

CHAPTER -4

(Quality Management Systems)

1. Definition & Concept of Quality Management:

- Quality management is the act of overseeing all activities and tasks that must be accomplished to maintain a desired level of excellence.
- This includes the determination of a quality policy, creating and implementing quality planning and assurance, and quality control and quality improvement.

2. Importance of Quality Management:

- Implementing quality management tools ensure high customer loyalty, thus better business and increased cash flow.
- Quality management system ensures higher employees satisfaction, healthy workplace and so on.
- Quality management processes make the organization a better place to work.
- Quality management enables employees to deliver more work in less time.

3. Quality Management Certification:

- Quality management system certification helps organization to continually improve through lessons learnt from past thereby to manage the present effectively and make planning to meet the challenges of future.
- ISO 9001:2015 standard sets out criteria for a quality management system that can be used by any organization, large or small, regardless of its field of activity.
- This standard is based on a number of quality management principles including a strong customer focus, the motivation and implication of top management, the process approach, risks and opportunities based thinking and to achieve continual improvement.

4. Total Quality Management and its benefit:

- Total quality management (TQM) is a management approach to long-term success through customer satisfaction.
- In a TQM effort, all members of an organization participate in improving processes, products, services, and the culture in which they work.
- TQM strengthens competitive position.
- Higher productivity.
- Higher profitability.
- Enhanced market image.
- Improved customer focus & satisfaction.

5. Quality by Design (QbD):

- QbD is a systematic approach to development that begins with predefined objectives and emphasizes product, process understanding and process control, based on science and quality risk management.
- The concept of QbD was mentioned in ICH Q8 guidelines which states that quality should be built into product by design and it cannot be tested into product.
- QbD leads to better understanding of the process.
- QbD leads to less batch failure.
- QbD leads to more efficient & effective control of change.
- QbD helps in efficient technology transfer to manufacturing.

6. Six Sigma concept:

- Six Sigma is a set of techniques and tools for process improvement.
- Six Sigma is now an enormous brand in the world of corporate development.
- Six Sigma seeks to improve the quality of process outputs by identifying and removing the causes of defects.

- Six Sigma approach is a collection of managerial and statistical concept and techniques that focuses on reducing variations in processes & preventing deficiencies in product.
- In a process that has achieved six sigma capabilities; the variation is small compared to the range of specification limit.
- A Six Sigma process is one in which 99.9999966% of the products manufactured are statistically expected to be free of defects.

7. Out of Specifications(OOS):

- If the analytical result(s) of a batch or material is /are falling out side of the established specification ranges, is called /considered as Out of Specification.
- Guidelines are available for defining to handle the OOS products.
- OOS found due to the following reasons:
 - ✓ Laboratory errors
 - ✓ Process related
 - ✓ Sample homogeneity
- The OOS may be observed during the analysis of:
 - ✓ Stability study
 - ✓ Finished API
 - ✓ Intermediates
 - ✓ In-process
 - ✓ Raw materials
 - ✓ Packing materials
- Procedure of OOS investigations: As per MHRA (EU GMP):
 - ✓ Phase-I Investigation (Primary & extended lab investigation).
 - ✓ Phase-II Investigation (Manufacturing investigation).
 - ✓ Phase-III Investigation (Extended manufacturing, Re-sampling & Re-analysis).

8. Introduction to ISO 9000 series of quality system standards:

- The ISO 9000 family of standards is related to quality management systems.
- ISO 9000 deals with the fundamentals of quality management systems, including the eight management principles on which family of standards is based.
- ISO 9000 Series is classified as:
 - ✓ ISO 9000- Explains fundamental quality concepts.
 - ✓ ISO 9001- Model for QA in design, development, installation & servicing.
 - ✓ ISO 9002- Model for QA in the production & installation of manufacturing systems.
 - ✓ ISO 9003- QA in final inspection & testing.
 - ✓ ISO 9004- Guidelines for the applications of standards in quality management & quality systems.

9. ISO 14000:

- ISO 14000 is a family of standards that is related to environmental management.
- It helps in minimizing operations which negatively affect the environment.
- This series complies with the applicable laws, regulations, and other environmentally oriented requirements.
- ISO 14001- Environmental Management Systems- Specifications with guidance for use.

10. NABL [National Accreditation Board for Testing and Calibration Laboratories]:

- NABL is an autonomous society providing accreditation of technical competence of a testing, calibration, medical laboratory & proficiency testing provider (PTP) and reference material provider.
- NABL is an autonomous body under the aegis of department of science & technology. It is only one of its kind that assesses laboratories in India for quality and consistency in the results.

11. GLP [Good Laboratory Practices]:

- GLP is an FDA regulation.
- GLP embodies a set of principles that provides a frame work within which laboratory studies are planned, performed, monitored, archived and reported.
- GLP is to assure the quality & integrity of data submitted to FDA in support of the safety of regulated products.

Learning Outcome: To understand the Quality Management System.

Important questions:

[Two marks Questions]

1. Define Quality Management System (QMS).
2. What is NABL?
3. What is GLP?
4. What is QbD?
5. What is OOS?
6. Define change control.

[Five marks Questions]

1. What are the objectives of Quality Management System?
2. What is the role of quality in pharmaceutical industry?
3. Discuss the Six Sigma concept in detail.
4. Discuss the ISO 9000 series in detail.
5. Add a note on ISO 14000.

[Ten marks Questions]

1. Explain the Quality Management system in detail by giving some suitable examples of quality standards.
2. Discuss the quality standards like ISO 9000 series, ISO 14000 and Six Sigma in detail.

