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THE IMPORTANCE OF QUALITY MANAGEMENT SYSTEM IN PHARMACEUTICAL INDUSTRY

Richa Shukla
Department of Quality Assurance
Indore Institute of Pharmacy
Indore, Madhya Pradesh, India

Gurmeet Singh Chhabra
Department of Quality Assurance (HOD)
Indore Institute of Pharmacy
Indore, Madhya Pradesh, India

Abstract: **One of the businesses with the most regulations is the pharmaceutical industry. Implementing a quality management system helps the pharmaceutical business deliver high-caliber finished goods to the market. Quality management system has played an important role in producing a high quality of produced yield as well as it is more supportive in managing, balancing and continuing the quality status in their services or products. This review article goes into detail about the ICH Q10, their purpose, history, GLP and ISO. This review article also covers audits, QMS, their implementation, risk management, certification and industrial influence on standards and quality. This review article in short covers all the important and valuable aspects of QMS from how is QMS implemented and what are its effects on industrialization and its audit and certification.**

Keywords - **Quality management, ICH Q10, QMS, GLP, CIP, Pharmaceutical industry.**

I. INTRODUCTION

The context of quality has become significant in the current situation. In general, "quality" refers to a factor that determines whether a good or service is superior or poor. Comprehending the extent to which a product fulfills its criteria is a gauge of quality.

Since pharmaceutical products are directly injected into the bodies of its consumers, identity, purity, safety, and finally the right product quality are vitally important. This makes quality control in the pharmaceutical industry a crucial topic. Every pharmaceutical sector is required to adhere to a number of global guidelines that have established norms or criteria.

A formalized system that records duties, processes, and procedures for accomplishing quality policies and objectives is known as a quality management system, or QMS. A QMS aids in organizing and directing an organization's operations to satisfy legal and customer requirements and continuously enhance its efficacy and efficiency. [2]

II. QUALITY IN PHARMACEUTICAL INDUSTRY

Since Quality directly affects the revenues from sales, quality is a crucial necessity for items in any business. There is, nevertheless, one more significant reason why high-quality products are required in the pharmaceutical sector. This is really one of the main causes of this industry's extreme regulation, as any mistakes made during the production process could have harmful or even lethal effects on the patients who consume the products. Pharmaceutical items must therefore be produced in a way that satisfies strict regulatory requirements. [3]

Quality cannot be adequately described in one word. Each individuality can define it in their own unique way. The satisfaction is the sole factor that unites them all. The product must fulfill the manufacturer's requirements. Consequently, a product's ability to fulfill requirements is a measure of its quality. Since pharmaceutical items are intended for human use, quality should not be compromised. Thus, the product's identification, safety, chastity, and quality are required. Vibrant recommendations recommend that each pharmaceutical association adhere to certain standards and regulations. The highest quality position is guaranteed with fewer recall or unfavorable occurrences when the fundamentals of the quality operation system are used. [4]

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A. History of Quality Management System -

There has been a possibility that certification of a Quality Management System does not guarantee stakeholders that goods or services will be supplied to the customer on time since the introduction of the ISO series of quality management standards in 1987. QS-9000 was launched in 1995 with the expectation that things would improve. Ultimately, all of these had the same objective of satisfying customers by providing high-quality goods or services on schedule. What the organizations fail to recognize or comprehend is that their qualification now allows them to grasp the correct things.

In 1924, Walter A. Shewhart made a significant contribution to the field of quality management when he developed a statistically based system for industrial quality control. His work on statistical quality control was built upon this. [7]

During World War II, W. Edwards Deming employed statistical process control techniques in the US to improve the quality of weapons and other critical products manufactured.

Shewhart's theories were promoted in Japan starting in 1950 by W. Edwards Deming. His management concept of establishing competitive position, productivity, and quality is what made him most famous. He came up with 14 points.

These fourteen principles cover important ideas like:

- No departmental barriers.
- Management should take on duties and exercise rule leadership.
- Supervision should be for the assistance of people and machines and other devices to facilitate work.
- Constantly and always improve production and service.
- Establish a program for education and self-improvement.

In the field of quality, Philip Crosby—known as the Guru of Quality Management—was a legendary figure. The greatest quality expert, advisor, and writer, he is best known for advocating for "zero defects" and characterizing quality as requirement compliance. [5,7]

III. DEFINING QUALITY MANAGEMENT

The resources, methods, procedures, and organizational structure required to accomplish quality management are collectively referred to as a quality management system (QMS). [9]

In other words, a quality management system is a set of interrelated components that organizations use to direct and control how quality policies and processes are regulated and quality objectives are successfully achieved. [6]

Quality management is a activity run by everyone in an organization, governed by Executive management and regulated by the Quality Management Department.

However, by the 20th century, labor were the most costly subjects in most of the industrial matter, so it lead to the team work and the hard work, especially for the problems coming through a continuous improvement cycle.

And today, in the very 21st century, QMS is twinning with sustainability and transparency concepts, so both investor and customer satisfaction and quality are related to these factors. [5]

IV. ICH Q10

The full form of ICH is “International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.” [10]

This body was established to examine technical and scientific elements of drug registration by bringing together representatives of regulatory agencies and the pharmaceutical sector. Drug manufacturers had to invest a lot of time and money on repeating test procedures in order to market their goods internationally due to the disparities in technical standards across nations as the pharmaceutical business became increasingly global. Ensuring that patients worldwide have access to safe and effective medications without delays resulting from regulatory bodies in different countries adopting inconsistent policies has become increasingly crucial. As a result, there was a need to integrate and rationalize drug rules, which led to the creation of ICH in 1990. [2,6]

The goal of ICH can be summed up as follows:

- Guaranteeing the efficacy, safety, and quality of pharmaceuticals.
- Standardization of medication technical specifications.
- Prevent doing duplicate human clinical trials.
- Minimize the utilization of animal testing while maintaining the integrity of drug safety and efficacy assessments. [2,6]

A. History of ICH -

A technical prerequisite for medications intended for human consumption is the International Council for Harmonization (ICH). Bringing the pharmaceutical industry and regulatory bodies together to discuss the scientific and technical aspects of drug registration is a novel step. Since its establishment in 1990, ICH has progressively changed to address the increasingly global nature of drug research. The International Conference on Harmonization (ICH), formerly known as the International Council for Harmonization (ICH), conducted its first assembly meetings on October 23, 2015, thus established the ICH as a legal organization under Swiss law and an international association.

The goal of ICH is to increase global harmonization in order to guarantee that high-quality, safe, and effective medications are developed and registered in the most resource-efficient way possible. [3,6]

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B. Q10: pharmaceutical quality system -
It is a management system to direct and control a pharmaceutical company with regard to quality. ICH Q10 is based upon ISO 9000: 2005. [10]
The basis for ICH Q10 is the relationship between ISO standards, ICH Q7 guidelines, or "Good manufacturing practice guide for active pharmaceutical ingredients," and regional GMP regulations. Additionally, ICH Q7 guidelines and ISO quality management system recommendations are related to each other. ICH Q10 supplements GMPs by outlining particular quality system components and management roles in order to achieve the goals listed below. In addition to regional GMP regulations, ICH Q10 offers a harmonized model for a pharmaceutical quality system throughout a product's lifecycle. [12]
It is not specifically stated in the regional GMPs that every phase of the product lifecycle is covered (such as growth). The goal of the quality system components and management duties outlined in this guideline is to promote continuous improvement across the whole product lifecycle by encouraging the application of science and risk-based techniques at every step of the lifecycle**.** [3]

C. Definition of GLP –
"GLP," as defined by the FDA, is a collection of rules intended to guarantee the quality and objectivity of non-clinical laboratory investigations meant to support research or marketing authorizations for products overseen by government bodies. [15]
An in-vitro or in-vivo experiment where the product under evaluation is tested in systems in a lab environment to ascertain its level of safety is called a non-clinical laboratory investigation.
Consequently, GLP ensures that testing facilities fulfill the FDA's minimal requirements for the planning, carrying out, and sharing of safety studies related to non-clinical testing. GLP provides a rigorously regulated study framework that guarantees full accountability. [2]

V. ISO FAMILY

According to the International Organization for Standardization, which creates and publishes international standards:
"A standard is a set of rules, guidelines, specifications, or other qualities that can be applied consistently to guarantee the suitability of materials, goods, procedures, and services." [11]
The goal of the ISO International Standards is to guarantee the quality, dependability, and safety of goods and services. These standards are tactical instruments used in the corporate world to assist cut expenses by reducing waste and errors and boosting efficiency. It enables businesses to enter new markets, evens the playing field for emerging nations, and promotes free and equitable international trade. [5]

A. Development of ISO Standards -
A technical committee's group of specialists creates an ISO standard. After determining the necessity for a standard, these experts get together to debate and negotiate a draft standard. Once a draft has been created, it is shared with ISO members, who are then requested for feedback and a vote. The draft becomes an ISO standard if agreement is reached; otherwise, it is sent back to the technical committee for additional revisions.
ISO has many management system standards, each focuses on different issues, some of are these:

- ISO 50001 – Energy Management
- ISO 9001 – Quality Management
- ISO 14000 – Environmental Management
- ISO 22000 – Food Safety Management. [5]

VI. MISSION STATEMENT FOR THE QUALITY MANAGEMENT SYSTEM

The criteria of the ISO 9001 standards mandate that organizations create a QMS Quality Policy that will allow them to manage, control, and improve organizational processes in order to ensure that services and goods meet customer requirements. This policy will help organizations determine their objectives and quality policy. For instance: [5]
Our Principles - We adhere to the following principles:
Confidentiality, discretion, trust, propriety, and honesty.

- **Our clients:** We strive to give our clients the best service possible since we know that in order to succeed, they must remain loyal and supportive over the long term.
- **Our connections:** With our employees, clients, and suppliers, we establish long-term relationships that are mutually beneficial.
- **Our employees:** We treat them with respect and decency and are dedicated to assisting them in realizing their full potential via training and development. They are also urged to take part in choices that affect their day-to-day work activities.
- **Ideas:** We encourage our employees, clients, and suppliers to use innovation and creativity to solve issues and capture opportunities.
- **Quality:** We endeavor to create a culture where quality come.[5]

VII. IMPLEMENTATION OF QUALITY MANAGEMENT SYSTEM

A. Decide what your company wants to accomplish. Examples include –

- becoming more effective and profitable;

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- producing goods and services that consistently satisfy customers;
- increasing market share;
- maintaining market share;
- enhancing internal communications and morale;
- lowering costs and liabilities;
- And increasing trust in the production system. [5, 8]

B. Determine the expectations that others have of your company –

- Clients and end users;
- Staff;
- Vendors;
- Shareholders;
- Society. [5, 8]

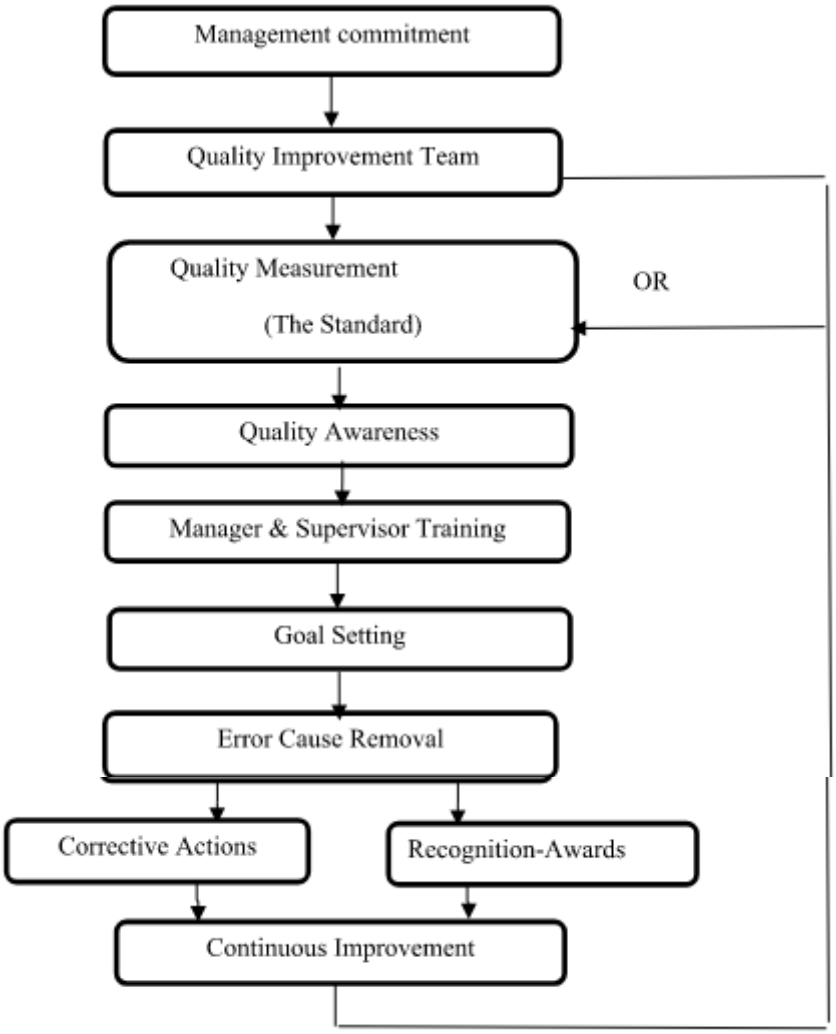

Fig 1. Ten step approach for QMS implementation

VIII. THE 8 PRINCIPLES OF QUALITY MANAGEMENT SYSTEM

1. First principle: client attention

Businesses must understand their customers' needs both now and in the future, meet their requests, and strive to go above and beyond their expectations because they are their lifeblood.

2. Second principle: leadership

Leaders set the direction of the organization and create a sense of unity. Workers must create and preserve a positive work environment if they are to actively contribute to achieving the organization's goals.

3. Third principle: Involvement of humans

People are an organization's most important asset, and when they participate fully, their skills may be used to the organization's benefit.

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4. Fourth principle: process-oriented approach
A more efficient way of achieving the intended outcome is to handle activities and related resources as a process.

5. Fifth principle: a systemic management strategy
The identification, understanding, and management of a network of interrelated activities toward a common goal increases the effectiveness and efficiency of the organization. An organization's processes and their interdependencies need to be defined in order to manage it successfully.

6. Sixth principle: ongoing development
The long-term objective of the company need to be to consistently raise its overall performance.

7. Seventh Principle: Making decisions based on facts
The fact-based approach to decision-making philosophy states that the analysis of data and information is the foundation for making effective judgments.

8. Eighth principle: supplier relationships that benefit both parties
Value creation by a business and its suppliers is interconnected, and a win-win collaboration makes that capacity stronger. [5]

IX. RISK MANAGEMENT IN ORGANIZATION

The importance of risk management in today's business world is only growing. You can no longer rely on corrective action being taken after a problem arises. The reputation of your business as a provider of high-quality goods or services may be irreparably harmed in today's era of instant information technology before you can take corrective action. What steps can you take to lessen this possibility? Plan for risk management!

Risk management seeks to shield businesses from vulnerability.
The first steps in the risk management process are to identify, evaluate, and prioritize potential hazards. Taking steps to reduce or eliminate the effects of unfortunate events is the next step in the process. [5]

Examples of typical risk categories whose effects management can influence include:

- Accidents that occur at work
- Severe weather events including fires, tornadoes, floods, and earthquakes
- Financial unpredictability, project failure, credit hazards, data storage, and security are legal concerns in addition to supply chain disruption.
- Other risks include fraud, theft, and sexual harassment.

There are as many methods for lowering or removing risk as there are risk factors. the four primary strategies listed below:

- Remain mute and accept the outcome.
- The transfer of risk to a third party is known as insurance.
- Eliminate risk by shutting down troublesome departments inside the company.

Every business should execute a risk management strategy since doing so is the appropriate course to follow in order to sustain a successful business that safeguards its clients, partners, and material assets. [5]

X. CONTINOUS IMPROVEMENT PLAN

Plans for continuous quality improvement, or CIPs, are programs created to examine particular circumstances and propose methods for upgrading or improving all associated elements. [14]
In almost any company environment, policies and procedures may be evaluated using a continuous improvement method.
The idea is to improve upon what is already excellent in order to benefit the business as a whole.
W. Edwards Deming, considered it to be a component of the 'system' that assessed customer and process feedback in relation to corporate objectives. The fact that it can be referred to as a management process does not entail that 'management' must carry it out; rather, it only indicates that it makes decisions regarding the delivery process's implementation and design.
The (self) reflection of processes is the central tenet of CIP. (feedback)
The discovery, mitigation, and abolition of suboptimal processes are the goals of CIP. (efficiency)
The focus of CIP is on continuous, incremental progress rather than huge leaps. (Evolution) [5]

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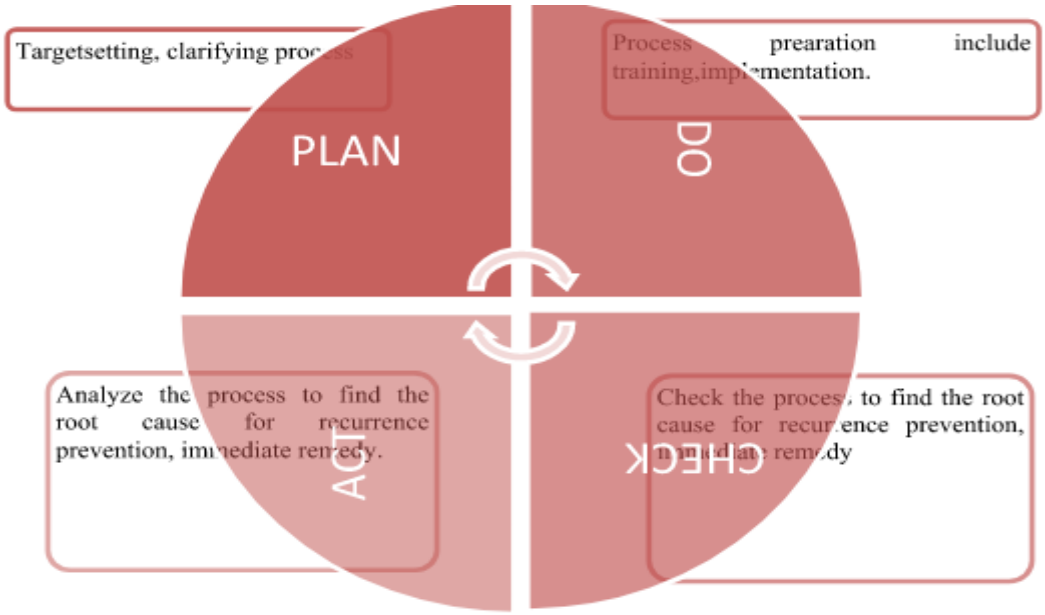

Fig.2.The PDCA cycle

XI. INDUSTRIAL IMPACT ON STANDARDS AND QUALITY

Early quality management systems were employed as benchmarks to regulate the outputs of processes and products during the Industrial Revolution. Best practices were required to guarantee high-quality results when more individuals had to collaborate to achieve results and production volumes increased. Best practices for regulating the results of processes and products were eventually developed and recorded. These well-documented best practices become the norm for quality control systems. [1]

A. The Development of Quality Management Systems -

Total quality operation (TQM), a strategy for quality operation that stressed not only data but also ways that embraced the entire association, was created as an American response to the quality revolution in Japan. Independent associations started developing guidelines to aid in the development and implementation of high-quality operational systems in the latter half of the 20th century. The name "Quality Management System" or "QMS" is favored due to the vast array of distinctive systems that can be used. As the twenty-first century got under way, QMS started to integrate with the concepts of transparency and sustainability as these concepts started to lose significance in terms of customer pleasure. Both quality and sustainability are addressed by the ISO 19011 inspection governance, as is their incorporation into associations. [1]

B. Other quality management standards, such as ISO 9001:2015 -

The most widely used and accepted quality management system standard in the world is unquestionably ISO 9001:2015. Companies can use the ISO 9001:2015 QMS criteria to create their own programs. ISO 9000 and ISO 9004 are two more ISO 9000 family standards that provide additional guidance for quality control systems.

Environmental management systems follow ISO 14000 guidelines.

- Medical device quality management systems are covered by ISO 13485,
- Auditing management systems are covered by ISO 19011, and
- Automotive industry-related products are covered by ISO/TS 16949. [1]

C. Advantages of quality control procedures -

An organization's performance is impacted in every way by the implementation of a quality management system. Designing and implementing written quality management systems has two main advantages, which are as follows:

1. Fulfilling the client's needs helps to build the client's trust in the company, which in turn encourages additional clients, sales, and repeat business.
2. Fulfilling the organization's criteria, which guarantees regulatory compliance and ensures the success of goods and services in the most resource- and cost-efficient way, allowing for room for expansion, growth, and profit. Within these, there are advantages like assisting in communicating a willingness to deliver consistent outcomes, preventing errors, lowering expenses, making sure that procedures are

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specified and controlled, and consistently enhancing the organization's services. [1]

XII. THE AUDIT

An internal, external, or audit team will typically conduct a quality audit, which is the act of methodically analyzing the quality management system of a company.

In order to guarantee that a company has clearly defined internal system monitoring methods connected to successful action, quality audits are often conducted at certain intervals. Audits test a quality management system's suitability and proper execution. This might involve either procedural or results-based assessment criteria, and it can help establish whether the organization adheres to the defined quality system processes.

Quality audits should not only highlight areas of best practice for the organization but also reveal non-conformances and corrective actions. As a result, other departments may exchange information and modify their operational procedures, furthering the goal of continuous development. [5]

There are four steps in the audit process:

1. Planning - designate auditors, settle on an audit program, compile and examine all supporting paperwork, and create a checklist.

2. Performance - open meeting, audit, meeting of the audit team, and meeting adjournment.

3. Reporting - an audit report must be finished and given to the auditee within fourteen days of the audit's conclusion.

4. **Follow-up** - found non-conformances need to be fixed. [5]

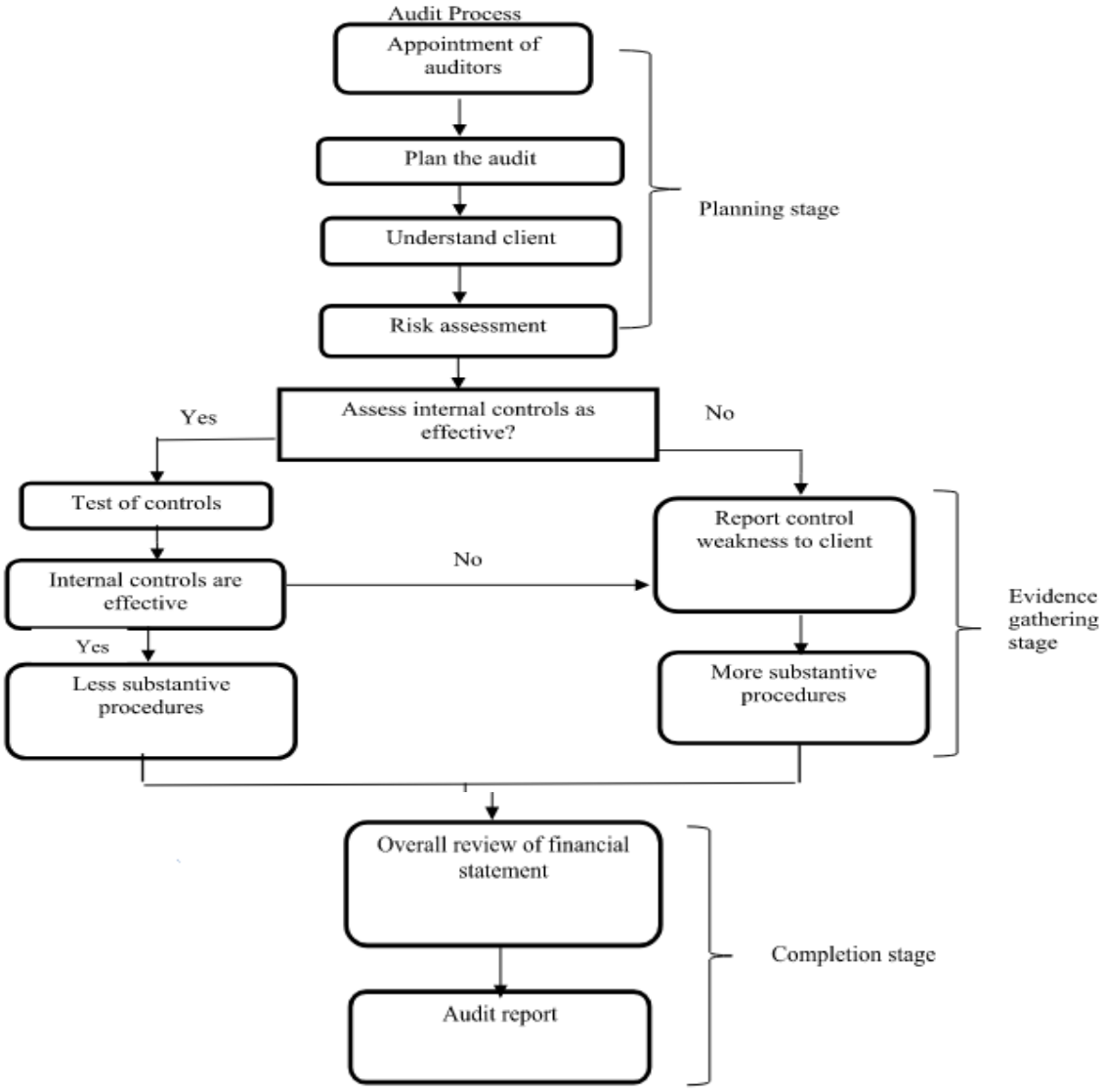

Fig.3. The flowchart of audit process.

XIII. THE CERTIFICATION

The process of having a third party's compliance with particular requirements verified by an impartial, certified entity is known as certification, ISO does not certify organizations by itself.

There are many certification agencies that examine businesses and, if successful, provide certifications of ISO 9001 compliance. The real standard to which a company's quality management system can be certified is ISO 9001:2008, despite the name "ISO 9000" being used frequently in reference to it. To approve ("accredit") the certification bodies, numerous nations have established accreditation agencies. To guarantee that certificates issued by one of the accredited certification bodies (CBs) are recognized globally, the various accreditation bodies have bilateral agreements with one another. [13]

XIV. CONCLUSION

There is no single definition of the word quality. People define it in different ways since it is tensile, yet all definitions have the quality of satisfaction. When a product satisfies a customer's need, the manufacturer is glad since it has met its specifications. Quality, however, is a modern necessity that cannot be ignored. When it comes to the pharmaceutical industry, quality is a legal concern that must be upheld in pharmaceutical products. The focus of the current study is on a few issues and the necessity of sustaining pharmaceutical quality through a quality management system. In order to produce a quality, safety and zero-defect product at an economical rate, the implementation of quality management system is very much essential in pharmaceutical sector. Also, this principle is very much important aspect towards the minimization or complete removal of any type of defects or dangerous contaminations which are occurring in the microbiological pharmaceutical production.

REFERENCES

[1]. Anup, Sehrawat V., Singh N. and Nitin, (Nov/2017), "Quality Management System (QMS)", IAETSD Journal For Advanced Research In Applied Sciences, volume 4, issue 6, (pp. 220-226).

[2]. Kashi R.Anusuya, sukumaran B. and P.Veena, (January 2020), " pharmaceutical Quality Assurance", 1 st edition,Pune, Nirali Prakashan, (pp. 1.1 - 15.6).

[3]. Paul S., and Jeswani G., (2020), "Pharmaceutical Quality Assurance", 2 nd edition, Punjab, S. Vikas and Company, (pp. 3 - 284).

[4]. Khatri M., R.B. Bodla and Singh B., (February 2020), "Role of Quality Management System in Pharmaceutical Industry", International Journal of Innovative Science, Engineering & Technology, Vol.7, Issue 2, (pp. 99-107).

[5]. Landerville T., (2013) "Quality Management Systems Guide", Santa Rosa, California; Isocert Solutions LLC,(pg. 1-26).

[6]. Pandey P. and Goyal A., (January 11, 2018), “Quality Management System in Drug Industry: A Review”, Biomedical Journal of Scientific & Technical Research, Volume 2- Issue 1, DOI: 10.26717/BJSTR.2018.02.000653, (pp. 2177-2179).

[7]. Zanje Abhijit L., and Jadhav Vaibhav A., (June 2022), “A Review of Total Quality Management in Pharmaceuticals”, International Journal of Research Publication and Reviews, Vol 3, no 6, (pp 2401-2409).

[8]. Mourougan S., and Sethuraman K., ((May. 2017), “Understanding and Implementing Quality Management System”, IOSR Journal of Business and Management, Volume 19, Issue 5. Ver. I, DOI: 10.9790/487X-1905014151, (pp 41-51).

[9]. https://en.wikipedia.org/wiki/Quality_management_system

[10]. https://en.wikipedia.org/wiki/International_Council_for_Harmonisation_of_Technical Requirements_for_Pharmaceuticals_for_Human_Use

[11]. https://en.wikipedia.org/wiki/International_Organization_for_Standardization

[12]. https://en.wikipedia.org/wiki/Good_manufacturing_practice

[13]. https://en.wikipedia.org/wiki/Certification

[14]. https://en.wikipedia.org/wiki/Continual_improvement_process

[15]. https://en.wikipedia.org/wiki/Good_laboratory_practice