmaceutical and health care products via air desires the institution of complex logistical techniques to maintain pharmaceutical shipments integrity. It requires unique equipment storage facilities, harmonized handling procedures and, above all robust cooperation among bloodless chain partners. Strategically a predominant component in a retailer's choice for the stock a supplier's merchandise are come to and out of the country thru transportation and it represents a fundamental determinant of a supplier's grant chain and business success like air transportation as Ethiopian Cargo logistics and transportation services and water transportation as Ethiopian Mojo Dry Port Logistics Services Enterprise.(Kristel & Mcadam, 2015)

As these enlarging cargo businesses, (García-Arca, et al., 2016) study on followed by warehousing, choosing and packing and eventually ends with transporting the merchandise for delivery. Picking the proper distribution channels, preserving a seen stock stocking gadget and optimization of delivery selections are basic strategies to make outbound logistics effective. In other words, there are multiple types of commodities that are transported in air cargo that need exclusive care shipment, amongst those the pharmaceutical and health care product are one of the primary the most rising business. In order to meet client requirements, there are developed system, manual and working procedure. Due to the lack of infrastructure such as roads, electric powered systems, communication amenities and internet, cargo facilities, negative statistics monitoring, transportation facilities, excessive temperature because of minimal rainfall are logistics challenges of fitness care commodities in Africa. These challenges become more

complex when it comes to temperature-controlled products and countries need to design and execute processes and innovations that mitigate associated risks. Logistics of pharmaceuticals need to be supported with research developments(Hanselmann & Woods, 2019).

Considering the above the systems shall have a take a look at and balance system amongst that great management system as we gotten from the world financial institution record in 2006. Any true fitness care system necessitates provide chains that can guarantee constant availability of affordable, extremely good medicines, vaccines and health merchandise at all health service delivery points,(World Bank, 2016).

Quality Management System is a set of interacting factors based totally on procedures, policies, resources, and goals that are hooked up at the same time to guide an organization. It also takes into account all relevant recommendations and policies that are designed to hold its robustness,(Choudhary, 2021).

Quality management gadget in prescribed drugs helps to enhance the product fantastic and limit the danger of product recall. Organizations engaged in the distribution, as well as the storage of materials along withproducts, should monitor,establish, hold and implement the components o f the fine administration system that lets in the transport of resources, product and services, and substances with the requisite pleasant and safety.(Choudhary, 2021).

Quality Management Systems for pharmaceutical transportation and handling based on international standards benefits manufacturers, service providers, users, consumers and regulators and supports sustainable development, so its popularity is relevant today. On having common standard different bodies have developed its own procedure, in Europe, there is EU guidelines on Good Distribution Practice of medicinal products for human use, WHO Good Distribution Practices Annex 5, and many regional and international organization have developed their own standards. As general standard for aviation industry, IATA have developed CEIV pharma, that use as so that all have uniform application of compliance, standard and procedure across all over the world air transportation supply chain. Airlines which cannot managing quality will mean no added and assuring value to the airlines,(Peters, 1999)

The great gadget is used for one-of-a-kind stakeholders, who are concerned on transportation of pharmaceutical that includes, freight forwarders, airlines and floor managing companies. In case of Addis Ababa airport Ethiopian airways play as airways for transportation from and to Addis Ababa as nicely as floor handling, that encompass brief stowage on its devoted pharma facilities. The services have specific stowageareas, beginning from committed docks fortop acceptance, sp ecific storage amenities primarily based on temperature specification, sorting area, tarmac transportation automobiles and transport corridors.

The use of a strategic strategy to excellent administration with the aid of airlines will consequently enhance their competitiveness(Ghobadian, et al., 1994). Ethiopian Cargo Pharma Wing has developed its personal Quality Management device by adopting one-of-a-kind regulatory bodies. The Quality Management System is dedicated to guarantee the guide lines, method and preferred working technique on coping with pharmaceutical and fitness care merchandise at some point of Ethiopian airways route, beginning from accepting of items from the shipper or its delegated physique up to its ultimate shipping factor for the consignee by retaining cargo nature requirement in all supply chain,(ETH, 2021).

This lookup by and large fascinated on the excellent administration device practices on the pharmaceutical merchandise transport, in Addis Ababa, Ethiopian. Addis Ababa airport is the HUB of Ethiopian Airlines Group and we pick the case find out about to be on Cargo division, which is surprisingly involving on air freight business, especially pharmaceutical transportation is newly immerging area with major technological advancement. When we say Ethiopian Cargo Pharma Wing we are also referring as the floor dealing with part too, in which this paper will have emphasis on ,(ETH, 2021).

1.2. Statement of the Problem

Air cargo transportation has been one of the convenient ways of transporting goods from point A, the origin, to point B, the destination. When an airline accepts goods, it has a responsibility to transport and deliver them on time by fulfilling its mandatory transportation requirements.

Members of the pharmaceutical supply chain have various global regulatory requirements to meet while handling, storing, and distributing environmentally sensitive products. Their focus is to provide cold chain management for temperature sensitive pharmaceuticals to ensure that the quality and efficacy of the product will not be compromised.(Rafik, 2006)

Medicines requiring controlled-temperature storage conditions must be distributed in a manner that ensures their quality will not be adversely affected. Following is an overview of key regulatory and industry guidance related to cold chain management. Content covered includes material from World Health Organization, International Conference on Harmonization, Food and Drug Administration, United States Pharmacopeia, Health Canada, and the European Union.(Rafik, 2006)

In recent years, global regulatory agencies have increased oversight to ensure the integrity of pharmaceutical products in the distribution chain. The study of Rafik H. document in conjunction with regulatory guidance's to industry, recent presentations by industry thought-leaders, and regulatory enforcement citations, outlines several common trends impacting cold chain management.

These trends include:

A. Responsibility for cold chain management ultimately resides with the manufacturer

B. Increased oversight, management, and control of environ mental conditions across the entire supply chain (from manufacturer to consumer) for temperature sensitive pharmaceutical products

C. Increased importance of temperature control and monitoring to mitigate and identify risks during cold chain transport

D. Heightened priority of Patient safety

In order to keep up with the above mentioned global regulatory requirements and trends, a quality management system (QMS) and risk assessment process become essential. Factors to be considered for the QMS may include but are not limited to the: Organization, roles and responsibilities, process, trained resources, implementation plan, compliance, change control, on-time delivery of right product, quality metrics, continuous enhancements, and monitoring customer satisfaction, (Rafik, 2006).

Therefore, the purpose of this research is to assess the factors affecting the quality management system of Ethiopian Cargo & Logistics Services in pharmaceutical transportation. In addition, this study also seeks an answer for; management involvement on to QMS implementation, such

as resource allocation, procedures adaptation in relation to regulatory requirement and its feasibilities, and company manuals and guidelines implementation against operational activities

1.3. Research Questions

For the fulfillment of the research purpose and with regards to the above mentioned research perspectives, the study is based on below major research questions.

- To what extent the functions of quality planning on quality management of pharmaceutical transportation in Ethiopian Cargo & Logistics Services?
- How quality assurance influence on quality management system on pharmaceutical transportation in Ethiopian Cargo & Logistics Services?
- Does the quality improvement have an effect on quality management system help on pharmaceutical transportation in Ethiopian cargo & Logistics Services?

1.4. Research Objectives

1.4.1. General Objectives

The general objectives of this research is to assess the practices of quality management system in Pharmaceutical Transportation in Ethiopian Cargo & Logistics Services and come up with the solution for the identified problems.

1.4.2. Specific Objectives

The research study has the following specific objectives:

- To evaluate the function of quality planning on quality management of pharmaceutical transportation in Ethiopian Cargo & logistics services.
- To determine the influence of quality assurance on quality management system on pharmaceutical transportation in Ethiopian Cargo & logistics services.
- To evaluate the result of quality improvement on quality management system help on pharmaceutical transportation in Ethiopian Cargo & logistics services.

1.5. Significance of the Study

This research provides information on Factors Affecting Quality Management System in Pharmaceutical transportation in Ethiopian Cargo Pharma Wing in comparison with other industry standards and recommendation practices. Some of the significance are listed below

- It provides the effective way of internal audit and inspection for the quality and safety of pharmaceuticals
- Try to adopt best benchmarked customer service and feedback handling methods
- Suggest a solution for the delivery of pharmaceuticals product services are in according to global standards.
- This document can be a reference for further study on the Factors affecting Quality Management System in pharmaceuticals transportation sector or other organization.

1.6. Scope of the Study

This research is mainly concerning on practices of implementing quality management system in transporting of pharmaceutical on Ethiopian airlines specifically at Addis Ababa airport by the dedicated subdivision of Ethiopian Cargo & Logistics Services. From different variables affecting Quality Management System; this study only focused on Quality Planning, Quality Assurance and Continuous Improvement as independent variables of the study.

1.7. Definition of Terms

CEIV Pharma: Centre of Excellence for Independent Validators in Pharmaceutical Logistics(IATA)

ECLS: Ethiopian Cargo & Logistics Services, on of business unit on Ethiopian Airlines Group, which is mainly responsible for transporting and handling of cargo

ECPW: Ethiopian Cargo Pharma Wing, a department formulated for handling of pharmaceutical products, that include staffs, equipment's, storage facility within ECLS.

EU: European Union

Good Distribution Practices (GDP): Good Distribution Practices are that part of quality assurance that ensures that the quality of a pharmaceutical product is maintained through adequate control throughout the numerous activities which occur during the transportation process(WHO, annex 9).

IATA: International Air Transport Associations

Quality System (Quality Management System QMS): Also known as Quality System, an appropriate infrastructure, encompassing the organizational structure, procedures, processes and

resources, and systematic actions necessary to ensure adequate confidence that a product (or services) will satisfy given requirements for quality (WHO, annex 9).

TCR: Temperature Control regulation (IATA)

USP: U. S. Pharmacopeial Convention

WHO: World health organization

1.8. Organization of the study

This thesis document is organized into five chapters; each chapter contents are listed in below:

The first chapter of this study it deals introduction parts includes background of the study, statement of the problem, research objectives, research question, significance, scope, limitation definitions and organization of the study.

Chapter two discussed on the available literature document that consists of theoretical, empirical and conceptual literature reviews on quality management system in pharmaceutical transportation.

The research methodologies used to start from data collection to data presentation and analysis method for the research have addressed on chapter three.

Chapter four summarize the results of the study and interprets and also discusses the findings.

Finally, chapter five gives summery, recommendations and suggestion for future studies by listing includes out summary of findings and conclusions.

CHAPTER TWO
REVIEW OF RELATED LITERATURE

2.1.Introduction

The aim of this literature review is to have a former study document with implementation evidence for quality management system in aviation industry by incorporating all requirements and regulatory outlooks. It includes conceptual and theoretical frameworks and empirical reviews on previously studied documents.

2.2. Theoretical Literature Review

2.2.1. Quality Management System

Acceding to(Dale, et al., 1994), fine management involves the system of strategies , putting dreams and objective, planning and implementing the plans; and using control structures for monitoring comments and taking corrective action. An organizations fine administration implementation are tow folds.

a) Satisfying customer's expectation and

b) Improvement in the overall business efficiency

(ISO , 2015) definition of Quality Management System (QMS) mentions to a system that documents processes, procedures, and responsibilities for achieving quality policies and objectives. Additionally, a QMS is a formal system that helps coordinate and direct an organization's activities to meet both customer needs and regulatory requirements.

Distributorsof energetic substances need to improve and hold a first-class system putting out responsibilities, approaches and chance management principles. This pleasant gadget needs to be appropriate and fitting to the man or woman organization. Sometimes well-known nice systems are put in area with solely minor modifications made, such as a change of address. This method fails to take into account the size, structure and complexity of the organization's distribution activities. This can lead to losses and expand the danger of falsified drug treatments getting into the provide chain.

A good QMS for GDP will operate in such a way so that:

- Active substances are procured, imported, held, supplied or exported in a way that is compliant with the requirements of national, regional or supranational GDP requirements for active substances.
- Active substances are delivered to the intended recipients within a satisfactory time period.
- Management responsibilities are clearly outlined.
- The GDP process has been risk assessed.
- Records are made contemporaneously.
- Any deviations from established procedures are documented and investigated.
- Suitable corrective and preventive actions are implemented to correct deviations and to prevent similar incidences from occurring.
- Any changes that may affect the storage and distribution of active substances are evaluated through change control.(Sandle, 2020)

As per satisfactory guru and international employer definition and pointers given through GDP an as it should be selected and implementation of QMS via our operation will make sure the pharmaceutical merchandise integrity as nicely as affected person safety. Effective implementation of safety additionally gives an aggressive gain such as limit client compliments and right enterprise photo on the global arena.

ISO, international organization for standardization, which is a standard is a document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose. Among all standards ISO 900 is dedicated for quality management system (Traveer, 2017).

As per USP definition for good distribution practices (GDP), A Quality Management System (QMS) is defined as a set of interrelated or interacting elements such as policies, objectives, procedures, processes, and resources that are established individually or collectively to guide an organization. An entity that engaged in the storage and distribution of materials and products should establish, implement, monitor, and maintain a QMS that allows the delivery of materials, products, and services with the requisite quality and safety. This includes ensuring the availability of resources needed to be in compliance. For this reason, each organization should define the scope of its QMS and present it in the form of a quality manual.

When an organization have quality assurance program. There should be a documented quality policy describing the overall intentions and requirements of the distributor regarding quality, as formally expressed and authorized by management. Additionally, the quality system should also include an appropriate organizational structure, procedure, processes and resources and systematic actions necessary to ensure adequate confidence that a product or service and its documentation will satisfy given requirements for quality. The totality of these actions is described as the quality system.(EFMHACA, 2015)

The following Quality Management Principles apply to the broader sphere of Business Management which underlies the ISO 9000 series of Quality Assurance Standards: (ECAR, 2016)

- Customer focus
- Leadership
- Involvement of people
- Process approach
- Systems approach to management
- Continual Improvement
- Factual Approach to decision-making
- Mutually beneficial supplier relationships

As defined in ISO 9000:2005, a QMS is a management system that directs and controls an organization regarding quality. Activities generally include the following:

a) establishment of a quality policy and quality objectives;
b) quality planning;
c) quality control;
d) quality assurance; and
e) quality improvement.(ICAO, 2010)

a. Quality Planning

Quality planning is a structured system for creating merchandise (both goods and services) that ensures that customer wants are met by using the ultimate result. The tools and methods of quality planning are integrated along with the technological tools for the unique product being

developed and delivered. Designing a new automobile requires automobile engineering and associated disciplines, growing a nice care course for juvenile diabetes will draw on the professional methods of specialized physicians, and planning a new approach for visitor services at a lodge will require the techniques of an experienced hotelier.

All three need the process, methods, tools, and strategies of excellent planning to make certain that the ultimate designs for the automobile, diabetic care, and resort offerings no longer solely fulfillthe exceptional technical requirements ofthe relevant disciplines however also meet the desires of the clients who will purchase and benefit from the products(Juran, 1999).

A Quality Plan is a document that outlines core quality objectives and the current projects being developed to enhance quality within the organization. According to ICH Q10-2009 (Pharmaceutical Quality System), the Quality Plan is: "Part of quality management focused on setting quality objectives and specifying necessary operational processes and related resources to fulfil the quality objectives."

The plan should form part of the Pharmaceutical Quality Management System (PQMS), with the PQMS representing a company's organizational structure, its planning, processes, resources, and documented information that coalesce to achieve the organization's quality objectives. The PQMS should be treated as a dynamic system that evolves over time through periods of improvement. This Quality Plan represents part of this improvement process. This takes the form of projects; quality plan represents part of this improvement process. This takes the form of projects.(Sandle, 2021)

To conclude on quality planning, The Quality Plan presents an effective way for an organization to clarify, sort, rationalize and plan its quality objectives and provide a single source from which to distil the key quality objectives organization wide. In general, a quality plan should be defined and documented; a document, or numerous documents, that is composed specify manuals, policies, procedures (standard operating procedure), quality standards, practices, resources, specifications, and the arrangement of activities relevant to a particular product or service.

b. Quality Assurance

Quality assurance is also a part of quality management, but it is focused on providing confidence that quality requirements will be fulfilled. In other words, it pertains to all those planned and systematic actions necessary to provide adequate confidence that a product will satisfy the requirements for quality. This is a fundamental shift in concept from the reactive downstream approach of quality control by means of detection, to a proactive upstream approach that controls and manages the upstream activities to prevent problems from arising.(ICAO, 2010).

Quality assurance's main purpose is to verify that control is being maintained. Performance is evaluated after operations, and the resulting information is provided to both the operating forces and others who have a need to know. Others may include plant, functional, or senior management; corporate staffs; regulatory bodies; customers; and the general public.(Eldin, 2011)

Another description on quality assurance, its 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,(Oakland., 2013). Dale & Cooper, (2014), also suggested 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. Hence, 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. 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 was suggested by,(Lockwood, 2016)**.**

c. Quality Improvement

Quality improvement is one of the focuses of present day nice lookup and practice. Enterprise should enhance the great of product and provider consistently and minimize the value to make consumer satisfactory. In furnish chain circumstance, the stress of chronic enhancement is more and more pressing because the market competition is greater and greater hard. Not solely the core organization but additionally the different members, such as suppliers, sellers, and logistics providers, need to improve their product and carrier respectively to construct the chronic improvement of merchandise and offerings all over the supply chain process. Then, the continual, stable and harmonious ability of great assurance can be established. Furthermore, the core business enterprise and other members must discover the methods and practices improving overall performance in or out of supply chain via benchmarking to make the continual enchantment pace quick than the one of rivals. However, it is ironical that one of the most essential reason,(Sharma, 2015).

Study conducted on Turkey on the effects of total quality management practices on performance and the Reasons of and the Barriers to TQM, 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. Workers' effective knowledge and learning capability will provide sustainability of quality management in the firm. Additionally, learning organizations adapt rapidly to the changes and develop unique behavior, which differentiates them from other firms and enables them to obtain better results. Quality is not only in one department or function; it is also the responsibility of the whole firm. Training should be given to all employees based on the results of the training needs assessment.(Sadikoglu & Olcay, 2014)

Quality improvement is another part of quality management that is focused on increasing the ability to fulfill quality requirements. It is not concerned with correcting errors but concerned with doing things better to improve system efficiency and effectiveness. ISO offers the PDCA cycle as a useful tool for continual improvement. The methodology applies to both high-level strategic processes and to simple operational activities.(ICAO, 2010).

The **PDCA** (**P**lan, **D**O, **C**heck, **A**ct) Cycle is a systematic series of steps for gaining valuable learning and knowledge for the continual improvement of a product or process. PDCA is an iterative four-step quality improvement and productivity improvement process typically used for the better of the business strategy. **PDCA** is a successive cycle which starts off small to test potential effects on processes, but then gradually leads to larger and more targeted change(Vivek & Pratik , 2016).

PLAN: Focused on setting quality objectives: Establish the objectives and processes necessary to deliver results in accordance with the expected target.

DO: Focused on implementing plan and quality system requirements: Quality control will be used to monitor and if necessary, containment / service recovery action may be required to ensure that the implementation will not differ from quality objectives.

CHECK: Focused on providing confidence that implementation and requirement of quality system is achieving the desired objectives. Any deviation will be handled by addressing the root cause and developing Corrective and Preventive Action. Some of activities in this process include audit, data and trend analysis, investigation on deviation, project progress assessment, management review and so on.

ACT: Focused on increasing the ability to fulfill quality management system requirements: If during check, it is proved that implementation of plan has been deviated from quality objective, act will ensure that proposed action plan from check will be deployed. This will ensure that the implementation will be back on track to achieve quality objective. Act will also identify changes for implementation towards continuous improvement.

2.2.2. Pharmaceutical Transportation

The overall pharmaceutical and health care products require special care when being transported, in any transportation ways, especially in air transport. Some shipments need to be delivered on schedule to protect their value of time. Other are fragile products and require special handling based on its nature. Many of the Pharmaceuticals presents a challenge to the shipper. Usually those products need to being shipped quickly with great care because are highly sensitive to environmental factors such as temperature, humidity, pressure, and sunlight. It is challenging to maintain appropriate conditions in secure temperature monitored warehouses. This work become

even more problematic when the pharma products are traveling in an airplanes cargo hold at cruising altitude. In some cases, due to inappropriate handling or storage during air cargo transport the pharmaceutical products are damaged or completely useless. In fact, more than half of all pharmaceuticals that become unusable due to extreme temperatures do so while in the airport or on the aircraft, (IATA, 2014).

I. Definition of Distribution

Distribution is the procedure of making a product or carrier accessible for use or consumption by way of a consumer or commercial enterprise user, using direct means, or the usage of oblique skill with intermediaries. Or are the movement of goods and services from the supply through a distribution channel, right up to the remaining customer, purchaser or user, and the movement of charge in the contrary direction, right up to the unique producer or supplier,(Ehikwe, 2002). Havalder & Cavall, (2007) have defined distribution the management of all activities which facilitate movement and consolidation of time and place utility in goods. It's the art and science of determining requirements, acquiring them, distributing them, and finally maintaining them in operationally ready conditions for their entire lives. (Sheelker, 2004) generally classified distribution as channel members and distribution. The channel members mainly include; wholesalers, retailers and agents, whereas physical distribution comprises: transportation, inventory management, packing, warehousing, and order processing, material management, and customer's service.

From the customer's perspectives, then, distribution service is the mechanism that assures goods will be available, (Perreault, et al., 2010). Distributions generally regarded as part of a general logistics concept, which also includes marketing customer service (Mentzer, et al., 2001). As (Xing & David, 2010) declared, distribution deals with finished products and is considered as a part of a firm's outbound logistics that incorporates a relationship between the firm and its customers.

II. Good Distribution Practices

The distribution says that all transporting, storing and product managing activities of a commercial enterprise and a whole channel system should be coordinated as one machine that seeks to limit the whole price of distribution for a given customer carrier degree,(Perreault, et al.,

2010). This systems approach to good distribution management results in lower costs and better customer service which help to increase customer value and customer satisfaction. The objective of good distribution management (GDP) is the minimization of total cost with the maximization of time and place utility in goods,(Coyle, et al., 2003). Early work in the field was concerned with the realization of cost savings. But this cost savings was unconstrained while good distribution service levels provided an inherent constraint upon good distribution system. Good distribution costs, i.e., transportation, warehousing, inventory, order processing, etc., are directly related to the level of service provided. No reasonable cost reduction decision can be implemented without consideration being given to the level of good distribution service necessary for a company to retain its competitive position in the market place.

III. Worldwide Good Distribution Practices

Good Distribution Practice (GDP) is that section of first-rate assurance which ensures merchandise are persistently stored, transported and dealt with below appropriate conditions as required by way of the advertising authorization or product specification. With increasing regulatory scrutiny pharmaceutical supply chain stakeholders need to focus their efforts on assembly the requirements of storage, transport and coping with of time and temperature-sensitive products. However, there are many factors to consider the temperature controlled distribution and storage of pharmaceutical products. Regulatory GDP guidance has large impact on the manufacture and distribution of pharmaceutical products and with over 30 regulations worldwide, it is a very complex environment. (Cold Chain IQ, 2018).

Pharmaceutical and health care products and should be stored and transported under conditions which ensure that their quality is maintained. Transportation should be regarded as an extension of the storage activities and each journey should be treated as unique, with the length and complexity, as well as any seasonal variations being considered when choosing the packing method and mode of transport. (Guidance for transportation of pharmaceutical in Kenya, 2019).

The thesis was like to look at some GDP related international standards and regulation for pharmaceutical and life science products.

a. European Union Good Distribution Practices (EU GDP)

Good storage and distribution practices apply to all organizations and individuals involved in any aspect of the storage and distribution of all drug products. Storage and distribution processes

may involve a complex movement of product around the world, differences in documentation and handling requirements, and communication among various entities in the supply chain. The good storage and distribution practices described in this chapter should facilitate the movement of drug products throughout a supply chain that is controlled, measured, and analyzed for continuous improvements and should maintain the integrity of the drug product in its packaging during storage and distribution.(USP-36, 2013)

The European commission has published EU Guidelines on Good Distribution Practice (GDP) in 1994. Revised guidelines were published in March 2013 in order to take into account recent advances in practices for appropriate storage and distribution of medicinal products in the European Union, as well as new requirements introduced by Directive 2011/62/EU(European Commission, 2013).

The wholesale distribution of medicinal merchandise is an essential undertaking in built-in grant chain management. Today's distribution community for medicinal products is an increasing number of complicated and involves many players. These Guidelines lay down excellent equipment to help wholesale distributors in conducting their activities and to stop falsified drugs from getting into the felony grant chain. Compliance with these Guidelines will ensure control of the distribution chain and therefore keep the exceptional and the integrity of medicinal products.

- ✓ According to Article 1(17) of Directive 2001/83/EC, wholesale distribution of medicinal products is 'all activities consisting of procuring, holding, supplying or exporting medicinal products, apart from supplying medicinal products to the public. Such activities are carried out with manufacturers or their depositories, importers, other wholesale distributors or with pharmacists and persons authorized or entitled to supply medicinal products to the public in the Member State concerned'.
- ✓ Any person acting as a wholesale distributor has to hold a wholesale distribution authorization. Article 80(g) of Directive 2001/83/EC provides that distributors must comply with the principles of and guidelines for GDP.
- ✓ Possession of a manufacturing authorization includes authorization to distribute the medicinal products covered by the authorization. Manufacturers performing any distribution activities with their own products must therefore comply with GDP.

- ✓ The definition of wholesale distribution does not depend on whether that distributor is established or operating in specific customs areas, such as in free zones or in free warehouses. All obligations related to wholesale distribution activities (such as exporting, holding or supplying) also apply to these distributors. Relevant sections of these Guidelines should also be adhered to by other actors involved in the distribution of medicinal products.
- ✓ Other actors such as brokers may also play a role in the distribution channel for medicinal products. According to Article 85b of Directive 2001/83/EC, persons brokering medicinal products must be subject to certain provisions applicable to wholesale distributors, as well as specific provisions on brokering.

The guidelines organized into 11 chapters.

Chapter 1: Quality Management

- ✓ Wholesale distributors must maintain a quality system setting out responsibilities, processes and risk management principles in relation to their activities.
- ✓ All distribution activities should be clearly defined and systematically reviewed. All critical steps of distribution processes and significant changes should be justified and where relevant validated.
- ✓ The quality system is the responsibility of the organization's management and requires their leadership and active participation and should be supported by staff commitment.

Chapter: Personnel

The correct distribution of medicinal products relies upon people. For this reason, there must be sufficient competent personnel to carry out all the tasks for which the wholesale distributor is responsible. Individual responsibilities should be clearly understood by the staff and be recorded.

Chapter 3: Premises and Equipment

Wholesale distributors must have suitable and adequate premises, installations and equipment, so as to ensure proper storage and distribution of medicinal products. In particular, the premises should be clean, dry and maintained within acceptable temperature limits.

Chapter 4: Documentation

Good documentation constitutes an essential part of the quality system. Written documentation should prevent errors from spoken communication and permits the tracking of relevant operations during the distribution of medicinal products.

Chapter 5: Operations

All actions taken by wholesale distributors should ensure that the identity of the medicinal product is not lost and that the wholesale distribution of medicinal products is performed according to the information on the outer packaging. The wholesale distributor should use all means available to minimize the risk of falsified medicinal products entering the legal supply chain.

Chapter 6: Complaints, Returns, Suspected Falsified Medicinal Products and Medicinal Product Recalls

This chapter deals with customer related feedback and information recording and handling in according to written procedures. Records should be made available to the competent authorities. An assessment of returned medicinal product should be performed before any approval for resale.

Chapter 7: Outsourced Activities

This chapter defined and clarify for activities, if any, that are outsourced to third should be correctly defined, agreed and controlled in order to avoid misunderstandings which could affect the integrity of the product. There must be a written contract between the contract giver and the contract acceptor which clearly establishes the duties of each party.

Chapter 8: Self-Inspections

Self-inspections should be conducted in order to monitor implementation and compliance with GDP principles and to propose necessary corrective measures.

Chapter 9: Transportation

It is the responsibility of the supplying wholesale distributor to protect medicinal products against breakage, adulteration and theft, and to ensure that temperature conditions are maintained

within acceptable limits during transport. Regardless of the mode of transport, it should be possible to demonstrate that the medicines have not been exposed to conditions that may compromise their quality and integrity. A risk-based approach should be utilized when planning transportation.

Chapter 10: Specific Provisions for Brokers

A 'broker' is a person involved in activities in relation to the sale or purchase of medicinal products, except for wholesale distribution, that do not include physical handling and that consist of negotiating independently and on behalf of another legal or natural person. They are subject to a registration requirement. They must have a permanent address and contact details in the Member State where they are registered. They must notify the competent authority of any changes to those details without unnecessary delay.

Chapter 11: Final Provisions

This chapter defines and clarify the current applicable of the Guidelines on Good Distribution Practice of medicinal products for human use.

b. WHO-GDP Guidelines

GDP, Good Distribution Practices for Pharmaceutical Products, is guideline published by WHO annex 5. Distribution is an essential undertaking in the built-in supply-chain management of pharmaceutical products. Various people and entities are commonly responsible for the handling, storage and distribution of such products. In some cases, however, a person or entity is solely concerned in and accountable for certain factors of the distribution process. The pointers use in ensuring the high-quality and identity of pharmaceutical products in the course of all aspects of the distribution process. These components include, however are not limited to procurement, purchasing, storage, distribution, transportation, repackaging, relabeling, documentation and record-keeping practices.

2.2.3. Pharmaceutical Distribution Quality Management System Practices

A research of this kind serves to integrate the research and the practice of the QMS in Pharmaceutical Transportations in Ethiopian Cargo Logistics& Services which will help the future researchers, and practitioners employing the suitable guideline or practice to develop their

decisions in advancement of the industry. Regarding the QMS in pharmaceutical and diverse drivers of quality are then identified, (Dean & Bruttin, 2001).

In keeping with the ISO 9001 definition (ISO,2015), a QMS is a formal system that helps coordinate and direct an organization's activities to meet both customer needs and regulatory requirements. Central to the QMS is the philosophy of continuous improvement, in order to improve effectiveness and efficiency. To deliver a successful QMS the correct management responsibilities need to be in place together with appropriate leadership within the organization (Savin, 2016). For pharmaceuticals it is customary to prefix the QMS with the nature of the industry – Pharmaceutical Quality System as set out in ICH Q10 (ICH, 2008).

ISO 9001:2015 specifies requirements for a quality management system when an organization:

a) needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and
b) aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

All the requirements of ISO 9001:2015 are generic and are intended to be applicable to any organization, regardless of its type or size, or the products and services it provides (ISO 9001:2015, 2022). The following Quality Management Principles apply to the broader sphere of Business Management which underlies the ISO 9000 series of Quality Assurance Standards: (ECAR, 2016)

- Customer focus
- Leadership
- Involvement of people
- Process approach
- Systems approach to management
- Continual Improvement
- Factual Approach to decision-making
- Mutually beneficial supplier relationships

2.3. Empirical literature review

The drivers for ISO 9001 certification vary from one company to another and from one country to another, though the basic themes supporting ISO 9001:2015 were the customer satisfaction and continual improvements. (Kumar & Balakrishnan, 2011), summarizing these drivers as pressures from existing customers, promotional value and the desire of improving management processes and enhancing customer service. (Magd & Curry, 2003) as cited by (Kumar & Balakrishnan, 2011), studied ISO 9001:2015 in Egypt and they concluded that the most common reasons for seeking certification in Egypt were to improve the efficiency of the quality system and pressures from competitors/foreign partners.

(Daniel, 2010), in his study on the impact of ISO 9000 certification on Quality management practices in EFFORT corporations in Ethiopia, concluded that the main drivers for the decision to go from ISO 9000 implementation and certification inside the selected EFFORT organizations were improving the organizations public image and establishing a quality management system.

The perfect motivators enhancing procedure and procedures, enhancing product or provider quality, while the least motivating factor reducing the wide variety of customer audits. Many researchers studied the capability of ISO 9001:2015 in achieving its main objectives of adding value to organizations implementing it in different economies in general or by different sectors in particular. Kumar & Balakrishnan, (2011) referring studies made by (Pan, 2003) discussed ISO 9001 and ISO 14001 implementation in Far East Countries, namely in Taiwan, Japan, Hong Kong and Korea. The study involved investigating firms' motivation for certification, their implementation experiences and the benefits received. The main conclusion for implementing ISO 9001 in these countries was positive in general with some differences in motivation for and benefits gained after implementing ISO 9001. He concluded that there are common factors between these countries to go for ISO 9001 certification, namely, external pressure, gaining competitive edge, internal and external portions and improvement of public relations. The common benefits of ISO 9001 certification among these countries are improved competitive edge, and improved public relations.

Although to a varying level of importance, several empirical researches by(Forgaciu & Rahau, 2008), revealed that well-managed quality systems will have impact on:

- customer satisfaction, loyalty and repeat business
- market share
- operational efficiencies
- flexibility and ability to respond to market opportunities
- effective and efficient use of resources
- cost reductions
- competitive advantages
- participation and motivation of human resources
- improved internal communication
- industry reputation better advertising potentials
- control on all processes
- improved delivery and reduction of defective products

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

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

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

- Society oriented gaps (Corporate Social Responsibility, Environmental Management and Sustainability

Global pharma industry is booming – the market for temperature management services is estimated at US$8.36 billion in 2014 and is projected to rise to US$10.28 billion by 2018. However, air cargo share of global pharma product transport has declined from 17% share in 2000 into 11% share in 2013(IATA, 2014).

According to (Guoxu, et al., 2021) the active pharmaceutical ingredient (API) manufacturers in China from 2010 to 2019, the linear regression with Pearson correlation coefficient is used to find the correlations between the proposed QMS operation indicators and performance indicators. (2) A stepwise multiple linear regression is used to identify the independent operation indicators with the biggest impact on a given performance indicator. (3) The Akaike Information Criterion is used to predict the performance indicators based on the operation indicators. The results (1) Correlation: the right-first-time rate correlates strongly with various changes and deviations; the customer complaints correlate with changes, deviations, and CAPAs; the deficiency rate of foreign inspections correlates with deviations and CAPAs; and the CAPA on-time completion rate correlates with changes, deviations, and the ratio of employees in quality. (2) Impact: the right-first-time rate and the customer complaints are mostly impacted by the total deviations; the deficiency rate of foreign inspections is mostly impacted by deviations in equipment and instrument, and deviations due to human error; the CAPA on-time completion rate is mainly impacted by deviations in facility and utilities. (3) Predictability: the right-first-time rate, the customer complaints, the deficiency rate of foreign inspections, and the CAPA on-time completion rate can all be predicted based on the existing data with statistical significance.

The predominant causes for this decline are a lack of compliance, standardization, accountability and transparency throughout the air transport furnish chain. The end result of this screw ups has end result products are rendered worthless and unsafe for patients due particularly to temperature deviations. In fact, over 50% of all temperature excursions occur while products are in the hands of airlines and airports, in figure, annual product losses range between US$2.5-12.5 billion, which is unacceptably high in a US$300 billion a year market.

Range of internal and external factors could also explain the motive to integrate forward for distribution. External factors include customer demand and the potential benefits involving

differentiation, increased information about customers, and supply chain efficiency improvement. Whereas, the most important internal factor driving the integration is company's Supply Chain positioning strategy. And, this affects company's functions, roles, required resources, added value, and competitiveness. All in all, the forward vertical integration for distribution creates potential for selling more products (Guan &Rhome, 2012).

Lack of strong quality sense, superficial of quality management activities instead of fundamentality, the focus of quality management is not for customer satisfaction are identified as a limitation of quality management initiatives in Ethiopia. In addition, as the result of poor management commitment in quality, most enterprises don't have their own business culture to support total employees' involvement in quality improvement. (Fasika BeteKitaw, 2003).

When we come to Ethiopian Airlines Quality Management implementation, there is corporate QMS & SMS department which oversite all divisional QMS & SMS departments, that are responsively for eight divisions and overall company compliance on quality and safety of the airlines.

For the last two decades' Ethiopian airlines is a certified IOSA (IATA Operational Safety audit) company, the audit will be conducted within two years' interval. Having IOSA audit mean the company is compliant with its operational management and control system, by international recognized and accepted evaluation system.

As per IATA CEIV pharma report (2021), Ethiopian airlines is also certified on IATA CEIV pharma as of December, 2021.CEIV pharma, helps an organization and an entire air cargo supply chain to get the right track to achieve pharmaceutical handling excellence, the certificate also ensure international and national compliance to safeguard product integrity of special air cargo needs.

2.4. Conceptual Framework of the study

Based on the nature of the study and the above literature reviews, the conceptual framework is proposed as the following figure.

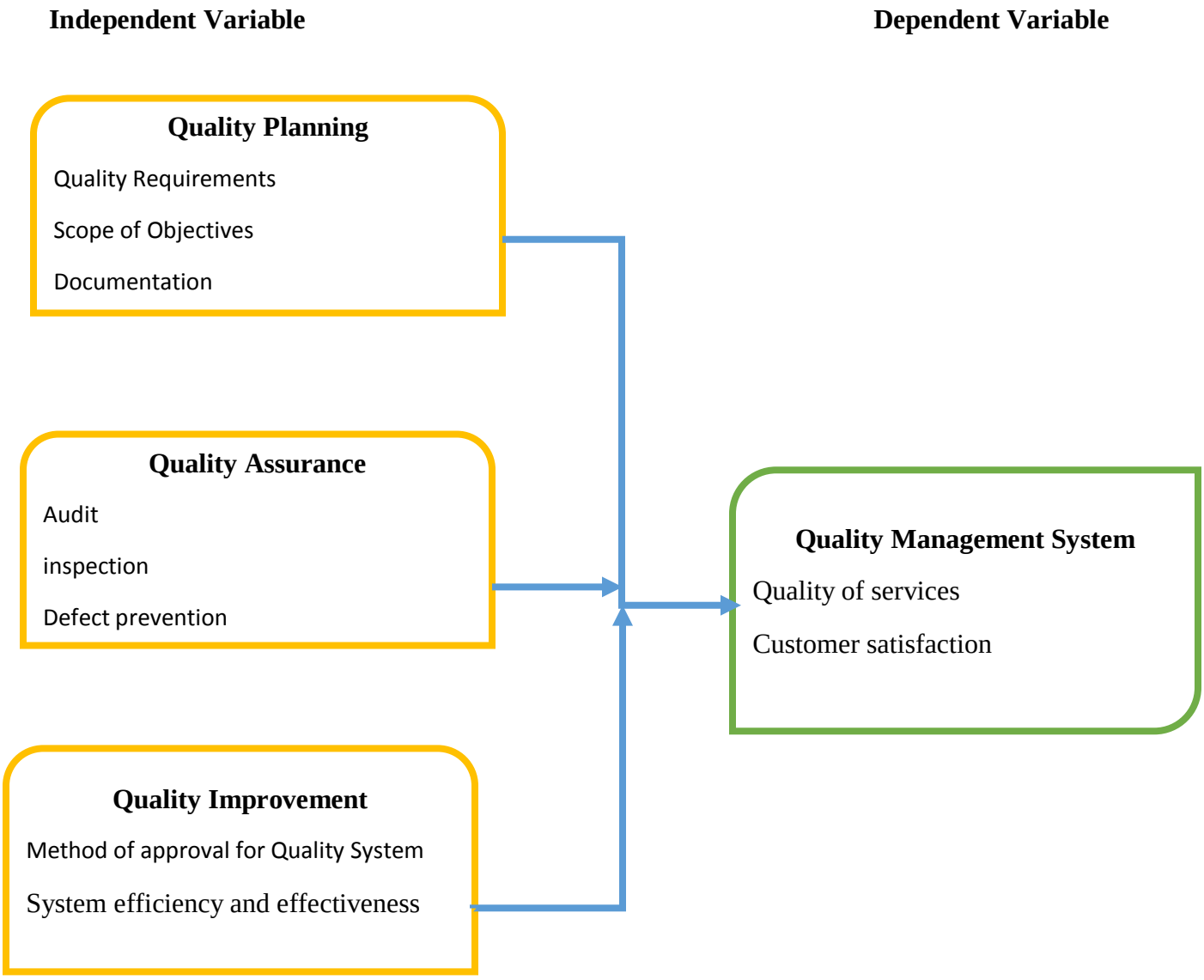

Figure 2.4. Conceptual framework

Adopted from Guidance on the interpretation and implementation of European Good Distribution Practice (2013)

2.5. Summary of Literature Reviews

Upon reviewing the previously highlighted guidelines and the practices that are widely applied in the pharmaceutical industry, it was noticed that there is an abundant number of papers and articles that explain the general guidelines and practices but the literature lack those describing application; case studies of the pharmaceutical factories applying those guidelines and significance of those guidelines and practices.

It is recommended that the literature would invest more in the area of application and significance of guidelines and practices. In line with that, there are some new practices that are recently applied to the pharmaceutical industry though they are widely applied in non-pharmaceutical industries, such as: the lean manufacturing; the Six Sigma; the total quality management. Both managers at the pharmaceutical industry and literature should focus on the adoption of such practices into the pharmaceutical industry making use of the previous research in the non-pharmaceutical industry application. Many case studies should be done to prove the feasibility of such practices.

CHAPTER THREE

METHODOLOGY

3.1. Description of the Study Area

Ethiopian Cargo & Logistics is the largest cargo network operator in Africa and one of the major global cargo carriers with a modern warehouse of 1million tons storage capacity. Currently, it has an annual cargo uplift of 432,417 tons and an estimated cargo uplift of 493,211tons by end of 2019/2020.

The airline providing freight services to our global customers in over 57 global destinations in Africa, the Gulf, Middle East, Asia, Europe and the Americas. Ethiopian airlines have been one of the vanguards of the global cargo business serving customers with our 12 dedicated freighters including 10 Boeing B777-200LRF and 2 Boeing B737-800F. Besides, Ethiopian has recently reconfigured its passenger aircrafts to boost cargo capacity and provide essential services at a time when they are desperately needed.

Ethiopian Cargo Pharma Wing, a department within Cargo & Logistics Services, have dedicated team specialized on healthcare logistics. A thorough knowledge, training and experience of our management and cool chain expert towards healthcare logistics, help to put a legacy product named “Pharma Wing” that was exploit the benefit of having modern freighter & belly hold fleet, 1-million-ton annual capacity state of the art facility which is +56% is dedicated for cold chain facility, best connectivity, freighter network on major trade lanes, best geographical location of the carrier’s hub,(ETH, 2021).

3.2. Research Approach

Researchers usually handle numerous problems and apply research methods to get the best guess answers to their questions. They may use a single study or a combination of two designs. The investigator has to decide about the types and combinations of research forms that best serve the goals of the study. Broadly speaking, there are two main domains of research frequently observed in the literature and these include Quantitative and Qualitative research(John, et al., 2007). The research has used quantitative approach on collecting and analysis of the data.

3.3. Research Design

There are multiple kind of paper design methods used like and related researches, such as explanatory, comparatives and case study and commonly all descriptive case studies.

The study was descriptive research method to obtain information relating to the research and it is found suitable for collecting, analyzing quantitative data.

Descriptive research is aimed simply at describing phenomena and is not particularly concerned with understanding why behavior is the way it is. This type of research is very useful for setting out baselines or 'templates' of how we think the world is.(John, et al., 2007)

Descriptive Statistics were used for frequency and percentage for analysis purpose and also Microsoft Office Excel and SPSS that was used to generate data presentation using tables, charts, and graphs**.**

In addition to descriptive analysis the research has also used inferential statistics to find the factor that affecting of quality management and its three dependent variables.

3.4. Population and Sample

3.4.1. Population of the Study

The study has used an intended target population, who have a relationship with pharmaceutical transportation process. The total population of Ethiopian Cargo & Logistics Services is 852 employees (December, 2021 data). Due to time and resource scarcity the research was use selected sample from the total population. Which is 600 target population, whom are directly involved in cargo transportation operational activities.

3.4.2. Sample Method

The sampling technique was use probable sampling in which each sample has a known population,(Greener, 2008).

Each groups are subdividing into cluster, who have similar jobs, namely operational personnel in handling and transporting with in ECLS, Quality Assurance Team, who are responsible for quality management (QMS) and safety management (SMS), Cargo facility maintenance, and ECLS managements representative in Addis Ababa, Ethiopian.

3.4.3. Sample Size

The research has used below formula to determine the size of the sample. Taro Yamane formula, provides a simplified formula to calculate sample sizes. This formula was used to calculate the sample sizes. A 95% confidence level and P = .5 are assumed.

$n = N / [1 + N (e)^2]$

Where n is the sample size,

N is the population size, and

e is the level of precision.

$n = 556 / [1 +556 (0.05)^2]$

Sample size of the study have used 240 out of 600 populations.

3.5. Data Source and Collection

The research used two types data collection method, namely primary and secondary data.

3.5.1. Primary Data

The primary data was collected from volunteer participant as a direct source of information. The data collection method was through semi-structured questionnaires, interview and survey from selected sample participant from population.

3.5.2. Secondary Data

The secondary data source was collected from literature on quality management system and pharmaceutical transportation, international manuals and guidelines company's' manuals, report, company's and different website, journal and database with available and accessible sources.

3.6. Data Analysis

This stage is where the study was collect data converted and analysis into meaningful insights which enable as to propose better quality management system practices on pharmaceutical transportation. Since this is case study with best practices from airlines industry, its more quantitative approach techniques and some qualitative approach.

The data was analyzed based on descriptive statistics, the questionnaire could let the respondents give their responses according to their personal experiences and opinions, to the different variables by point Likert scale (e.g. a scale from 1 to 5, strongly disagree = 1, to strongly agree = 5), open-ended and closed ended questions by using SPSS. The statistics will consist data collection, interpretation into meaningful data, and validation. In addition to that binary logistic regression used to assess the factors and its significance relationship.

3.7. Ethical Considerations

Every person involved on this research was respect their privacy and dignity. ECLS authorization have given for the research on the use of company data that doesn't violate non-disclosure agreement, confidentiality, and international documents based on their legislation rules. Additionally, all the reference documents, articles and reference literature sources was recognized and quoted with copy rights standard.

3.8. Reliability

Reliability estimates the consistency of the measurement or more simply, the degree to which an instrument measures the same way each time it is used under the same conditions with the same subjects (John, et al., 2007).The research have used The methodology of Cronbach alpha to check the consistency and data reliability. The total reliability was assumed to be above 0.7, which is the acceptable level of reliability for a certain study.

3.9. Validity

Validity is a very important and useful concept in all forms of research methodology. Its primary purpose is to increase the accuracy and usefulness of findings by eliminating or controlling as many confounding variables as possible, which allows for greater confidence in the findings of a given study,(Geoffrey, et al., 2005).

In order to confirm the research validity, the draft questionnaire have been reviewed by selected participants and modification was made accordingly so that the final questionnaire was fulfilled the study area accurately.

CHAPTER FOUR

DATA PRESENTATION, ANALYSIS AND INTERPRETATION

4.1. Introduction

In this chapter, the collected data from employees of Ethiopian Cargo & Logistics Services are presented, interpreted and analyzed in order to realize the ultimate objective of the study. Accordingly, demographic profile of the respondent, descriptive analysis and binary regression analysis was discussed. In order to address the research questions, 240 questionnaires were prepared and distributed to employees, out of these questionnaires 232 were filled and returned, the rest 8 questionnaires were unreturned, and no questionnaires were discarded due to missing data.

Table 4.1 Overall Response Rate

Description	NUMBER	PERCENT
Number of questionnaires distributed	240	100
Number of questionnaires Collected	232	96.67
Number of total usable questionnaires	232	96.67

4.2. Socio demographic characteristics of respondents

The total participants were 232. Among the participant's gender 124(53.4%) were male and 108(46.6) were female; 176of them 232 (75.86%) age found between 26-30 and majorities 167(71.98%) of education level was degree holders and in terms of experience half of them 117(50.4%) had 6-10 years.

Table 2 4.2. Socio demographic characteristics of respondents

Variable	Frequency	Percent
Gender		
Male	124	53.4
Female	108	46.6
Age		
<25	25	10.77
26-30	176	75.86
>31	31	13.36
Education		
Diploma	42	18.1
Degree	167	71.98
Masters	8	3.4
Others	15	6.4
Experience		
0-5 years	78	33.6
6-10 years	117	50.4
11-15 years	31	13.4
>15 years	6	2.6

4.3. Quality Planning

According to the effect of Quality Planning on Quality management system of pharmaceutical transportationabove half of them 127(54.74%)were strongly agree on their Our company has company manuals for implementing the QMS programme; again above half of them140(60.34%) strongly agree on their company has developed the standard operating procedures (SOPs) and most respondents146(62.93%)agree on I believe there is adequate and appropriate resource are available.

Table 3.3. The effect of Quality Planning on QMS of pharmaceutical transportation

Variable	Frequency	Percent	Mean	Std.dev	Min.	Max.
Our company has a company manuals for implementing the QMS programme			4.56	0.539	2	
Strongly disagree	8	3.43				
Disagree	4	1.7				5
Neutral	5	2.2				
Agree	88	37.93				
Strongly agree	127	54.74				
Our Company has developed the standard operating procedures (SOPs)			4.66	0.473	1	
Strongly disagree	3	1.29				
Disagree	5	2.16				5
Neutral	11	4.74				
Agree	73	31.47				
Strongly agree	140	60.34				
I believe there is adequate and appropriate resource are available			4.31	0.484	3	
Strongly disagree	4	1.72				
Disagree	6	2.59				5
Neutral	2	0 .86				
Agree	146	62.93				
Strongly agree	74	31.90				

The figure below shows that majorities of the respondents 41.4% were strongly disagree on there is develop system of policies & procedures that enable all operational activities to be performed effectively.

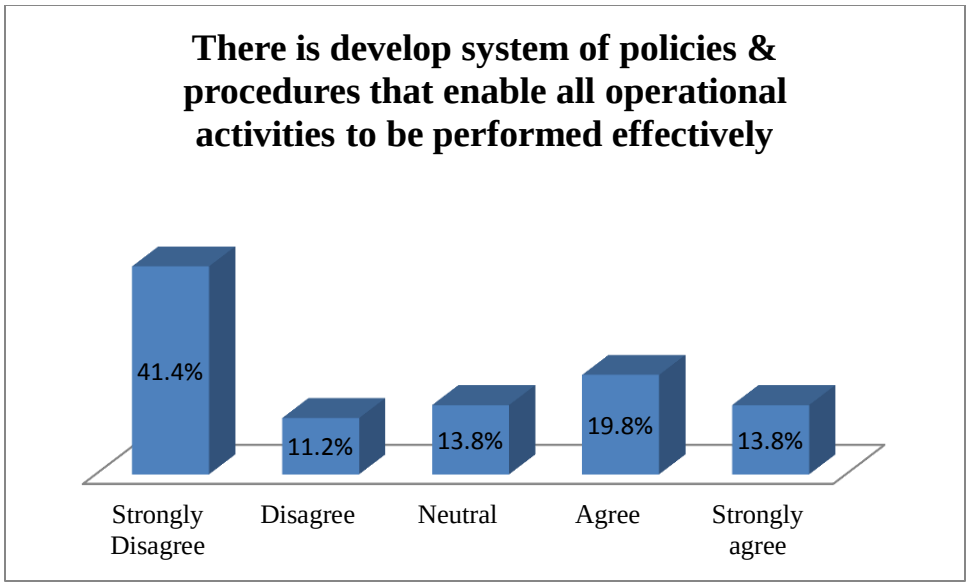

Figure 4. 3. Develop system of policies and procedures that enable all operational activities to be performed effectively

4.4. Quality Assurance

In terms of the effect of Quality Assurance on Quality Management System of Pharmaceutical transportationabove half of the respondents were118(50.86%) strongly agree on their organization have a regularly monitoring (audit, inspection) program for compliance check; majorities of them 146(62.93%) strongly agree on quality audit ensures that initial and continuous training program are implemented and maintained and most of the respondents 119(51.3%)agree on they believe the corrective and preventive actions (CAPA) taken ensures to correct deviations and prevent reoccurrence of the findings.

Table 4.4. The effect of Quality Assurance on QMS of Pharmaceutical transportation

Variable	Frequency	Percent	Mean	Std.dev	Min	Max
Our organization have a regularly monitoring (audit, inspection) program for compliance check			4.50	0.558	1.	5
Strongly disagree	5	2.16				
Disagree	8	3.45				
Neutral	15	6.46				
Agree	86	37.07				
Strongly agree	118	50.86				
Quality audit ensures that initial and continuous training program are implemented and maintained			4.63	0.535	1	5
Strongly disagree	2	0 .86				
Disagree	4	1.72				
Neutral	6	2.59				
Agree	74	31.9				
Strongly agree	146	62.93				
I believe the corrective and preventive actions (CAPA) taken ensures to correct deviations and prevent reoccurrence of the findings			4.24	0.677	2	5
Disagree	2	0.9				
Neutral	26	11.2				
Agree	119	51.3				
Strongly agree	85	36.6				

4.5. Continues Improvement.

According to the effect of continues improvement on quality management System of pharmaceutical transportation most participants 131(56.47%) agree on the employees undertakes regular trainings on employees so as to improve their skills and competences; above half of them 142(62.1%) strongly agree on there is a system in place to reduce the number of quality defects resulting from transportation and majorities 119(51.3%) agree on the organization have an effective change management system.

Table 4.5. The effect of Continues Improvement on QMS of Pharmaceutical transportation

Variable	Frequency	Percent	Mean	Std.dev	Min	Max
The employees undertake regular trainings on employees so as to improve their skills and competences			4.31	0.637	1	5
Strongly Disagree	2	0 .85				
Disagree	5	2.16				
Neutral	7	3.02				
Agree	131	56.47				
Strongly agree	87	37.50				
There is a system in place to reduce the number of quality defects resulting from transportation			4.58	0.583	2	5
Disagree	2	.9				
Neutral	5	2.2				
Agree	81	34.9				
Strongly agree	144	62.1				
The organization have an effective change management system			4.41	0.624	2	5
Disagree	5	2.2				
Neutral	2	.9				
Agree	119	51.3				
Strongly agree	106	45.7				

The figure below shows that above half of them (59.1%) agree on The company uses four steps method, the plan-do-check-act (PDCA) cycle, effectively for continuous improvement initiatives.

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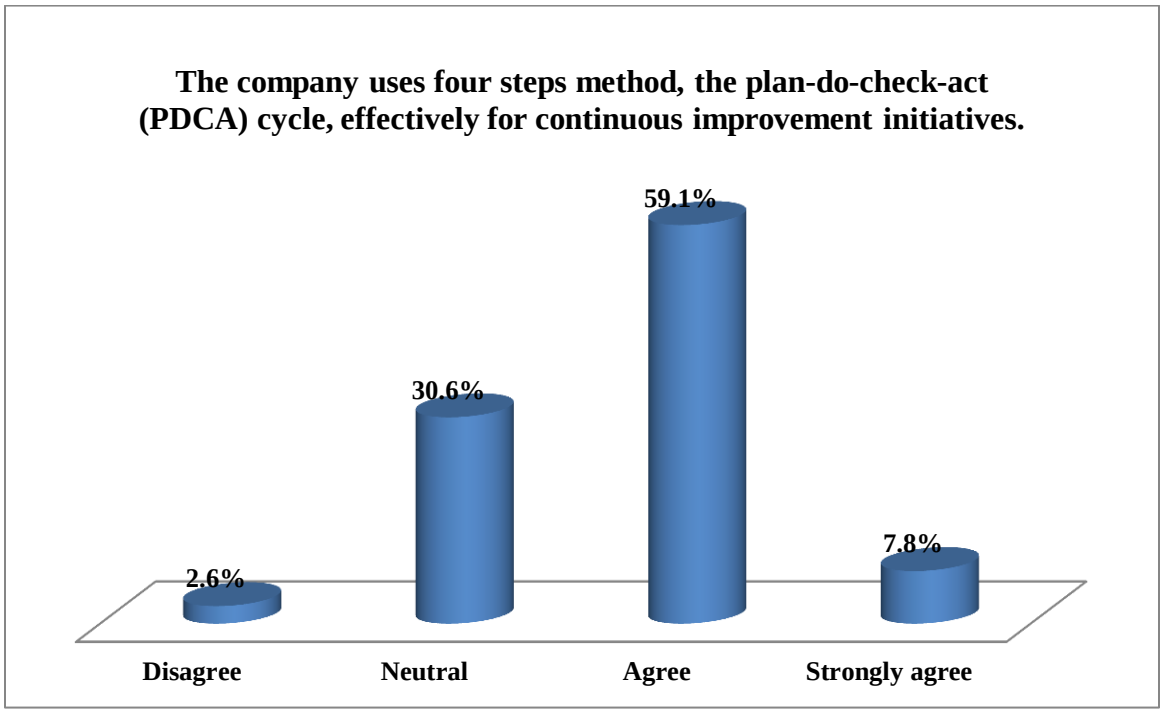

Figure 4.5. The company uses four steps method, the (PDCA) cycle, effectively for continuous improvement initiatives.

4.6. Quality Management System of Pharmaceutical transportation

In terms of theQuality Management System of Pharmaceutical transportation above half of them 122(52.6%)strongly agree on the implemented QMS uses for managing and improving quality of our service; majorities of them 144(62.1%)strongly agree on quality planning is the key factor in enhancing QMS practices in pharmaceutical transportation in our company; most of the participants 144(49.1%) agree on quality assurance is the key factor in enhancing QMS practices in pharmaceutical transportation in our company and majorities of the participants 165(71.1%) strongly agree on continues improvements is the key factor in enhancing QMS practices in pharmaceutical transportation in our company.

Table 4.4. The overall Quality Management System of Pharmaceutical transportation

Variable	Frequency	Percent	Mean	Std.dev	Min	Max
The implemented QMS uses for managing and improving quality of our service			4.52	0.518	3	5
Neutral	2	.9				
Agree	108	46.6				
Strongly agree	122	52.6				
Quality Planning is the key factor in enhancing QMS practices in pharmaceutical transportation in our company			4.57	0.606	2	5
Disagree	2	.9				
Neutral	8	3.4				
Agree	78	33.6				
Strongly agree	144	62.1				
Quality Assurance is the key factor in enhancing QMS practices in pharmaceutical transportation in our company			4.40	0.644	2	5
Disagree	5	2.2				
Neutral	5	2.2				
Agree	114	49.1				
Strongly agree	108	46.6				
Continues improvements is the key factor in enhancing QMS practices in pharmaceutical transportation in our company			4.69	0.518	2	5
Disagree	5	2.2				
Neutral	6	2.6				
Agree	56	24.1				
Strongly agree	165	71.1				

4.7. Regression analysis

The regression analysis was used to establish the relationship that exists between the research variables. The dependent variable was quality management and the independent variables were quality planning, quality improvement and quality assurance. This regression analysis was to know by how much the independent variable explains the dependent variable.

Table 4.5.1. Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics					Durbin-Watson
					R Square Change	F Change	df1	df2	Sig. F Change	
1	.911[a]	.831	.829	.207	.831	373.179	3	228	.000	2.250

a. Predictors: (Constant), Quality planning, Quality improvement, Quality assurance

b. Dependent Variable: Quality management

The Durbin-Watson statistic showed that obtained value was below which is positive auto-correlation. As indicated in the above table the coefficient of determinant R square is 0.831 and R is .911[a]. The coefficient of determinant R square indicates that 83.1% of Quality management. Thus, 16.9% of the variations are accounted for by other factor not presented in the model.

Table 4.7.2. Analytical model

Coefficients

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	.445	.112		3.984	.000
	Quality planning	.123	.037	.123	3.295	.001
	Quality improvement	.012	.028	.012	.423	.673
	Quality assurance	.823	.037	.822	22.141	.000

a. Dependent Variable: Quality management system

b.

From the analytical model developed show that quality planning (β1= -0.123, p= 0.001), Quality improvement (β2= -0.012, p= 0.673) and quality assurance (β3= 0.823, p=0.000) have a positive relation and two of them had significance on quality management system. Findings in the above table shows that the major significance variables were quality planning (P=.001) and quality assurance) (p= 0.000) while the not insignificance variable was quality improvement (p= 0.673). This shows that increases in the quality planning and quality assurance were cause increased quality management system. Except a variable of quality improvement was not significant in the quality management system.

The above table gives the results for the regression coefficient for the multiple linear equation; ($Y=\beta 0+\beta 1X1+\beta 2X2+\beta 3X3+\beta 4X4+\varepsilon$) &by supplying the coefficients it becomes:

where; Y –Quality management system,

X1 –Quality planning,

X2 –Quality improvement,

X3 – Quality assurance

CHAPTER FIVE

SUMMARY, CONCLUSION AND RECOMMENDATION

5.1. Summary

In other study results shows that range of internal and external factors could also explain the motive to integrate forward for distribution. External factors include customer demand and the potential benefits involving differentiation, increased information about customers, and supply chain efficiency improvement. Whereas, the most important internal factor driving the integration is company's Supply Chain positioning strategy. And, this affects company's functions, roles, required resources, added value, and competitiveness. All in all, the forward vertical integration for distribution creates potential for selling more products (Guan &Rheme, 2012). On the current study results shows that from the analytical model developed show that quality planning (β1= -0.123, p= 0.001), Quality improvement (β2= -0.012, p= 0.673) and quality assurance (β3= 0.823, p=0.000) have a positive relation and two of them had significance on quality management system. Findings in the above table shows that the major significance variables were quality planning (P=.001) and quality assurance) (p= 0.000) while the not insignificance variable was quality improvement (p= 0.673).

In other study findings shows that lack of strong quality sense, superficial of quality management activities instead of fundamentality, the focus of quality management is not for customer satisfaction are identified as a limitation of quality management initiatives in Ethiopia. In addition, as the result of poor management commitment in quality, most enterprises don't have their own business culture to support total employees' involvement in quality improvement. (Fasika BeteKitaw, 2003). In this study findings shows that According to the effect of continues improvement on quality management System of pharmaceutical transportation most participants 131(56.5%) agree on the employees undertakes regular trainings on employees so as to improve their skills and competences; above half of them 142(62.1%) strongly agree on there is a system in place to reduce the number of quality defects resulting from transportation and majorities 119(51.3%) agree on the organization have an effective change management system.

5.2. Conclusion

- Among the participant's gender majorities of were male, age found between 26-30, degree holders and had 6-10 years of work experience.
- According to the effect of Quality Planning on Quality management system of pharmaceutical transportation strongly agree on their Our company has company manuals for implementing the QMS programme, their company has developed the standard operating procedures (SOPs) and they believe there is adequate and appropriate resource are available.
- In terms of the effect of Quality Assurance on Quality Management System of Pharmaceutical transportation most of them strongly agree on their organization have a regularly monitoring (audit, inspection) program for compliance check, quality audit ensures that initial and continuous training program are implemented and maintained and they believe the corrective and preventive actions (CAPA) taken ensures to correct deviations and prevent reoccurrence of the findings.
- According to the effect of continues improvement on quality management System of pharmaceutical transportation most participants agree on the employees undertakes regular trainings on employees so as to improve their skills and competences, there is a system in place to reduce the number of quality defects resulting from transportation and the organization have an effective change management system.

5.3. Recommendation

- Make quality risk management as key elements during supply chain and establish risk mitigation tools during supply network.
- Enhance communication about risk elements and controls exercised across the supply chain
- Companies involved in pharmaceutical supply chain operation should adopt the concept of quality risk managements for the goal of business accomplishment by reducing the losses and rejections due to poor quality.
- Each pharmaceutical organization must establish a mechanism for quality risk management during distribution to accomplish the goals of customer satisfaction without apprehension of drug regulatory actions due to quality risk.

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Questionnaires

The purpose of this questionnaire is partial fulfillment for the requirements of master of art degree in logistics and supply chain management at Addis Ababa University College of Commerce. The study conducted under the title Factors Affecting Quality Management System in Pharmaceutical Transportation: In Case of Ethiopian Cargo & Logistics, Addis Ababa, Ethiopia

You are selected randomly and because of the nature of your work environment. You can help by giving your feedback and views. Your answers are completely confidential and will be released only as summaries in which no individuals can be identified

This survey is voluntary. However, you can help us very much by taking a few minutes to share your experiences and opinions. If for some reason you prefer not to respond, please let us know by returning the blank questionnaire.

I would greatly appreciate your participation in this survey. Please help me by completing the questionnaire today.

Your answers to the survey are completely confidential and operate under the ethics standard of the research.

Name: ErmiasAdera

Email: ermacsed@gmail.com

Mobile: +2519991866722

Thank you for your valuable time.

Part A: Demographics

1. Gender **A)** Male **B)** Female
2. Age **A) <25** **B)** 26—30 **C)** 31-35 **D)**>35
3. Education **A)** Diploma **B)** Degree **C)** Masters **D)** Others
4. Experience **A)** 0-5 years **B)** 6-10 years **C)** 11-15 years **D)**>15 years

Please indicate the extent to which you agree with the following statements by ticking on the box you select.

Strongly Disagree=1, Disagree=2, Neither agree or disagree=3, Agree=4, Strongly agree=5

Part B: The effect of Quality Planning on Quality management system of pharmaceutical transportation

No.	Question Items	1	2	3	4	5
5.	There is develop system of policies & procedures that enable all operational activities to be performed effectively					
6.	Our company has a company manuals for implementing the QMS programme					
7.	Our company has developed the standard operating procedures (SOPs)					
8.	I believe there is adequate and appropriate resource are available					

Part C: The effect of Quality Assurance on Quality Management System of Pharmaceutical transportation

No.	Question Items	1	2	3	4	5
9.	Our company has a quality manual for implementing the QA programme					
10.	Our organization have a regularly monitoring (audit, inspection) program for compliance check					
11.	Quality audit ensures that initial and continuous training programme are implemented and maintained;					
12.	I believe the corrective and preventive actions (CAPA) taken ensures to correct deviations and prevent reoccurrence of the findings					

Part D: The effect of Continues Improvement on Quality Management System of Pharmaceutical transportation

No.	Question Items	1	2	3	4	5
13.	The company uses four steps method, the plan-do-check-act (PDCA) cycle, effectively for continuous improvement initiatives.					
14.	The employees undertakes regular trainings on employees so as to improve their skills and competences					
15.	There is a system in place to reduce the number of quality defects resulting from transportation					
16.	The organization have an effective change management system					

Part E: Quality Management System of Pharmaceutical transportation

No.	Question Items	1	2	3	4	5
17.	The quality system is fully documented and its effectiveness monitored.					
18.	The implemented QMS uses for managing and improving quality of our service					
19.	The implemented QMS uses to fulfil the customer's needs and requirements					
20.	Quality Planning is the key factor in enhancing QMS in pharmaceutical transportation in our company					
21.	Quality Assurance is the key factor in enhancing QMS in pharmaceutical transportation in our company					
22.	Continues improvement is the key factor in enhancing QMS in pharmaceutical transportation in our company					