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**Evaluation of Total Quality Management (TQM) ingredients in Sudan  
pharmaceutical industries**

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## الآية

بسم الله الرحمن الرحيم

قال الله تعالى:

{ هُوَ الَّذِي جَعَلَ الشَّمْسُ ضِيَاءً وَالْقَمَرَ نُورًا

وَقَدَرَهُ مَنَازِلَ لِتَعْلَمُوا عَدَدَ السِّنِينَ وَالْحِسَابَ

مَا خَلَقَ اللَّهُ ذَلِكَ إِلَّا بِالْحَقِّ يُفِطُّ الْآيَاتِ

لِقَوْمٍ يَعْلَمُونَ {سورة يونس الآية {5}

صدق الله العظيم

## **DEDICATION**

We dedicate our effort in this work firstly to our families whom guaranteed our well-being and success, and the prayers of our mothers, and the kind hearts of the school of mechanical engineering, and to our passion the mechanical engineer itself.

## **ACKNOWLEDGEMENT**

Our deepest appreciation, thanks and gratitude to the mechanical engineering staff in general and the production department in specific, to all those who spent long days and nights for us to reach this far.

Our gratitude also reach both AZAL and AMIPHARMA factories whom welcomes us with open hands and helped us – as possible as they can – to fulfil our research requirements for our sake, their interests and the pharmaceutical industry in Sudan, our gratitude to our supervisor Dr. Hassan Osman who made time to review the progress of our work as busy as he is. And our greatest appreciation to Nor Aldyn Osman who ensured by himself that we acquire all the information needed to accomplish the study's objective.

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## **ABSTRACT**

Raising quality has become the number one concern for all companies and factories both service and manufacturing sections, the scale goes as high as an entire governments, Total Quality Management is defined as an integrated organizational efforts designed to improve quality at every level to produce a high quality products, Lack of Total Quality Management awareness and the ignorance of its positives outcomes which candecrease the operational costs and raise the quality of the pharmaceuticals products significantly. The pharmaceutical industries is very strict because fatality may occur, and the vulnerability of the environment made it a global priority, which made it very important to increase quality implementation to produce high quality safe products and to decrease the hazard wastes to minimum. This study targets AZAL and AMIPHARMA pharmaceutical factories to review and evaluate the five Total Quality management ingredients (Strategic Commitment-Employee Involvement-Material-Technology-Method), after evaluating the ingredients we concluded that the main setback is in the Strategic Commitment, the problem is to commit the top management to –hard to implement- Total Quality Management (TQM) program which may be found expensive at the start. The minor setback is in AZAL is a weak Employee Involvement plan, both the factories had a standard relationship with the supplier when it comes to the Material, from the results found this study recommends to re-evaluate and re-consider the strategic commitment plan, and to review the supplier-manufacturer standard relationship in regard to the Materials and the Employee Involvement plan.



## التجريدة

تحقيق الجودة اصبح الهدف الاسمى لجميع الشركات والمصانع في قطاعي التصنيع والخدمات، وتطبيقها يمكن ان يشمل مستوى حكومات دول بأكملها، تعرف اداره الجودة الشامله على انها جهد متكامل يسعى لزياده الجودة في كل مرحله من مراحل الانتاج، لأننتاج منتج ذو جوده عاليه. الجهل بفوائد اداره الجودة الشامله والتي ان طبقت يمكن ان تقلل من تكاليف التشغيل وزياده الجودة في المنتجات الدوائيه. لا يوجد في الصناعات الدوائيه مجال للخطأ لان الاخطاء قد تتسبب في وفيات مباشره، كذلك الوضع الحساس للبيئه جعل من تقليل المخلفات الدوائيه الخطره اوليه اولى مما زاد اهميه تطبيق الجودة لزياده جودة المنتجات الدوائيه وتقليل المخلفات الخطره. هذه الدراسه تهدف الى دراسه و تقييم المكونات الخمس لاداره الجودة الشامله ( الالتزام الاستراتيجي - تهيئه وتحفيز الموظفين وتدخلهم في العمليه الانتاجيه - المواد الخام المستعمله - التكنولوجيا - طرق التشغيل واداء العمل ) وبعد تقييم هذه المكونات توصلنا لان هنالك عقبه كبيره وعقبات صغيره، عقبه الكبرى هي في التزام الاداره بتطبيق خطه اداره الجودة الشامله والتي تكون مكلفه في البدايه، العقبات الصغرى في مصنع ازال هي عدم وجود خطه تحفيز للموظفين من الاساس، اما بالنسبه للمواد الخام المستعمله فكلا المصنعين يملكان العلاقه العاديه(علاقه الشاري/البائع) مع المصنع. نتائج هذه الدراسه اوضحت اهميه اعاده النظر وتقييم الالتزام الاداري بنظام اداره الجودة الشامله وكذلك اعاده النظر في العلاقه الطبيعيه بين المصنعين ومورد المواد الخام وخطه تهيئه وتحفيز الموظفين في ازال.

# **Chapter One**

# Chapter One

## INTRODUCTION

### 1.1 Research Background

Raising quality has become the number one concern for all major, med-size, small companies and factories both service and manufacturing sections, the scale goes as high as an entire governments, the term quality depends on two major factors, the first is the purpose of the use for the product, the second is the selling price, those two factors concern both the provider and the customer, and when a product exceeds our expectations that's what we call quality.

The more we commit to quality management implementing the further we extent our reach. Japan in specific took a great care of implementing the quality to all the industries to the letter which transformed post war Japan to the world number one manufacturing power and titled it name as the quality supreme.

Embracing knowledge can't be done without the search of the history and essence of the subject under study, we know for sure that quality goes as early as industry itself, during the middle ages the quality of craft-men products were monitored by guilds since they looked for non-stop improvements, but it really started to make a difference and to be taken seriously during the industrial revolution era.

Total Quality Management is defined as an integrated organizational efforts designed to improve quality at every level and as the process to produce a perfect products by series measures requires an organized effort by the entire company to prevent or eliminate errors at every stage of the production. Pharmaceuticals industry is a major segment of the healthcare system which conducts researching and manufacturing and marketing of medical products and devices.Total Quality Management is a system adopted worldwide in the pharmaceuticals industry and the good implementation of a Total Quality Management (TQM) system is a priority. The responsibility of maintaining the quality of the pharmaceutical products in rests on the Quality Assurance department and there is more to it than mere samples testing and final dosage checking.

## **1.2 Research Problem**

Lack of Total Quality Management (TQM) awareness and the ignorance of its positives outcomes, which candecrease the operational costs and raise the quality of the pharmaceutical products significantly.

## **1.3 Objective**

The objective of this research is to

- Evaluate and Review Total Quality Management (TQM) ingredients in pharmaceutical factories.

## **1.4 Scope**

This study targets the pharmaceutical industry in Sudan, it specifies two factories in Bahri industrial area which are AZAL and AMIPHARMA pharmaceutical factories.

## **1.5 Significant of Research**

The pharmaceutical industries is very strict because fatality may occur, and the vulnerability of the environment made it a global priority, which made it very important to increase quality implementation to produce high quality safe products and to decrease the hazard wastes to minimum.

## **Chapter Two**

# Chapter Two

## LITERATURE REVIEW

### 2.1 Introduction

Definition of the term quality evolved around times, at the early beginning quality meant that a product met its specifications, then it became more statistical when the quality charts got involved, and at last it reached the idea of that quality affects the entire organization, it works as all of the organization seeks to a better products and services, it's not the action of one, it's the action of all.

The purpose of implementing Total Quality Management in pharmaceutical industries are to reduce costs, wastages and increase the efficiency of services. To fully understand the Total Quality Management (TQM) movement, we need to look at the philosophies of notable individuals called 'Quality Gurus' who have shaped the evolution of Total Quality Management (TQM). W. Edwards Deming stressed on improving quality through the using of statistical quality control technique. Deming proposed 14 principles of quality management. Some of which are- Top Management commitment to quality, Continuous search for and correction of quality problems, Effective communication between supervisors and employees, Companywide training and education in quality. Joseph Juran defined Quality as Fitness for Use. Juran is also credited for developing the concept 'Cost of Quality'. He has originated the idea of Quality Trilogy i.e. Quality planning, Quality control and Quality

Improvement. Armand V. Feigenbaum proposed the concept of ‘Total Quality Control’ and advocated the idea of a work environment where quality developments are integrated throughout the entire organization, where management and employees have a total commitment to improve quality and people learn from each other’s successes. This philosophy was adapted by the Japanese and termed “company-wide quality control.” Philip B. Crosby developed the phrase “Do it right the first time” and the notion of zero defects, arguing that no amount of defects should be considered acceptable. Kaoru Ishikawa is best known for the development of quality tools called cause-and-effect diagrams, also called fishbone or Ishikawa diagrams [1].

Total Quality Management (TQM) is widely known for improving quality and other performances such as productivity, profit, market share, and competitive edge of organizations of various types [2].

The need for quality as a fundamental component in the formulation of strategies for organizations and firms to implement Total Quality Management (TQM) is clearly outlined by all quality experts who stated that quality, as a macro function of organizations, must be present in the day-to-day running of an organization, in aspects such as establishment of policies, the decision process, selection of personnel, allocation of resources, definition of priorities and service delivery to satisfy customer requirements. It also stated that the quality approach, as a strategic element, has brought to organizations a new manner of conceiving quality, as it engages the top decision-makers of the organization in the effort for better performance in service delivery, which leads us to the conclusion that quality is no longer an optional extra; it is an essential strategy to survive.



Total Quality Management (TQM) also demands changes, the changes involve moving away from a situation where control is exercised over employees and their activities to an approach where employees are supported and empowered in their attempts to establish continuous improvement. By following this approach employees are forced to continuously develop new ways of doing things and to question the manner in which the organization functions[3].

Total Quality Management (TQM) views an organization as a collection of processes. It maintains that organizations must strive to continuously improve these processes by incorporating the knowledge and experiences of workers, the simple objective of Total Quality Management (TQM) is to do the right thing at the first time every single time; Total Quality Management (TQM) is infinitely variable and adaptable. Although originally applied to manufacturing operations, and for a number of years only used in that area, Total Quality Management is now becoming recognized as a whole concept, not just a single idea. Total Quality Management (TQM) is therefore a solution for improving the quality of products and services. Before one can discuss its concepts, one first needs to discuss, understand and analyze the concept of 'quality' itself.

Quality, Reliability, Delivery and Price build the reputation enjoyed by an organization. Quality is the most important of these competitive weapons and is an extremely difficult concept to define in a few words and it's not only refer to goods and services but includes quality of time, place, equipment and tools, processes, people, the environment and safety, information and measurement [4] . Quality is an ongoing process that has to be so pervasive throughout the entire organization that it becomes its philosophy and culture. All of the organization and each department within

it need to adopt the same strategy, to serve the customer with even better quality, lower cost, faster response and greater flexibility.

Total Quality Management (TQM) is a never-ending goal, there is no satisfaction of a specific situation no matter how good it is. The market is ever changing and the rivals are always developing and researching, so organizations should always look for a better implementation, yet Total Quality Management (TQM) is so important that every step of its implementing is explained and discussed for a success transformation. The fundamental part of implementing Total Quality Management (TQM) is to follow its ingredients[5].

## **2.2 Total Quality Management ingredients**

The first ingredient in quality is the Strategic commitment. Quality is not an ideal state we can reach and maintain, it's a goal we must at all times pursue ,Implementing a new quality system is expensive, we must buy new equipment and re-facilitate, A new quality system with no real commitment from top management will not give back.

The second ingredient is the employee involvement. It is a critical component, and every employee must be responsible, accounting responsibilities for rights and wrongs improve performance. The constant searching for better materials is the third ingredient in quality. The ingredient number four is the technology. Where investing in new machines may prove to be expensive but in return, it improves quality that appears in a better product, less manufacturing time. The last quality ingredient is the methods. They are the operating systems used by the organization during the transformational phase[6].

## 2.3 Total Quality Management Review

To fully understand the Total Quality Management (TQM) movement, we need to look at the philosophies of notable individuals called 'Quality Gurus' who have shaped the evolution of Total Quality Management (TQM). W. Edwards Deming stressed on improving quality using statistical quality control technique. Deming proposed 14 principles of quality management. Some of which are Top Management commitment to quality, Continuous search for and correction of quality problems, Effective communication between supervisors and employees, Companywide training and education in quality. Joseph Juran defined Quality as Fitness for Use. Juran is also credited for developing the concept 'Cost of Quality'. He has originated the idea of Quality Trilogy i.e. Quality planning, Quality control and Quality Improvement. Armand V. Feigenbaum proposed the concept of 'Total Quality Control' and advocated the idea of a work environment where quality developments are integrated throughout the entire organization, where management and employees have a total commitment to improve quality and people learn from each other's successes. This philosophy was adapted by the Japanese and termed "company-wide quality control." Philip B. Crosby developed the phrase "Do it right the first time" and the notion of zero defects, arguing that no amount of defects should be considered acceptable. Kaoru Ishikawa is best known for the development of quality tools called cause-and-effect diagrams, also called fishbone or Ishikawa diagrams[7].

Total Quality Management (TQM) as a management strategy is applied actively by more and more organizations and considered by many in order to obtain the competitive edge. Total Quality Management (TQM) is a

concept rather than a technique. A philosophy stresses a systematic, integrated, and consistent perspective that would involve everyone and everything in the organization[8].

Total Quality Management (TQM) is a management philosophy that builds a customer-driven, learning organization that is devoted to the total customer satisfaction through continuous improvement in the effectiveness and efficiency of the organization and its corresponding processes[9].

A common definition of quality however is a must to prevent confusion among staff and help to resolve any arguments, which may arise from time to time within and between departments in an organization, it's safe to say that every organization must have its own definition of quality, It's also safe to say that the impact of international competition in a sanction-free world market forces organizations to follow multi-dimensional survival strategies in which the potential of each available resource is fully utilized.

Total Quality Management (TQM) is a management strategy that firstly enhances an organizational culture, embracing continuous improvement and realizing the potential of personnel in order to face known problems. Secondly, Total Quality Management (TQM) enhances the integration of quality technologies within each process of the organization in order to provide products and services both economically and customer-friendly

## **2.4 Hard and Soft Total Quality Management Implementations**

Soft practices are long term factors that are related to management issues and aspects and must be considered and targeted in a company's Total Quality Management strategy and subsequent implementation plan [10]. Soft practices generally deal with human resource management and concentrates on behavioral sides including training for employees, management leadership, teamwork, supplier relationship and management, creating value to customers, and achieving customer satisfaction [11]. In order to maximize the effect of soft practices, they should be enhanced by the hard Total Quality Management (TQM) practices [12]. Soft practices are harder to quantify and, therefore, the measurement and assessment of them is a challenging issue for management.

In 1995, Powell asserted that organizations, which implemented soft Total Quality Management (TQM) practices, could perform better than competitors without the associated Total Quality Management philosophy.

The Hard Total Quality Management (TQM) practices are related to improvement tools and systems of quality management and are expected to enhance and support the implementation of soft Total Quality Management (TQM) practices [13]. Hard aspects generally include practices such as quality systems, continuous improvement, process management, and information feedback [14]. While soft aspects are regarded as intangible, hard aspects are more tangible and, therefore, easier to be measured and assessed [15]. The importance of hard aspects of Total Quality Management (TQM) should not be underestimated.

Deming in 1986 pointed to the crucial role of hard aspects by stating, “in God we trust - all others must use data”. Goetsch and Davis 1994 defined management tools as “collecting and displaying information in ways to help the human brain grasp thoughts and ideas that, when applied to physical processes, cause the processes to yield better results”.

## **2.5 The Pharmaceutical industry**

The pharmaceutical industry has an increasingly complex and dynamic environment, there have been a lot of change in the recent years, and this trend is likely to continue. The openings of market, increased buyer – cost sensitivity, global competition and technological advancements have increased levels of uncertainty. There has been an inexorable rise in patient expectations, increased costs of health-care and the inability of economics to meet the increased costs.

Consequently, governments have introduced a number of measures aimed at increasing competition and accountability and thus reducing costs. One major change has been the emergence of the generic drugs, which is a threat to the loyalty of major branded drugs. A generic product is a product manufactured after patent expiry by another manufacturer, normally at a cheaper price, led to the growth of many organizations that has rested on the success of technological advances in manufacturing new product[16].

Apart from safety, the pharmaceutical industry is heavily regulated and the reasons are obvious: mistakes in product design or production can have severe, even fatal, consequences for patients[17].

Examples of recall of the drugs from the market are:

a) VIOXX- is in a class of drugs called non-steroidal anti-inflammatory drug, which was used to reduce pain, inflammation and stiffness. It got approval from United States Food and Drug Association (FDA) in 1999. Merck, the manufacturer of the drug, voluntarily withdrew it from the market due to safety

Reasons- increased risk of Heart attacks. Within this period, the drug caused nearly 28000 or more cases of heart attack or sudden cardiac deaths.

b) Thalidomide (KEVADON) was launched in 1957 as a treatment for morning sickness during pregnancy. Heavily marketed, its sales soon spread abroad. It took four years before the connection was made between the drug and its side effects. By which time at least 10,000 children had been born with shortened limbs and other complications. The scandal transformed drug regulation. Drug Research regulations made more stringent [18].

The customer demands made it possible for the small companies to compete in the market as they used the flexibility and innovation to the limit and that granted them an advantage that allowed them to compete to an extent.

The technological advancement will provide a new set of technology, which may prove hard to deal with by an ordinary employees, some may need an Information Technology(IT) specialist, and so the pharmaceutical companies need to think differently on how they going to respond to the always demanding and always shifting market.

## **2.6 Total Quality Management implementation in pharmaceutical industries**

Total Quality Management (TQM) implementation in either Pharmaceuticals, medical devices, biotech or host of other life sciences manufacturer can be difficult to achieve and maintain whether a company is striving to maintain high level of quality for its own sake or keep up with International Standardization Organization (ISO), Food Drugs Administration (FDA), Europe Middle East and Africa (EMEA) Regulations.

Total Quality Management (TQM) cannot be easily achieved without considerable organizational and human resources, it is a method by which management, and employees can become involved in the continuous improvement process of the production of goods and services. It is a combination of quality and management tools aimed at increasing business and reducing losses due to wasteful practices.

The concept of quality assurance and quality control develops and follows Standard Operating Procedures (SOP) directed towards assuring the quality, safety and efficacy. World Health Organization (WHO) has issued a primary or fundamental regulation to pharmaceutical industries entitled Good Manufacturing Practice (GMP) for pharmaceuticals. Based on World Health Organization (WHO) and Good Manufacturing Practice (GMP), many countries have formulated their own requirements for Good Manufacturing Practice (GMP). In USA, as the Food and Drug Administration (FDA) has a mandate that the marketed drug product be safe and effective, the drug product must meet certain criteria for quality and



purity. The Food and Drug Administration(FDA) has issued regulatory guidelines known as current Good Manufacturing Practice (cGMP) and Good Laboratory Practice (GLP) to assure the public that the marketed drug product has been properly manufactured and clinically tested respectively. According to food and Drug Administration(FDA) regulations, a drug product that does not meet the Good Manufacturing Practice(GMP) requirements is considered unacceptable. Thus, quality is critically important ingredient to organizational success today, which can be achieved by Total Quality Management (TQM) in an organization wide approach that focuses on quality as an overarching goal [19].

The poor quality of pharmaceutical products, drugs in specific are not only a health hazard but also a waste of money for both government and individual consumers.

The difficulties that faced the pharmaceutical companies are the same that faced any other company in any other industry in any other place of the world, those difficulties exist because it's so hard to convince the entire organization to embrace the culture of continuous improvements, and it's also difficult to overcome the lack of confident through the entire levels of management, and the difficulty of understanding Total Quality Management (TQM) in itself.

## **2.7 Good Manufacturing Practice (GMP)**

According to the World Health Organization (WHO), Good Manufacturing Practice (GMP) is part of quality assurance which ensures that products are consistently produced and controlled according to the

quality standards suitable for their intended use and as required by the marketing authorization. According to the current Good Manufacturing Practice(GMP), the modern quality systems include quality, quality by design and product development, quality risk management, change control, quality unit as well as Corrective Actions and Prevention Actions (CAPA).

Compliance towards Good Manufacturing Practice(GMP) requirements minimizes the contamination risk, mix-ups or any sort of error. International regulatory authorities such as World Health Organizational(WHO) established its Good Manufacturing Practice(GMP) guidelines initially in 1967. Later in 1972, Pharmaceutical Inspection Cooperation Scheme adopted its guidelines, and followed by authorities at country level such as United States Food and Drug Administration (FDA), Malaysian National Pharmaceutical Control Bureau (NPCB) and Chinese State Food and Drug Administration (SFDA). The regulations are adopted to safeguard consumers, provide information for medical practitioners and improve the quality standards of the medicines produced by manufacturers.

World Health Organizational (WHO) estimates that 25% of the medicines supplies in the developing countries are sub-standard, about 10% of the supplied medicines in developed countries and approximately 30% in the developing countries are counterfeit medicines. The challenge faced by the regulatory authorities is in combating counterfeit, substandard, fake, contaminated or adulterated medicines that threaten public health however, without impeding the registration of lifesaving drugs.

Pharmaceutical authorities and manufacturers play a crucial role in the implementation of Good Manufacturing Practice (GMP) guidelines and requirements to ensure the quality, safety, efficacy, affordability and accessibility of medicines.

The role of the regulatory authorities is to ensure the quality, efficacy and safety of medicines and that they are appropriately manufactured. Other aspects include, advertisement control, accessible information about the rational use of drugs as well as the storage, distribution and dispensing in addition to the enhancement of the affordability and accessibility of medicines as documented in the 13th International Conference of Drug Regulatory Authorities in Berne 2008.

Good Manufacturing Practice (GMP) inspection is one of the essential tools to ensure that manufacturers comply with the requirements adopted by the regulatory authorities. According to World Health Organization(WHO), there are six areas to be inspected which include quality management, facilities and equipment, production, packaging and labeling, materials management and laboratory control. The regulations are adopted to safeguard consumers, provide information for medical practitioners and improve the quality standards of the medicines produced by manufacturers [20].

## **2.8 International Standardization Organization (ISO)**

The International Organization for standardization (ISO) is an international organization whose purpose is to establish agreement on international quality standards. It been created to develop and promote quality. International Standardization Organization (ISO9000) consists of a set of standards and a certification process for companies. By receiving International Standardization Organization(ISO 9000) certification, companies demonstrate that they have met the standards specified by the

International Standardization Organization(ISO). The standards are applicable for all types of companies and have gained global acceptance. In many industries International Standardization Organization(ISO) certification has become a requirement for doing business, and it's a proof to the customer that the company's products are satisfying.

In some places the International Standardization Organization(ISO 9000) certificate become a necessity for doing business since it got an international approval, Studies has shown that the level of commitment by the top and middle management affects the outcome, alot of studies done in the pharmaceutical industries concluded that companies with International Standardization Organization(ISO 9000) and non-International Standardization Organization(ISO 9000) do differ in the level of commitment to quality implementation, so The pharmaceutical companies started walking the path of getting International Standardization Organization(ISO 9000) certificate which considered an international proof of excellence.

International Standardization Organization (ISO 14000) is an environmental management system, describes the requirements for organization's environmental management system and can be used for certification/registration and/or self-declaration of an organization's environmental management system[21].

## **Chapter Three**

## **Chapter Three**

### **METHADODOLOGY**

#### **3.1 Introduction**

This study targets the five Total Quality Management (TQM) ingredients in AZAL and AMIPHARMA pharmaceutical factories, the aim of the study is to evaluate and review Total Quality Management (TQM) implementation through the five ingredients.

#### **3.2 Total Quality Management Ingredients**

##### **3.2.1 Strategic Commitment**

A vital element of any Total Quality management program is the commitment of top management to the success of the program. Such commitment is important for several reasons. First the organizational missions and goals must change to include quality as a high priority goal.

This can only be done by top management. Second, the organization culture must change so that all persons must pursue quality individually in their efforts. Third, pursuit of Total Quality Management (TQM) requires high capital expenditure which can only be authorized by top management. Hence, quality improvements necessarily requires commitment from top management.

### **3.2.2 Employee Involvement**

Total Quality Management requires that all employees be involved in every step of the production process. Studies have shown that a high degree of worker involvement reduces the number of quality problems.

Most of the quality problems have to do with materials and processes and these problems can only be eliminated by serious and sincere commitment of all workers who understand the shortcomings of the system.

Some of the famous techniques to improve the involvement of the employee is to build communication networks with open channels including all employees, motivate the workers and supportive supervisors and delegating the responsibility to people who are closer to the theatre of operations.

### **3.2.3 Materials**

The output cannot be of high quality unless the inputs are also of high quality. All raw materials for production and all finished goods for final assembly are acquired from outside suppliers.

Accordingly, it's necessary to have a kind of partnership with suppliers. Many factories and firms have increased the quality requirements they impose on their suppliers as a way of improving quality of their own products.

Suppliers are often involved with buyers, as members of quality improvement teams. Such partnership is crucial to some industries.

### **3.2.4 Technology**

New forms of technology are very useful in Total Quality management (TQM) programs because of precision and consistency that the new advanced equipment creates in the products.

Automation, computers and robotics perform the jobs more accurately than people and make fewer mistakes.

The results in better quality products. Hence, investments in higher-grade machines capable of doing jobs more precisely and reliably is justified as the quality of the output is highly improved.

### **3.2.5 Methods**

The pharmaceutical factories uses the “Process Validation” method, which includes four different techniques, the first technique is the “Perspective Validation” technique and it’s done by experimenting the processes of producing three experimental batches before starting the main production, this step determines the critical points for material usage, process time, contamination levels, temperature degree and humidity and other related factors.

The second technique is the “Concurrent Validation”, it studies three batches after production to check the critical points and review the personnel and equipment production steps, which once improved leads to a result of reducing time and wastages.

The third technique is the “Retrospective Validation”, it’s considered a preventive action. It’s done annually at the end of every year. Tests for the



humidity and contamination levels and weight and etc... Are run for at least 30 batches, then control charts are made to recognize non-conformities patterns.

“Re-Validation” is the fourth technique, the technique is used when a change at the machine occurs, and the change may be the location of the machine itself or a major spare part. We re-validate the process and determine the critical points all over again.

**Fig. 3.1** show the overall project flow chart for evaluating the five ingredient in the tow factories .

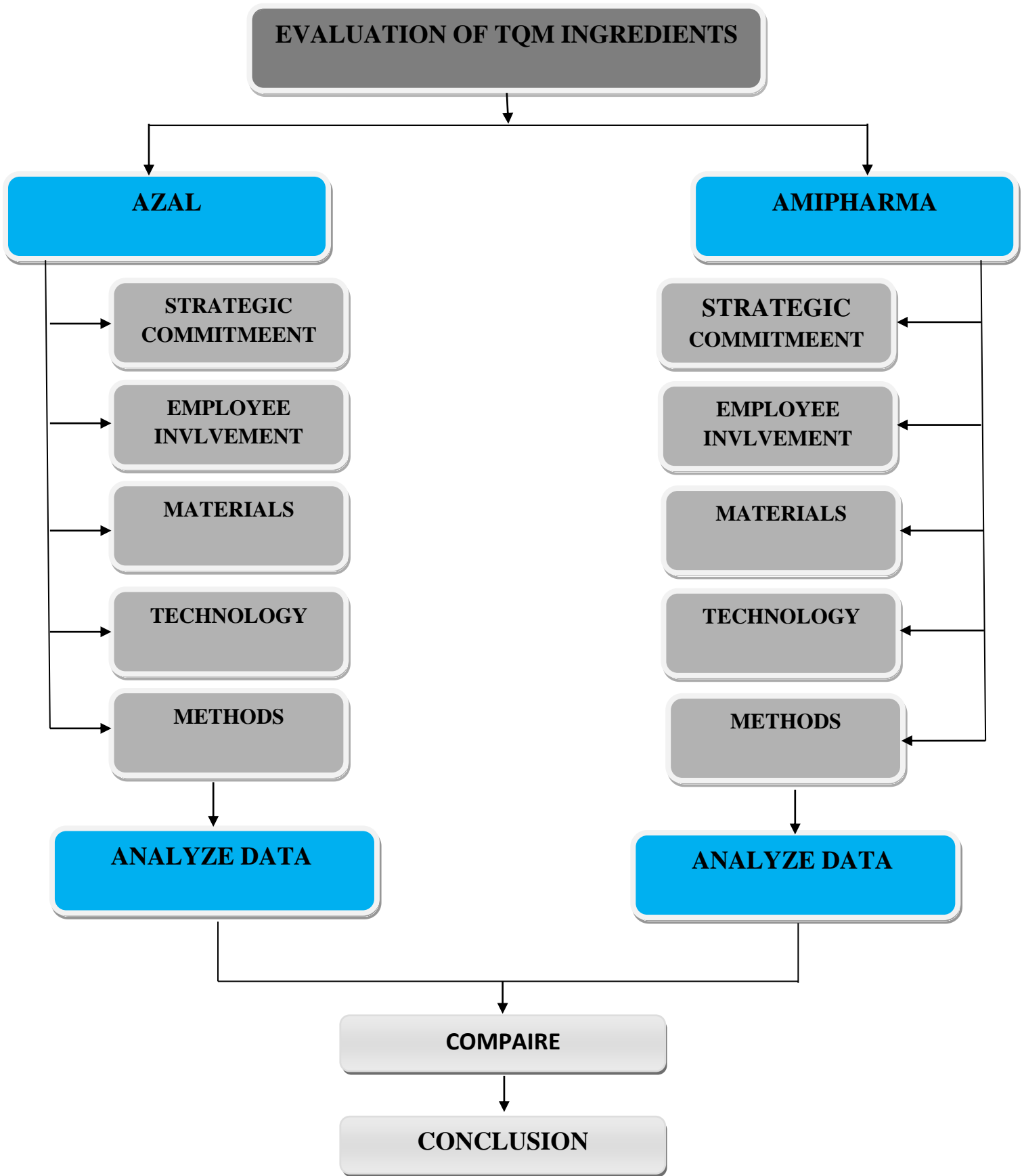


Figure 3.1 :Project flow chart

## **Chapter Four**

# **Chapter Four**

## **Results and Discussion**

### **4.1 Introduction**

The data acquired by the field visits to both AZAL and AMIPHARMA factories in regard to the Total Quality Management ingredients went under evaluation and analyzing to highlight the shortcomings and setbacks, and to improve the quality.

### **4.2 AZAL's Total Quality Management ingredients evaluation**

AZAL already started fulfilling the requirements of acquiring the International Standardization Organization (ISO 9000) certificate, but not acquired it yet. But hasn't taken any steps of acquiring the International Standardization Organization (ISO 14000).

From the start AZAL main attention was focused on the Good Manufacturing Practice (GMP) and lately the (ISO 9000), and more recently started a step by step implementation of the Total Quality Management (TQM) but hasn't fully applied it yet.

### **4.2.1 Strategic Commitment**

AZAL's top management selected to implement the Total Quality Management (TQM) step by step, a step every year. They started an annual Total Quality Management (TQM) goal that must be fulfilled.

The top management provided enough technology to pass and fulfil the Good Manufacturing Practice (GMP) inspections and requirements.

AZAL focuses on the quality of the product more than the production quantity, which has cost the factory a significant amount of funds. And also trained all the employee's production related and non-production related to the factories vision of quality, which has added expenses but will saves time and expense in the long term.

### **4.2.2 Employee Involvement**

AZAL's employee involvement plan is to open channels of communication between the production and quality assurance personnel. Quality Assurance have an office located in the production zone called In Production Control (IPC) which supervise the production process and have the authority to pause it if necessary. AZAL has no permanent worker motivation plan or system, but AZAL accountability system is to account the operator if it's a clear, standard and reckless error. And it's the management accountability if the error is a result of insufficient training, and part-operator, part-management if the error is in between.

AZAL integrated both its employee involvement and problem solving plans, which resulted in the use of Quality Control Circle of Activity (QCCA), a committee will form the circle, the circle members range from four to five members for medium size problems and max number of nine for large problems, the members are problem related personnel, in general the members are the operator, quality control and quality assurance personnel a technician and an engineer if it's a maintenance problem. Besides the Quality Control Circle of Activity AZAL uses the brainstorming technique with all related personnel to solve problems.

### **4.2.3 Materials**

AZAL has the standard relationship with the supplier, no techniques or steps were done to ensure a better quality of the imported raw material.

### **4.2.4 Technology**

AZAL's technology is - to an extinct - primitive, the factory has no all employees channel, and no server and no whole factory network, but they invested well in the production line and the quality control laboratories, production line machines are the state of the art Chinese machines, they are manufactured by the "Futchang" and "JiangJan" famous companies, which are ISO certificated, most of the machines are fully automated PLC machines,

And the rest are semi-automated.

#### **4.2.5 Methods**

AZAL uses the “Process Validation” method, which includes four different validation techniques, two of the four techniques are used by AZAL, the techniques used are the “Concurrent Validation” and “Retrospective Validation”, the “Perspective Validation” is currently not used in AZAL due to the high cost of studying three whole batches before and outside production, “Re-Validation” is the fourth technique and it is also not used at the moment.

#### **4.3 AMIPHARMA Total Quality Management ingredients evaluation**

AMIPHARMA factory started as a very small workshop with a staff of seven personnel in 1984, they started from the need of the Sudanese population to medicine, it was very rare and difficult to find, and if found very expensive. The seven persons whom started the factory are still the owners of the factory till this day, they insist on carrying on the mission they started when they first started the factory, and the mission model is “Quality products, affordable prices”.

The pursuit of Total Quality Management (TQM) started from the beginning, and as time passes the factory grew tremendously, expanded relatively at a very fast phase. AMIPHARMA met the Good Manufacturing Practice (GMP) requirements and the International Standardization Organization (ISO) 9000 requirements, after pursuing those two goals and

solving the shortcomings, and by the endless search for better ways, material and time reduction and better quality products they implemented the philosophy of Total Quality Management (TQM) but hasn't implement it by name. To this day they recognize the implementation of the Good Manufacturing Practice (GMP) and ISO (9000) only.

Total Quality Management ingredients evaluation results concerning AMIPHARMA factory are:

### **4.3.1 Strategic Commitment**

AMIPHARMA's management commits to the ultimate pursue of quality, but not Total Quality Management (TQM) itself, although this procedure resulted in some setbacks, but at the long term it showed benefits.

AMIPHARMA management developed a clear managerial structure, with an explained authority and a specific job description, the managerial structure is reviewed every five years to determine the flaws and shortcomings. A result of the managerial structure reviewing meetings AMIPHARMA created new job positions to relief the pressure from the overloaded jobs.

The management provide a mandatory quality courses for new employees after hiring and an in job training, this provides a detailed explanation of the most effective and time efficient way to accomplish a job. The management also spared no costs of improving the overall technology of the factory, latest production and quality control technology are purchased



once released. And an obvious expansion in the production lines and departments and facilities area is the proof.

### **4.3.2 Employee involvement**

All the head of departments have a meeting annually “Annual Management Committee” that discusses the obstacles reported by employees and discusses the solving and preventive actions, so that the problems found and solved are prevented once and for all, the head of departments meets with the employees weekly to discuss issues and a better performing method for better outcomes and shorter processing time.

AMIPHARMA provides an excellent working environment, they have an inside cafeteria with variety of selections. They have an excellent transportation program, the program contains 42 buses, and the routes are selected based on a traveling time doesn't surpass 45 minutes, to ensure accurate attendance time and to increase the reliability of the buses.

All AMIPHARMA employees with no exception are offered a five months bonus every year as a motivation. They also have individual motivation that rewards after the performance reports are reviewed.

Ten opportunities are offered annually to employees to attend the holy “HAJJ”, this program started at year 2000, and have a medical insurance program which covers the costs of treating patients at the factory expense, and in door clinic.

AMIPHARMA's accountability and penalty system is to investigate the unknown causes of an error through the Fish Bone technique. Error

caused by reckless and careless behavior have a list of guidelines to determine the penalty according to the Labor Office.

AMIPHARMA uses all the seven Total Quality Management (TQM) techniques, and also the Quality Control Circle of Activity (QCCA) not just to solve problems, they went a step further and used it in planning for new projects, as an example a circle was formed and it included the operator worked in the previous or pre-expansion location, technicians, and engineers to determine the best layout for the new facility. They also rely on Brainstorming technique for outside the box solutions.

### **4.3.3 Materials**

AMIPHARMA inspects the supplier factory to ensure that the raw material meets their requirements. The inspection process is either by sending a quality team to the location of the factory, or by reviewing the CV of the factory or by reviewing a completed reliable and guaranteed inspection.

### **4.3.4 Technology**

AMIPHARMA heavily invested on the latest Programmable Logic Controlled (PLC) machines for the production lines to meet the requirements of the annual production goal. The latest PLC machines are used in the production departments where needed, and the latest Quality Control

equipment are provided for a faster processing time and more accurate results.

AMIPHARMA uses the Enterprise Resource Planning (ERP), it's a category of business management software, that collect, store, manage and interpret data and shows financial information. The (ERP) connects the whole factory in one network, the top management personnel have access to confidential information from each head of departments account. The senior employees have a lower access pass than the top management, and the general employees have the lowest information access.

The factory also have a WI-FI internet service, and surveillance system that cover the whole factory ground.

#### **4.3.5 Methods**

AMIPHARMA runs both equipment and process validation programs. The first validation is the Design Qualification (DQ) where the machines to be installed designs are inspected, the manufacturer company sends the blueprints to the factory before manufacturing or shipping.

After the Design Qualification (DQ), the next step is the Installation Qualification (IQ) where the technicians finish the installing process according to the manufacturer Standard Operating Procedure (SOP), then they run the machine to ensure that's it's functional in what's called Operation Qualification (OQ), the last step is to produce samples using the machine to ensure that it delivers the same specific required product in what's called Performance Qualification (PQ).

In regards to the process validation AMIPHARMA uses all the four validation techniques.

## **Chapter Five**

## **Chapter Five**

### **Recommendations and Conclusion**

#### **5.1 Conclusion**

After the evaluation of the Total Quality Management ingredients (TQM) in both AZAL and AMIPHARMA factories, we concluded that in regard to the general quality plan, AZAL uses a step by step Total Quality Management (TQM) program.

AMIPHARMA hasn't pursued the Total Quality Management (TQM) by its name, but pursued the overall quality in all directions, which resulted in achieving many Total Quality Management (TQM) goals.

In regard to the Strategic Commitment, AZAL management committed to provide enough technology to pass the Good Manufacturing Practice (GMP) inspections, but in their annual Total Quality Management (TQM) they will invest a significant amount of capital to improve the production lines. AZAL also allocated huge amounts of funds to ensure and review the quality of the products.

AZAL also offers to all employees a mandatory course about the factory vision of quality, and a job specification and description course to ensure safe and efficient performance.

AMIPHARMA review and re-structure every five years. They create new jobs to relief the pressure from overloaded jobs and provide mandatory quality courses for all employees and in job training and outside courses.

In regard to Employee Involvement AZAL opened channels of communication between the Quality Assurance and Production Department, AZAL have no systematic plan to motivate the employees, AZAL relies on the Quality Control Circle of Activities (QCCA) and Brainstorming to solve problems.

In regard to the Materials both factories inspects the supplier to ensure that the raw material meets their quality standards.

In regard to the technology used AZAL focused on the production lines and the Quality Control. AMIPHARMA uses the (ERP) system and have a network connecting all employees and a server.

In regard to the Methods both factories uses the “Process Validation” techniques. AZAL uses the “Concurrent Validation” and the “Retrospective Validation” only. AMIPHARMA uses all four techniques besides an Equipment Validation technique.

## 5.2 Recommendations

- This study scope targets two factories, the results acquired don't represent all the Sudanese Pharmaceutical industries, expanding the scope will provide more accurate results.
- After evaluating and reviewing the five ingredients, the conclusion is that the Strategic Commitment is the biggest setback, so it needs the most attention.
- Exchanging knowledge and managerial and production techniques between the pharmaceutical factories will raise the Sudan overall quality, which will open opportunities for foreign markets.
- This study targeted the five Total Quality Management ingredients, it will be beneficial to evaluate and review the quality of the production line processes.



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