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A Comprehensive Review on Pharmaceutical Quality Management

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Abstract: Quality plays a crucial role in the growth of every organization and it is the key element that aids in attaining customer satisfaction. In terms of pharmaceutical industry quality is assured and inevitable factor as the pharmaceutical product formed are directly or indirectly delivered to customers body so it is essential that the product should be pure, safe and fit for use. To regulate various aspect of quality ICH (International Conference on Harmonization) has defined an ICH Q series where Q9 guideline enlists various tools that can be used for managing risk to the quality of pharmaceutical product and Q10 guideline which is a Pharmaceutical Quality system model. ISO 9001 also contributes in management of quality by setting various standard to meet quality expectation of the customer. Managing quality in pharmaceuticals can be tricky and time-consuming job if done manually so to make it less complex various QMS software's have been developed and are being used by various industries for monitoring and managing quality at every step of products lifecycle. This paper focuses on various dimensions of quality and its management, Total Quality Management (TQM), Software used in QMS and guidelines for quality management- ICH Q-series (with emphasis on Q9 and Q10) and ISO 9000:2015(Quality Management System)

Index Terms **- Quality, QMS Software, ICH, ISO, Quality Risk Management, TQM.**

I. INTRODUCTION

Quality Management System is the system that has been setup to command and regulate an organization with respect to quality. It is a foundation of all the systems that run within the organization. In today's scenario people are wise enough to differentiate product on basis of quality and due to enhancing competition the only key element that aids in making your organization more profitable as compared to competitor is quality.[1] Definition of quality vary from individual to individual from an organization perspective quality is manufacturing a product that meets customer needs and is safe, pure, effective with no adverse effect which further leads to customer satisfaction and finally resulting in economic profit of the organization. [2] Pharmaceutical industry being the most sophisticated industry is governed by the various regulatory framework who have laid foundation of various standards that have to be fulfilled at every step of development and manufacturing in order to sale the products in the market. As the product of this industry are consumed directly by the customer or are used on various part of the body so it should be sole responsibility of the manufacturer that it should be non-toxic, safe and should have no compromisation with quality and this job of ensuring quality throughout the product's lifespan till it is sold is done by the Quality Assurance department.[3] As we know that pharmaceutical industry is most complex and dynamic industry so earlier it was very difficult to keep the record and manage every system manually but today due to evolving technologies computer software have lessen the burden of the healthcare professionals from daily documentation to fully automated process technology has created a boom in this sector. Today every company uses numerous software to manage their work flow and to keep their data secure and transparent, thus these software's help in managing the quality and quality related processes in the pharmaceutical industry. [4, 5]

II. QUALITY

Quality in aspect to pharmaceutical can be defined as degree to which a drug or medicated product fulfills or meets its intended use and results in a therapeutic effect. The quality of drug is critical factor that can affect the patient so before the drug is consumed by humans it should be ensured that they comply with regulatory requirements as set by various regulatory bodies. [6, 7]

III. QUALITY MANAGEMENT FROM A STRATEGIC PRESPECTIVE

Joseph M. Juran discussed the strategic perspective of managing quality and according to him it is a systematic technique for establishing and accomplishing quality objectives throughout the product's lifespan. [8] There are five phases of SQM process –

1. Setting a Quality Objective
2. Building Quality Standards.
3. List ongoing and yearly quality targets.
4. Quality-driven design.
5. Designing Strategy for establishing quality.[9]

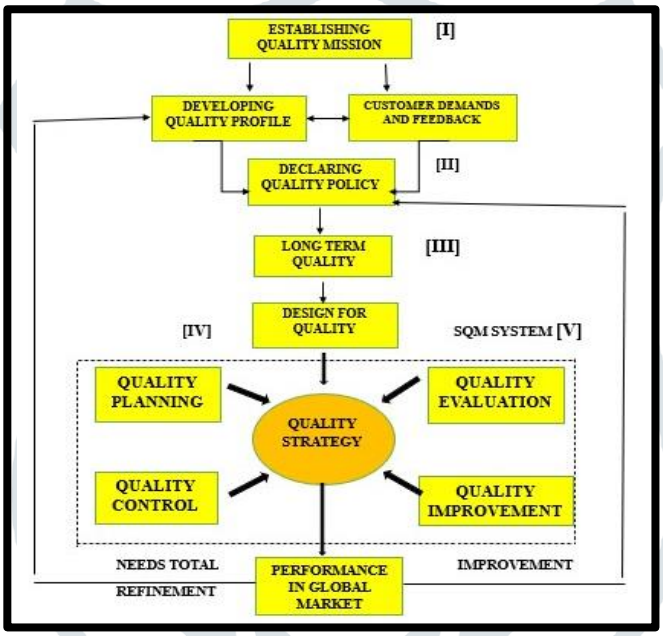

Figure 1:SQM Process

IV. QUALITY MANAGEMENT SYSTEM

A System for Quality Management can be defined as comprehensive and scientific approach to establish – policies, documents and procedures in such a way that the principles and standards of quality are meet and fulfilled during the pharmaceutical products lifecycle. A well-developed QMS builds up customer reliability and trust on the organizations product and to attain this the organization should follow these four steps- creating the strategies for achieving quality product, assuring quality is incorporated at every step, reviewing the quality with respect to standards set and continuous progression in quality. [10]

The pharmaceutical quality management system has various key factors that help to keep a track on the product's quality, the factors include– [11]

1. Document management – In Pharmaceuticals documentation means to keep written records of procedures to minimize the errors and misinterpretation and it also allow to track historical batches which leads development of quality product. This act as an asset to the manufacturers as it decreases the cost of non-conformance.
2. Change control – change can be defined as any planned permanent or temporary modification or complete alteration in approved process and the various document required to make this change are called change control. This change control is preferred when an enhanced quality procedure is obtained. Ex- change in Batch size, manufacturing process, formulation, raw material, documents and SOP's.
3. Training Management – QMS ensures that the employs are trained and qualified enough to perform the assigned task in terms to the standards set and they are well aware of their role and responsibilities as healthcare professionals.

4. Audit Management – The primary objective of audit is to check compliance and potency of the QMS and to spot or identify the errors in the system that are affecting the quality of the product.
5. CAPA Management – CAPA means corrective and preventive actions. Corrective action is a reactive action which is addressed when the issue has occurred in the system and to avoid its recurrence root cause analysis is done. Preventive action is proactive action in this risk is identified before it happens and it is done by risked based thinking.
6. Deviation Management – Deviation is any unwanted event that represent departure from the approved procedure. It can befall at the time of – packing, mass production, sampling and verification of drug product and it can be managed by raising a CAPA or by root cause analysis.

Historical milestones of quality Management

The past of quality management can be linked back to the initial days of industry, with significant advances occurring in various eras. The following are an outline of the major landmarks in the growth of quality management: [12, 13]

- Early Years: In the early days of pharmacy, quality management was often informal and based on the skills and knowledge of individual pharmacists. The emphasis was on compounding and dispensing medications accurately.
- Regulation and Standards (20th century) – As the pharmaceutical sector grew, governments implemented laws and standards to make sure that the drug is safe and efficacious. The formation of regulatory framework such as the United States Food and Drug Administration (FDA) in 1906, was an enormous accomplishment in pharmaceutical quality assurance.
- Good Manufacturing Practices (GMP) (20th century) – The creation and widespread acceptance of Good Manufacturing Practices in the mid-20th century substantially reinforced the quality management systems in pharmaceutical manufacturing. GMP provided particular rules for the production, testing, and quality assurance of pharmaceutical goods.
- Quality Control and Assurance (mid-20th century) – The establishment of quality control laboratories and quality assurance systems became more common in the pharmaceutical sector. These initiatives were created to monitor and enhance the standard of ingredients, production processes, and final products.
- International Harmonization (late 20th century) – The pharmaceutical sector witnessed efforts towards harmonized legislation and standards at the international level. Organizations such as the International Conference on Harmonisation (ICH) made guidelines for the qualification of the drug for human use.
- Pharmaceutical Quality Systems (21st century) – The International Council for Harmonisation's (ICH) Q10 guideline defined Pharmaceutical Quality Systems as a framework for incorporating quality management principles into all phases of product lifecycle including development, production, distribution, and pharmacovigilance. Continuous improvement methodologies, such as Six Sigma and Lean, also found applications in pharmaceutical settings.
- Patient-Centric Quality (Present) – Modern pharmaceutical quality management emphasizes on patient outcomes and safety. Patient-centric approaches seek to guarantee that pharmaceutical products and services fulfil patients' needs and expectations while adhering to the highest levels of safety and efficacy

V. TOTAL QUALITY MANAGEMENT

- Total – inclusive of all the system or function
- Quality – Degree to which a pharmaceutical product meets its expected efficacy.
- Management – manner or way of handling, controlling or directing.

TQM is comprehensive approach managing all the systems to attain excellency. As we know that customer is treated as the king of the market so profit, status and image of business depends on customer satisfaction. TQM is a customer-oriented process which states that long term success can be achieved by meeting customer expectation. It makes sure that all the employees of the organization work towards a common goal of improving product and process quality. [14]

Basic Principles of TQM [15]

1. Employee Empowerment – Creating a culture within the organization where employee will be empowered and have right to evaluate the quality of product at their level.

2. Continuous Improvement – Improvement in the quality should be continuous process, though in the organization it is a top-down procedure but it is initiated from the top management and implemented from bottom level. It aids organization to become more effective and meet customer satisfaction.
3. Customer Focus – Every organisation strives to achieve customer satisfaction because at the end it is the customer who rates the product depending on quality, so the organization should never compromise with the quality of the product or services as it directly affects the profitability of the organization.
4. Process Oriented – Process is the series of steps that is based on taking input and receiving output in the form of product that is delivered to the customer. Process oriented means not only the final product but every step in its production is monitored.
5. Fact Based Decision Making – Organization continually collects and analyze data to make accurate based on facts or data.
6. Communication – It is the key for maintaining a good relationship with customer and employee and should be open at all level of organization and to boost morale of the employee and motivate them to strive harder to achieve their goal.
7. Strategic and Systematic Approach – Setting a strategic plan which has quality as its core component and the whole production process has a systematic flow.
8. Integrated System – it means maintaining a good quality culture with quality standards which will further lead to customer satisfaction and continuous improvement.

Benefit of TQM [16, 17]

1. It aids in prevention and elimination of error.
2. Increases Customer Satisfaction.
3. Boosts employee's morale.
4. Reduces the cost of service and increases the profit.
5. Enhancement of Organizational culture.
6. Increases shareholder and stakeholder value.
7. Continuous improvement to meet quality standard.

Disadvantages of TQM [16, 17]

1. The expenditure on the initial introduction.
2. Effects may take years to emerge.
3. Employees may oppose change.

VI. PHARMACEUTICAL QUALITY MANAGEMENT SOFTWARE

The pharmaceutical industry is dependent on numerous software tools for establishing effective quality management systems (QMS) that meets regulatory standards and ensures that the safety and quality parameters are fulfilled in the pharmaceutical products. The application of quality management software in the pharmaceutical sector is critical for a number of reasons – compliance with regulatory framework as we know that pharmaceutical industry is regulated by various regulatory bodies such as GMP, ICH and GLP so these software help in compliance with these regulatory standards by providing assistance in managing documents, monitoring performance, and audit trails. Being a dynamic industry change control are the important aspect of pharmaceutical so these software help in streamlining change control processes and ensure that the changes are properly evaluated, documented and registered in order to avoid the potential risks. These software's also provide assistance in quality risk management, CAPA (Corrective action and Preventive action) and in securing the data and conserving its integrity thus contributing in maintaining the excellent quality in the pharmaceutical goods. All the software that are used in pharmaceutical industry comply with 21 CFR part 11. [18, 19, 20,21]

Table 1: Software used in Pharmaceutical Quality Management

SOFTWARE'S	USE IN PHARMACEUTICAL INDUSTRY
1.SAPQM (Quality Management)	One of SAP's primary benefits is its efficiency in successfully managing the supply chain. The program lets organizations track and manage the shipment of raw material from vendors to manufacturers, managing inventory, tracking delivery period and guaranteeing quality. SAP S/4HANA Cloud is widely used in pharmaceutical industry that uses intelligent cloud ERP. [21]
2.MasterControl	MasterControl supplies pharmaceutical organizations with a variety of tech based pharmaceutical quality control tools that optimize, simplify, and streamlines various procedures, documents into a quick and efficient quality management system. This software controls various quality assurance (QA) processes such as inspection, variations, nonconformity, change control, and CAPAs. [22]
3. TrackWise	TrackWise helps to ensure quality and compliance. It Reduces the product recalls by detecting the deviation or errors at early stages and performing CAPA before delivering the product to the customer thus ensuring customer safety. [23]
4.EtQ Reliance	It helps in validation, complaint handling, supplier corrective action by collaborating with them and reduce corrective action closure time. It has advanced quality analytics which enables databased decision. [24]
5.Veeva QualityOne	It incorporates best practices into all of your quality procedures. From CAPA management to auditing, supplier quality management, and complaints. it is able to adjust to any regulatory requirement. [25]
6.Arena QMS	This software links required quality to the design of the product in a single system. It is a product-based quality management system. [26]
7.Pilgrim SmartSolve: OOS	Pilgrim's Out of Specification Management program is designed to comply with FDA guidance on out-of-specification lab result investigations and provides risk-reduction by corrective and preventive actions (CAPAs). [27]
8.LabWare LIMS (Laboratory Information Management System)	It helps in Quality Control and Quality Assurance testing. It provides automation in final product testing, raw material testing and in process batch testing. It also Provide solutions for stability study management and it manages products specification and control limits. [28]
9. AssurX	It fully automates the quality management system which increases the transparency and reduces error from manual input. It stores all the information related to CAPA, deviation, audit, document control in a single system where it can be easily accessed by the regulators. It helps to solve quality issues. [29]
10.Oracle Agile PLM	It aids in managing the product lifecycle by facilitating the development of drugs portfolio management, complete drug production records, effective clinical supply chain management, quicker transfer of technology, and unified quality and risk management methods. [30]

The use of these software's depends on pharmaceutical company's size and specific needs. In addition, software and systems can be tailored to meet regulatory standards of internal quality processes. Before adapting any software, organizations usually conduct a thorough study to ensure that it adheres to their specific regulatory and operational requirements.[31]

GUIDELINES FOR QUALITY

CONCLUSION

In Pharmaceutical a product is termed to be a quality product if it is safe and effective for the patients or customer, so this quality should be built in the product starting from its development till it is dispatched, in order to keep quality intact throughout product lifecycle an organization needs a well-defined Quality Management System but now a days various software have been launched and are being used to manage quality in pharmaceutical industry, these software's are fully automated and comply with regulatory

guidelines thus they have lessen the burden of healthcare professionals by saving time and reducing wastage of the product. QMS is important segment of pharmaceutical as it helps in fulfilling customer expectation of quality and keeps customer satisfied with the product thus eventually leading to profitability of the organization. Throughout the review we have explored the pivotal role of TQM, QMS software's, ICH, ISO and Quality Risk Management tools in fulfilling industry commitment of providing safe and efficacious medication to the patients.

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VII.

7.1. ICH

ICH stands for International Conference on Harmonization, it is a collaborative initiative by- Japan, USA and Europe. ICH addresses technical requirement that are need to be fulfilled for approval of pharmaceutical product for consumption by humans in the ICH region. [32]

Aim

The foundation of ICH was laid in 1990 by the 3 member (Triad) - Japan, USA and Europe to attain greater international harmonisation for discovery and authorization of safe, effective and excellent quality medicine in most economically feasible manner and meeting high quality standards. To ensure that the medicinal product reaches to the patient at bare minimal time. [33]

ICH Guidelines

The guidelines of ICH are categorized into four types- [34]

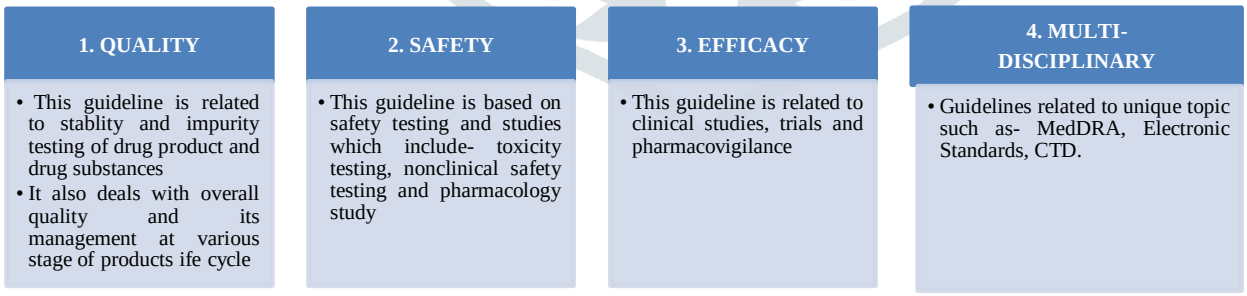

Figure 2: ICH Guidelines (QSEM)

7.1.1. ICH Q9: QUALITY RISK MANAGEMENT [35, 36]

Quality Risk Management is an organized approach for the evaluating, controlling, reporting and reviewing risk to the quality of the pharmaceutical product throughout its lifespan. Today Quality System has been acknowledged as core value by pharmaceutical industries and quality risk management is the key component of an excellent quality system. An efficient QRM ensures that the risk to quality is proactively identified at the time of the development and manufacturing of the product and a safe and high-quality product is delivered to the patients.

Fundamentals of QRM

- Analytical and science-based information and data should be used to assess quality risks, with a particular emphasis on patient safety.
- The amount of effort done to reduce or manage the risk should match the degree of risk addressed.

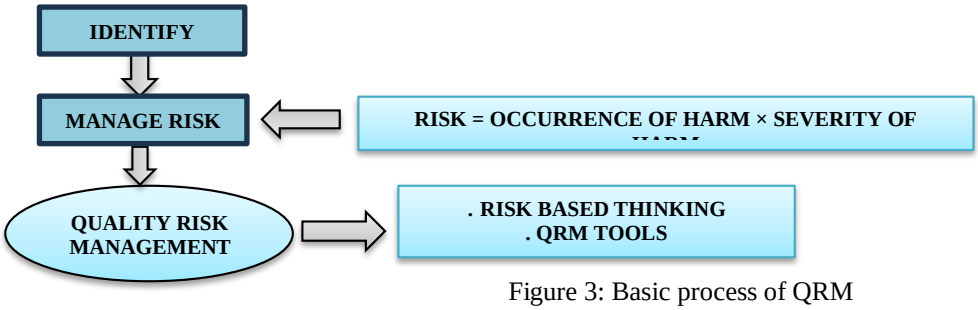

Figure 3: Basic process of QRM

Process of QRM

1. Initiating a QRM process – A proactive procedure should be started in which possible risks should be defined and all the data associated with the potential of the risk should be collected. A leader having a risk-based thinking and decision-making skills should be appointed and provided with resources to initiate the process of QRM for potential risk.
2. Assessment of risk – It means- recognizing, analysing and evaluating the risk. Risk assessment answers three key questions: 1. What error can occur? 2. What will be the chances of occurrence of error? 3. What will be the outcome?
3. Risk Control – It means planning and making decision to reduce the risk to a level where negative impacts are negligible. Communication is the key parameter that is involved in every step of QRM process it states that the risks, its management and acceptance criteria should be shared and communicated within the organization and with the regulatory authorities.
4. Risk Review – The results of the QRM process are reviewed and monitored continuously in order to determine how these events are causing threat to quality of the product and to find out whether they are intentional or unintentional. The periodicity of the risk review depends upon the severity or harm that the risk possesses and the risk review has immense impact on the risk acceptance decision.
5. Risk Management Methodology – QRM encourages both analytical and methodological approach for making decisions, it provides documented, transparent and reproducible methodologies to assess the probability, severity and detectability of risk. Earlier the risk to quality was assessed by some informal methods such as observations, trends and gathered information, but today along with these informal methods a scientific approach that is use of Risk Management Tools is used to assess and manage risks to quality of pharmaceutical product.

Table 2: Quality Risk Management Tools [37]

TOOLS	DESCRIPTION	AREA OF USE
1. Basic Risk Management Facilitation Tools	These are the tools that help in organizing data and facilitate decision making in QRM process it includes- flowcharts, check sheets and fish bone diagram (for root cause analysis)	These are basic tools that are mainly used in compilation of data that may further help in understanding deviations and complaint regarding the product
2. Failure Mode Effect Analysis (FMEA)	It is a proactive approach to determine the upcoming risk or failure in the process to prevent them from happening and reduce its severity by finding out where the failure can happen and what will be its impact. In this a Risk Priority Number (RPN) is determined	FMEA can be applied to determine the potential failure of any equipment, facilities and method and its affect in the product.

	(RPN= severity × probability × detectability) a scale is set from 1(minor severity) to 5(high severity) and depending on the RPN calculated corrective action and preventive action (CAPA) is done.	
3. Failure Mode Effect and Criticality Analysis (FMECA)	It is an updated and improved version of FMEA with incorporation of detection of the failure along with the severity it will cause. FMECA goes into more detail to give more precise and accurate result. Before performing FMECA there is a requirement of FMEA for the criticality analysis.	FMECA is mostly used for the risk associated with the manufacturing procedures. The result comes in the form of score according to which the action is taken to resolve the problems.
4. Fault Tree Analysis (FTA)	It is a top-down analysis that evaluates if there is any failure in the mode of action of the product or process. The output is generated in the form of picture with the help of logical operator (AND, OR etc)	FTA determines the main cause of the risk with the help of pictorial diagram. It is used both in risk evaluation and in making a risk recording program.
5. Hazard Analysis and Critical control points (HACCP)	This technique uses technical and scientific ideas to investigate, assess, minimize and avoid risks associated with product design, development, production, and usage. It consists of 7 steps: 1. Perform analysis of hazard and develop precautionary measures for every phase of the method. 2. Identify the important control points. 3. Setup the critical limit for the procedure. 4. create a program for recording critical control point. 5. Establish correction to be done when recording shows that the critical control points are not within the set limits.	HACCP is use to detect, minimise and control or risk related to physical chemical and biological hazard. It is useful when overall knowledge of product and process is known and critical control point are established. This helps to manage the risk by monitoring critical control points during the products lifecycle.

	6. Develop a program to validate the effectiveness of the HACCP. 7. Build a record maintaining and tracking system as well as documenting the procedures.	
6. Hazard Operability Analysis	It states that risk is caused due to deviation from the set parameters. In this, guidewords (No, More, Other Than, Part of, etc.) are used in various parameters to detect the deviation. To conduct this analysis there is a requirement of a team of people having in depth knowledge and who have key role in product and process design.	HAZOP is applicable to all manufacturing processes, including subcontract manufacturing and design, as well as vendors, machinery, and infrastructures. It is used for the determining various hazard to safety. HAZOP generates a list of vital and crucial operation that needs constant monitoring to keep system in state of control.
7. Preliminary Hazard Analysis	PHA is used to identify the future hazard and hazardous situation and the probability of its occurrence by using the prior knowledge of hazard. It consists of – 1. Estimation of probability that the risk will occur. 2. A qualitative assessment that how much damage the risk can cause to health. 3. Ranking the severity of the hazard. 4. Determine possible corrective measures.	PHA is employed at the onset phase of product creation when a little knowledge of the product is known so after PHA the products are also analyzed under other tools. It can be used in design of product as well as process and to determine various risk in product and process prototype.
8. Risk Ranking and Filtering	This tool is used for comparing and aligning risk. In this various quantitative and qualitative factor related to risk are evaluated. The tool breaks down basic risk question into many elements and further these elements are combined to form a risk score according to which the risks are ranked and filtered.	It can be used to hierarchize manufacturing sites for audits. This tool is used in complex situation where risk and its consequences are so much diversified that they are difficult to compare with just one tool. It is mostly used when both qualitative and quantitative risk are evaluated.

9. Supporting Statistical Tools	In this data is assessed to help in reliable decision making. Some of widely used statistical tools in pharmaceutical industry are – • Control charts – 1. Acceptance Control Charts 2. Control Charts with Arithmetic Average and Warning Limits 3. Cumulative Sum Charts 4. Shewhart Control Charts • Design of Experiment • Histograms • Pareto charts	These tools are used to identify important factors leading to deviation and investigation of root causes.

7.1.2. ICH Q10: Pharmaceutical Quality System [38]

It is the inclusive model for Pharmaceutical Quality System given by ICH and is based on ISO 9000: 2015 concepts. PQS can be implemented across product's lifespan for advancement, progression and to make strong connection between invention and production process of pharmaceutical products. It includes 3 key aspects –

1. cGMP Regulation.
2. ICH Q8 (Pharmaceutical Development)
3. ICH Q10 (Quality Risk Management)

Objectives of ICH Q10

1. Achieve Product Realisation – To setup a system that will produce a high-quality product with compliance to regulatory requirement and will lead to customer satisfaction.
1. Develop and provide a state of control – determine effective monitoring and control system and assuring that product quality is maintained throughout its lifecycle. Various tools for managing risk can be used to keep the systems in state of control.
2. Facilitate Continual Improvement – It aid in improving the quality of the product, reducing the variability, strengthening the pharmaceutical quality system and fulfilling quality needs. Quality risk management tools can be used to find area of continual improvement.

Scopes of ICH Q10

1. It is applicable for manufacturing and development of API, Drug Product, Biotechnological Product and Biological Product throughout their lifecycle.
2. ICH Q10 guideline is applied to each stage of product lifecycle, so this guideline divides the product lifecycle into 4 phases –

   Phase 1 – Pharmaceutical Development

   Phase 2 – Transfer of Technology

   Phase 3 – Commercial Manufacturing

   Phase 4 – Discontinuation of the Product from the market

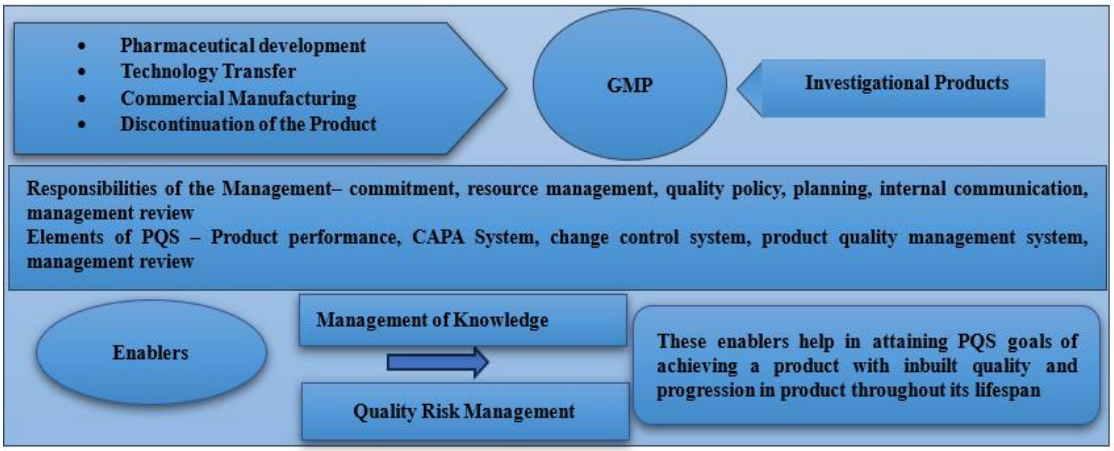

Figure 4: ICH Q10 Model

7.2. ISO (International Organization for Standardization) [39]

ISO is a world-wide confederation of national standard committees which was established in 1946 in Geneva, Switzerland. It brings global experts together to form ISO technical committee whose work is to develop series of international standard for quality system.

Benefits of ISO in Pharmaceutical Industry [40]

1. Enhancement in the Performance of the Organization.
2. Reduction in the risk to safety of the employees.
3. Quality is maintained throughout product lifecycle.
4. Protection of the data.
5. Helps in attaining customer satisfaction.
6. Increases customers reliability on the product.

ISO 9001

It is used as Quality Management Standard worldwide. Currently the fifth edition that is ISO 9001:2015 has replaced the fourth edition ISO 9001:2008 and is being used as standard in pharmaceutical industries for managing quality and it ensures that the product and services of ISO 9001 certified industry are safe and effective. [41]

- It supports risk-based approach and thinking to solve a problem.
- It is based on PDCA Cycle approach that is planning, operation (do), evaluation (check) and improvement (act). The main aim of this cycle is to fulfil customer needs and requirement and providing them best product.
- Leadership is the key and central element of the system as it is the responsibility of the leader to maintain the overall system in state of control and if any risk detected it should be his duty to imply QRM tools or CAPA to reduce the risk
- Customer Satisfaction is an important and must for the pharmaceutical companies as the product is directly consumed by the customer and has great impact on his health so it is the sole duty of every healthcare professional to make high quality product that is safe, effective and has no adverse-affect and if the product has the mentioned characteristics, then customer satisfaction is attained.

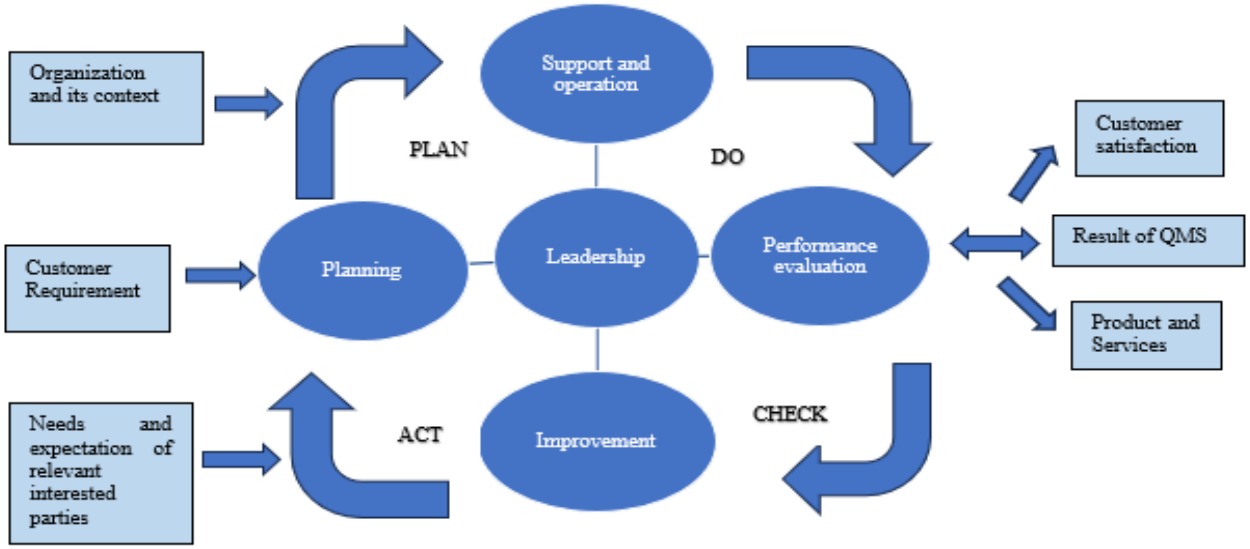

Figure 5: The Generic ISO 9001: 2015 [43]

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