(QMS), management responsibility, Product realization

A **quality management system** (**QMS**) is a collection of business processes focused on consistently meeting customer requirements and enhancing their satisfaction. It is aligned with an organization's purpose and strategic direction (ISO 9001:2015). It is expressed as the organizational goals and aspirations, policies, processes, documented information, and resources needed to implement and maintain it. Early quality management systems emphasized predictable outcomes of an industrial product production line, using simple statistics and random sampling. By the 20th century, labor inputs were typically the most costly inputs in most industrialized societies, so focus shifted to team cooperation and dynamics, especially the early signaling of problems via a continual improvement cycle. In the 21st century, QMS has tended to converge with sustainability and transparency initiatives, as both investor and customer satisfaction and perceived quality are increasingly tied to these factors. Of QMS regimes, the ISO 9000 family of standards is probably the most widely implemented worldwide – the ISO 19011 audit regime applies to both and deals with quality and sustainability and their integration.

Other QMS, e.g. Natural Step, focus on sustainability issues and assume that other quality problems will be reduced as result of the systematic thinking, transparency, documentation and diagnostic discipline.

The term "Quality Management System" and the initialism "QMS" were invented in 1991 by Ken Croucher, a British management consultant working on designing and implementing a generic model of a QMS within the IT industry.

Process

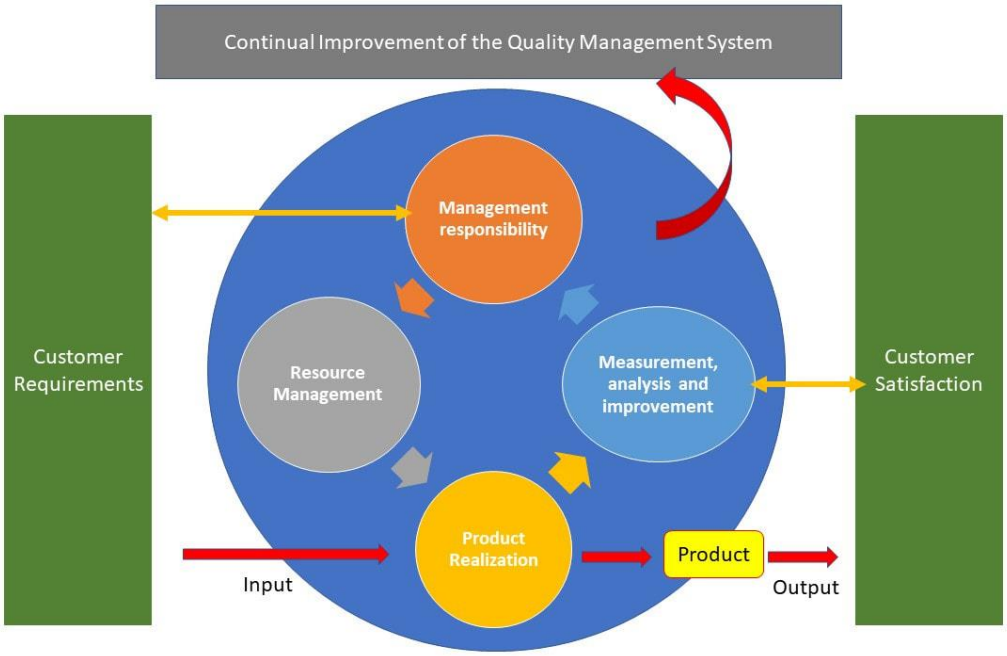
A QMS process is an element of an organizational QMS. The ISO 9001 standard requires organizations seeking compliance or certification to define the processes which form the QMS and the sequence and interaction of these processes. Butterworth-Heinemann and other publishers have offered several books which provide step-by-step guides to those seeking the quality certifications of their products[5], [6][7][8][9][10]

Examples of such processes include:

- order processes,
- production plans,
- product/ service/ process measurements to comply with specific requirements e.g. statistical process control and measurement systems analysis,
- calibrations,
- internal audit,
- corrective and preventive action,
- identification, labeling and control of non-conforming products to prevent its inadvertent use, delivery or processing,
- purchasing and related processes such as supplier selection and monitoring

ISO 9001 requires that the performance of these processes be measured, analyzed and continually improved, and the results of this form an input into the management review process.

Software



QMSElements of Quality management system: An overview

Quality management system (QMS) is the linking system between customer requirement and customer satisfactions. Universal goal of quality system is the consistent manufacturing of safe and effective products. As per **ICH Q10** : management responsibility, Continual improvement of process performance, continual improvement of product quality and continual improvement of pharmaceutical quality system via management review are the key components of the pharmaceutical **quality management system**.

What are the Elements of Quality management system?

Quality management system is having four arms by which it runs; each part having similar king of Impact on the development and run of Quality management system.

- Management Responsibility
- Resource management
- Product realization
- Measurement, analysis and improvement

Management responsibility

Management responsibility is one of the essential elements of Pharmaceutical **Quality management system**, **WHO** says Quality management system should facilitate senior management / Top management to achieve quality objectives set by the management in the form of quality policy.

It is responsibility of top management of the firm to manage the design, Implementation and management of the quality system, with the combination of good manufacturing practices and good business practices.

Leadership should show strong and visible support for the quality system and ensure its implementation throughout the organization.

Organizational structure is important to identify the problems and apply the rectifications.

Quality system building is required to ensure the compliance with the good manufacturing regulations developed by the various regulatory authorities; this includes Change procedure, Document control procedure, scientifically sound and appropriate written controls for Operating procedures, Test specification, plans.

Establishment of policies and procedures to run the quality system is the best way to articulate the vision on management towards quality to all levels of the organization. A strong commitment to quality is required by the management in the organization that could be defined as a Quality Policy.

Management review system; any system seeks a robust review system to run effectively and adequately. Hence, for an effective quality system it is required to review performance of the system by top management with a planned schedule.

Management quality system review strategy should includes; Product review, process review, customer requirement.

Quality Metrics data evaluation can be the best way to review the Quality system by the management; **FDA (US) published Draft guidance** on the same **Learn More..**

Why Quality management system review is required?

Review of quality system benefits to the quality system;

- To improve the quality system.
- To improve manufacturing process and products as per the customer and regulatory requirements.
- Rearrangement of the resources.

Resource Management

Resource allocation and management helps to develop a **Quality Management system** with the established quality goals and to run quality system complying the good manufacturing practice regulations.

- Sufficient resource should be allocated for quality system and operational activities.
- Skilled personals are the backbone of quality system, personals those are part of the quality system should be qualifies to perform the operations those are allocated to them.
- Identification and selection of the personal should be done based on their scientific and technical knowledge, technical understanding, and product and process knowledge.
- Continued training is critical component to ensure that the employee remain proficient with respect to the current Good Manufacturing practices requirements. Training should be focused on function specific and related regulatory requirements.
- Facility and equipment are the main technical resources of an organization as well as for quality management system.
- Technical resources also includes technical man power like engineers, development scientists etc. those understand the technical problems, risk factors and the manufacturing process related to the products.
- Technical resource like facility, equipment should be qualified, calibrated, cleaned and well maintained as well, this is important for the intended product identity, strength, quality and purity.

Product realization

Management is having responsibility to review the product and its performance over the time of periods;

- A product developed by the manufacturer should define / introduced from the design stage to delivery stage. Process of designing includes development of the product and process which should be documented in terms of responsibility for designing or changing products.
- **Quality management system** includes documentation of the products includes its life history as well, i.e. designing, development, manufacturing, Quality controls, monitoring, validation, Product stability, packaging, Storage, product distribution etc. QMS approach starts from the starting material to end product. Input material examination also includes supplier verification along with the supplied material quality.
- Each and every material being used for the manufacturing of the product is having significant amount of impact on the quality of the end product. Hence, Quality of the input material must be in-line to the product or process requirement designed during the development.
- Various **Regulatory Agencies** all over the world suggest **Supplier qualification** and periodic audit of supplier. An audit should also include a systematic examination of the supplier's quality system to ensure that reliability is maintained.
- In a robust quality system, production and process controls should be designed to ensure that the finished products have the identity, strength, quality, and purity they purport or are represented to possess.
- Process performance need to be monitored during the manufacturing with the established manufacturing process. Under a quality system, written procedures should be followed and deviations from them should be justified and documented to ensure that the manufacturer can trace the history of the product.
- Discrepancies may be detected during any stage of the process or during quality control activities. Not all discrepancies will result in product defects; however, it is important to document and handle discrepancies appropriately.
- A discrepancy investigation process is critical when a discrepancy is found that affects product quality. Hence, it is important to acknowledge the non conformance.

Documentation process could be helpful to the management for the review of product, process performance over the time of periods.

Evaluation process for Continual improvement of process performance

Various parameters are there to ensure the continual improvement of the process like;

- **Quality Management system** approaches defined continually monitoring trends and improving systems. This can be achieved by monitoring data and information, identifying and resolving problems, and anticipating and preventing problems. Trending analyses can help focus internal audits.

- **Internal audit** at planned intervals is required to evaluate effective implementation and maintenance of the quality system. Effective decision-making in a quality systems environment is based on an informed understanding of quality issues.
- Elements of risk should be considered relative to intended use of a product. Risk management is used as a tool in the **quality management system** for development of product specifications and critical process parameters.
- **Corrective action** can be taken for system / process improvement with respect to the identified risk. It is essential to determine what actions will reduce the likelihood of a problem recurring.
- **Preventive action** should be evaluated and recorded, and the system should be monitored for the effectiveness of the action. Problems can be anticipated and their occurrence prevented by reviewing data and analyzing risks associated with operational and quality system processes, and by keeping abreast of changes in scientific developments and regulatory requirements.

Final wards; Implementation of the Quality Management System (QMS) approaches as defined in the various regulatory agencies may help to get the desired quality of the product as well it helps to achieve the goal i.e. “Customer Satisfaction” as per the “Customer Requirement”.

We hope this article of total pharmaceutical topic helps you to refreshing your knowledge bucket; other useful articles may uplift the information stock of the mind.