Quality Assurance and Management

Learning objectives

Students will be able to:

1. Describe the historical evolution of key quality concepts and terms
2. Explain the fundamental principles of a Quality Management System (QMS)
3. Outline the key elements and enablers of the Pharmaceutical Quality System (PQS) as per ICH Q10

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1. Introduction

In the dynamic landscape of the pharmaceutical industry, Quality Assurance and Management stand as the cornerstones of ensuring that every medication, from the simplest painkiller to the most complex life-saving drug, meets the highest standards of quality, safety and efficacy. Therefore, understanding the intricacies of quality in pharmaceuticals is not just an academic pursuit; it is a commitment to safeguarding public health and making a real impact.

2. Historical overview of quality

Timeline of the development of key quality concepts and terms, with their definitions and main focus.

Concept	Date	Definition	Main Focus
Quality control (QC)	Before 1920	The process of inspecting products and services to ensure that they meet predetermined standards.	Identifying and correcting defects
Statistical quality/process control (SQC/SPC)	1920s	The use of statistics to improve the quality of manufacturing processes	Preventing defects from occurring
Quality assurance (QA)	1940s	A systematic approach to ensuring consistent, high-quality predetermined standards	Preventing defects and maintaining consistency
Total quality management (TQM)	1950s	A management approach that focuses on continuous improvement of the quality of products, services, and processes.	Involving all employees in the pursuit of quality excellence
Lean management	1950s	A production approach that focuses on eliminating waste and maximizing efficiency.	Identifying and eliminating non-value-added activities from all aspects of the production process

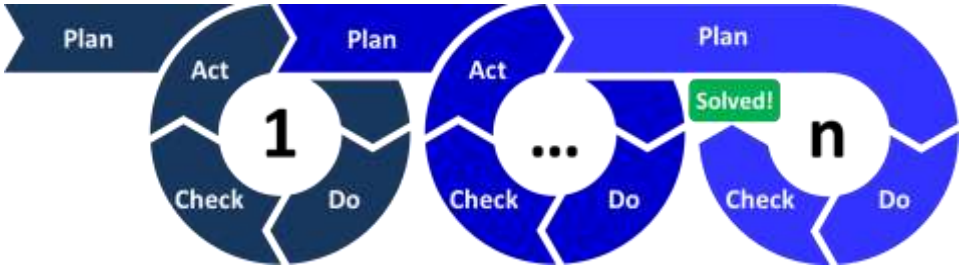
Quality by design (QbD)	1980s	A systematic approach to product development that focuses on building quality into products from the beginning.	Identifying and optimizing the critical factors that affect the quality of a product
Quality management system (QMS)	1980s	A collection of business processes focused on consistently meeting customer requirements and enhancing their satisfaction.	Ensuring that products and services meet customer requirements and expectations
Six Sigma	1986	A quality improvement methodology that uses data and statistical analysis to identify and eliminate the root causes of defects.	Reducing defects and variation in processes
ISO 9000 standards	1987	A set of international standards that provide guidance on a variety of management systems, including QMS.	Implementing best practices for quality management
Data analytics	After 2010	The use of data and AI to identify patterns and trends that can be used to improve quality.	Identifying patterns and trends in data that can be used to improve products, services, and processes

3. Quality assurance

Quality is a broad concept emphasising excellence.
Quality Control (QC) is about inspection and monitoring.
Quality Assurance (QA) focuses on systematic processes to ensure quality,
The QA process is typically iterative, with each step being repeated until the desired level of quality is achieved. The QA process can be divided into four main phases: Plan, Do, Check, and Act (PDCA)

- **Plan**: Identify objectives, set goals, and develop a plan.
- **Do**: Implement the plan and execute the proposed actions.
- **Check**: Monitor and evaluate the results, collect data, and analyse performance.
- **Act**: Take corrective actions based on the results, standardise improvements, and repeat the cycle for ongoing enhancement.

PDCA is an iterative process, promoting continuous problem-solving and improvement.



4. Quality management system (QMS) and ISO 9000 family

A quality management system (QMS) is a set of policies, processes, and procedures that help organisations to consistently produce high-quality products and services. QMSs can be used in any industry and by any type of organization, regardless of size.

The ISO 9000 family of standards is a set of international standards that provide a framework for developing and implementing a QMS. The ISO 9000 family includes a number of standards, including:

- ISO 9000:2015 - Fundamentals and vocabulary
- ISO 9001:2015 - Requirements

ISO 9000:2015 provides the fundamental concepts and principles of quality management systems. It defines key terms and provides a common understanding of quality management principles, which are:

- Customer focus: The organization must understand the needs of its customers and strive to meet or exceed those needs.
- Leadership: Top management must be committed to quality and create an environment where employees can contribute to quality improvement.
- Engagement of people: All employees must be involved in quality improvement.
- Process approach: The organization must manage its activities and processes as interrelated processes.
- Improvement: The organization must continually improve its QMS and its products and services.
- Evidence-based decision making: The organization must make decisions based on evidence and data analysis.
- Relationship management: The organization must manage its relationships with key stakeholders to maximize value.

ISO 9001:2015 - Requirements

ISO 9001:2015 is the most widely used QMS standard in the world, with over one million organisations certified worldwide. ISO 9001:2015 It is the only standard in the ISO 9000 family that can be certified. It can offer a number of benefits to organisations, including:

- Improved customer satisfaction
- Reduced costs
- Increased efficiency
- Enhanced reputation
- Competitive advantage

The other standards in the ISO 9000 family provide guidance on a variety of topics related to quality management, such as auditing, continuous improvement, and quality management systems for specific industries.

The ISO 9000 family of standards is a valuable resource for organisations that want to improve their performance and achieve their goals.

5. Pharmaceutical quality system (PQS)

The main goal of PQS is to establish an effective QMS for the pharmaceutical industry based on ISO quality concepts and GMP regulations. PQS is described in ICHQ10. It applies across product lifecycle from development to discontinuation. The objectives are as follows:

- Achieve product realisation
- Establish and maintain state of control
- Facilitate continual improvement

A Quality Manual should describe PQS and contain information about:

- quality policy,
- scope of the system,
- management responsibilities within the system.

Figure. Diagram of the ICH Q10 Pharmaceutical Quality System Model

5.1. Management responsibility

Good leadership is vital for making sure that everyone in the company is fully committed to maintaining high quality and ensuring the PQS works well. Their responsibilities are as follows:

i. Management Commitment
ii. Quality Policy
iii. Quality Planning
iv. Resource Management
v. Internal Communication
vi. Management Review
vii. Management of Outsourced Activities and Purchased Materials
viii. Management of Change in Product Ownership

5.2. Elements

These elements should be applied in a manner that is appropriate and proportionate to each of the product lifecycle stages. The PQS elements serve as the major pillars under the PQS model.

a. Process performance and product quality monitoring system

- Establish control strategy using quality risk management
- Tools for measurement and analysis
- Verify operation within state of control

- Identify sources of variation

b. Corrective and preventive action (CAPA) system
- Investigate deviations and defects
- Take action to prevent recurrence
- Drive product and process improvements

c. Change management system
- Manage and document changes
- Assess impact and need for regulatory filing
- Ensure no unintended consequences

d. Management review of process performance and product quality
- Review process performance and product quality
- Assessment of quality system and processes
- Drive improvements and resource allocation

5.3. Enablers

These enablers are essential for effective ICH Q10 implementation, enabling science and risk-based decisions on product quality.

Knowledge Management:
- Systematic approach to gather, analyze, and share product and process information.
- Sources include prior knowledge, development studies, manufacturing experience, and more.

Quality Risk Management:
- Integral to a robust quality system.
- Proactively identifies, evaluates, and controls quality risks.
- Facilitates continual improvement of process performance and product quality.
- ICH Q9 provides principles and tools for risk management.

5.4. Continual Improvement

This section describes activities that should be conducted to manage and continually improve the PQS.
- Review pharmaceutical quality system
- Monitor internal and external factors
- Improve processes, update objectives

6. Conclusion

QMS and PQS (ICH Q10) are essential for pharmaceutical organisations that want to produce high-quality products. QMS provides a framework for quality management and continual improvement, while ICH Q10 provides specific guidance on QMS implementation in the pharmaceutical industry.

7. References

- ICHQ10
- https://asq.org/quality-resources/history-of-quality
- https://www.iso.org/files/live/sites/isoorg/files/store/en/PUB100080.pdf
- https://www.simplerqms.com/ich-q10-pharmaceutical-quality-system/