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Review Article

A Review on Quality Assurance and Quality Management System in Pharmaceutical Industry

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ABSTRACT

Quality assurance (QA) and quality management (QM) are critical pillars in pharmaceutical science and industry, ensuring the safety, efficacy, and reliability of pharmaceutical products. QA focuses on implementing systems and processes to prevent quality issues, emphasizing Good Manufacturing Practices (GMP), documentation, and regulatory compliance. On the other hand, QM provides a comprehensive framework, integrating QA and quality control (QC) with strategies like Quality by Design (QbD), risk management, and continuous improvement. Together, QA and QM uphold global regulatory standards, foster innovation, and enhance product quality, ultimately safeguarding public health and building trust in pharmaceutical products. The pharmaceutical industry relies heavily on robust quality assurance (QA) and quality management (QM) systems to ensure the production of safe, effective, and high-quality medicines. This project explores the principles and implementation of QA and QM, highlighting their roles in compliance with regulatory frameworks such as Good Manufacturing Practices (GMP) and ICH guidelines. QA focuses on preventing errors through well-defined processes, while QM integrates QA and quality control (QC) to establish a culture of continuous improvement and risk management. By analysing real-world applications, this project underscores the importance of QA and QM in enhancing patient safety, regulatory adherence, and operational efficiency within the pharmaceutical sector.

INTRODUCTION

QA in the pharmaceutical industry involves implementing systems and processes to ensure that products consistently meet or exceed

established quality standards. It encompasses activities such as Good Manufacturing Practices

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(GMP), Quality Management Systems, and adherence to regulatory requirements.

● Quality Assurance

According to WHO, quality assurance is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. With regard to pharmaceuticals, quality assurance can be divided into major areas: development, quality control, production, distribution, and inspections. ISO 9000 defines as "part of quality management focused on providing confidence that quality requirements will be fulfilled" Quality Assurance (QA) is a wide concept and covers all aspects that could have an impact on the quality of prescribed pharmaceutical products. The objectives of QA are: to ensure that the prescribed medicine competently provides the desired effect to the person taking it; to protect patients from accidentally being administered an incorrect or contaminated medication; and to ensure medicines comply with the regulation.

● objectives

1) products design and development are in according with requirements of CGMP Good Laboratory practices (For non-clinical development studies) and Good clinical practices (For clinical studies).

2) Every production batch is certified by authorized persons before it is relised for sale and supply.

● Scope

- ★ To prevent defects with a focus on the process
- ★ To improve development and test process so that defects do not arise

★ Prevention of quality problems through planned and systematic activities

● Quality management

■ The pharmaceutical quality management system is a comprehensive collection of policies process, and procedure designer to ensure and maintain uniform and high quality in the production of pharmaceuticals product

■ The pharmaceutical industries are vital segment of the health care system that conducts research, Manufacturing and marketing of pharmaceutical, biological product and medicinal devices used for the diagnosis as well as treatment of disease. If products are not of appropriate quality, then they could be resulting severe adverse effect or even death of the consumers or patients.

Initially concept of total quality control is used that quality is assured just on basis of quality control parameter but the concept of Total Quality Management involves building quality in a pharmaceutical product as it involves complete records such as standard operating procedure for every state validation record etc.

● Quality management system

Quality management is the administrative role responsible for defining and implementing the organization's quality policy, which is authorized by senior management. Quality management involves establishing an appropriate infrastructure or "quality plan" that comprises organizational structure, processes, and resources. B) Systematic steps required to verify that a product (or service) meets the specified quality standards. The essence of these actions is called "quality assurance."



➤ **Responsibilities of Pharmaceutical Quality Assurance: -**

1. Establish a quality system
2. Monitoring compliance with quality system
3. Establish procedures and details
4. Establish production controls
5. Performing laboratory tests or tests
6. Review and approve or reject all cGMP items
7. Ensuring non-compliance investigations
8. To keep managers informed

❖ **Managing Quality System: -**

Total quality management (TQM) is a widely used approach to quality management that aims to integrate quality into all aspects of an organization's operations. The main components of TQM are mentioned below.

1. **Strategic Commitment:** The first aspect of TQM is strategic commitment to management (Fig. 1). To achieve quality, the organization's culture must shift to prioritize it as a priority. Pursuing a quality goal involves significant costs, such as new equipment and services. Without commitment from senior management, quality improvement will remain a term or gimmick, resulting in minimal change.
2. **Staff engagement:** Staff engagement is another crucial component of TQM. Almost all successful quality improvement programs require keeping the person responsible for the work accountable for its appropriate

completion. Employee engagement is a key aspect in enhancing quality.

3. **Materials:** Another important part of TQM is to improve the quality of materials used by the organization.
4. **Technology:** New technologies are also advantageous for TQM systems. Investing in a high-performance machine can enhance accuracy and reliability, ultimately improving quality.
5. **Method:** Improved procedures can increase the quality of both products and services. Organizations employ these strategies during real-world transformations.

❖ **Components of Total Quality Management**
Total Quality Management (TQM) is a comprehensive approach focused on improving quality across all aspects of an organization. Key components include:

- **Customer Focus:** Organizations prioritize understanding and meeting customer needs. Continuous feedback from customers helps improve products and services
- **Leadership:** Effective leaders create a vision for quality and promote a culture that supports continuous improvement. They empower employees and establish clear goals.
- **Engagement of People:** All employees are encouraged to participate in quality initiatives. Their involvement fosters a sense of ownership and responsibility for quality outcomes.

- **Process Approach:** TQM emphasizes understanding and managing processes to achieve desired results. Organizations analyse processes to identify inefficiencies and areas for improvement.
- **Improvement:** Continuous improvement is a core principle. Organizations adopt methodologies like PDCA (Plan-Do-Check-Act) to systematically enhance processes and products.
- **Evidence-Based Decision Making:** Decisions are based on data and factual analysis rather than intuition. This involves collecting and analysing relevant information to inform strategies and improvements.
- **Relationship Management:** Building strong relationships with suppliers, customers, and other stakeholders is essential. Collaborative partnerships enhance quality and reliability throughout the supply chain.

Software used for management of quality in pharmaceutical industry: -

1. **Ample logic software:** Ample logic software offers automated and computerized solutions to pharmaceutical industry. It serves numerous purposes in the pharmaceutical sector, including CASPA, OOS, and OOT, to improve quality implement including.
2. **Track wise:** Handles change control, complaints, and audits. Track Wise Digital is an industry-leading, cloud-based quality management system (QMS) with integrated modules that work together to support quality, compliance, and more efficient and effective decision-making.
3. **Assur X:** Used for QMS (Quality Management System). Assur X allows regulated businesses to quickly identify and control risk exposure and avoid quality or noncompliance problems while improving workflow. Assur X quality management software is uniquely configurable to fit any

established or dynamic business requirements — in the cloud or on -premise.

4. **Emc Documentum:** Provides document and content management. Enterprise content management (ECM) is a set of capabilities for capturing, storing, activating, analyzing and automating business content, used to provide new value from data that was previously unstructured and unavailable.
5. **ISOX Press:** An EQMS (Enterprise Quality Management System). An eQMS is an Electronic Quality Management System that helps companies automate and streamline their quality management processes. Companies use eQMS primarily to streamline processes, ensure regulatory compliance, and improve overall quality management across their operations.

Quality Assurance and Quality control in Pharmaceutical Industry

Quality Assurance (QA) and Quality Control (QC) are two Independent but interconnected components that are critical to guaranteeing pharmaceutical product safety, efficacy, and dependability. In the pharmaceutical business, QA and QC work together to create a c" maple's framework for ensuring high-quality standards throughout the manufacturing process. Here's a simple comparison between QA and QC In the pharmaceutical industry. In the pharmaceutical sector, quality assurance is putting in place systems and processes to ensure that goods meet or surpass defined quality requirements on a constant basis. It includes operations such as Good Manufacturing Practices (GMP), Quality Management Systems, and regulatory compliance. QA is a proactive method that eliminates faults and deviations by developing strong processes, conducting risk assessments, and executing continuous improvement activities. It entails creating and enforcing quality policies, standard operating procedures (SOPs), and detailed



documentation to guarantee that all aspects of pharmaceutical manufacture adhere to predetermined quality requirements. Quality control, on the other hand, refers to a set of activities and techniques used to monitor and regulate the quality of production processes and finished goods.

1. Quality control tests and inspects raw materials, in-process materials, and finished goods. This is done to ensure that they comply with preset requirements.
2. Quality control uses a variety of analytical techniques to assure the identification, purity, potency, and safety of pharmaceutical products.
3. QC is a reactive approach. It focuses on identifying and fixing deviations from quality standards that occur during or after the manufacturing process.

❖ **Quality assurance work in industry**

Quality assurance (QA) in industry refers to the systematic processes and practices used to ensure that products or services meet certain quality standards before they are delivered to customers. It involves preventing defects and ensuring consistency in production. Here's an overview of QA work across different industries:

1. Manufacturing Industry:

1. Process Control: Ensures each step of the manufacturing process adheres to set standards and specifications.
2. Inspection and Testing: Finished products are inspected for defects and tested to ensure they meet safety and performance standards.
3. Statistical Process Control (SPC): Uses statistical methods to monitor and control quality during production.
4. ISO Standards (e.g., ISO 9001): These international standards set requirements for a quality management system (QMS).

5. Root Cause Analysis (RCA): Identifying underlying causes of defects to prevent recurrence.

2. Software Industry:

1. Testing: Involves different types of testing (unit, integration, system, and acceptance testing) to ensure that software functions as intended without bugs.
2. Automation: Automated tools (e.g., Selenium, Junit) are used to run tests repeatedly and efficiently.
3. Agile and DevOps Integration: QA teams work closely with development in Agile and DevOps environments to ensure continuous quality checks.
4. Defect Tracking: Tools like JIRA or Bugzilla are used to track and manage bugs and defects in software products.

3. Pharmaceutical Industry:

1. Good Manufacturing Practice (GMP): A set of guidelines that ensures products are consistently produced and controlled according to quality standards.
2. Quality Control (QC): This is a subset of QA, focusing on testing raw materials and final products to ensure compliance with regulatory standards.
3. Validation and Verification: Ensures that all processes (e.g., manufacturing, packaging) produce consistent results.
4. Regulatory Compliance: QA ensures products meet the standards set by regulatory bodies (e.g., FDA, EMA).

4. Construction Industry:

1. Material Testing: Ensuring materials (concrete, steel, etc.) meet quality specifications.
2. Site Inspections: Frequent inspections during construction to ensure adherence to design, safety, and quality standards.



3. Non-Destructive Testing (NDT): Methods like ultrasound or X-ray are used to test structures without causing damage.
4. Compliance with Building Codes: QA ensures that construction projects meet local and national building regulations.

5. Food and Beverage Industry:

1. HACCP (Hazard Analysis and Critical Control Points): A management system that addresses food safety through the analysis and control of biological, chemical, and physical hazards.
2. Product Testing: Regular testing of ingredients and final products for quality, freshness, and contamination.
3. Regulatory Compliance: Ensuring adherence to food safety standards like those set by the FDA, USDA, or EFSA.
4. Labeling and Packaging: QA ensures that food is packaged correctly and labels are accurate.

Common Tools and Techniques in QA:

- Six Sigma: A method that uses data-driven techniques for eliminating defects.
- Lean Methodology: Focuses on improving efficiency and reducing waste in processes.
- Auditing: Internal and external audits ensure processes adhere to standards.
- Continuous Improvement (Kaizen): Ongoing efforts to improve products, services, or processes.
- Corrective and Preventive Actions (CAPA): Identifying root causes of issues and preventing future occurrences.

Key Roles in QA:

- QA Analyst: Focuses on testing and analysing products for quality.
- QA Engineer: Develops testing plans, procedures, and processes, often involving automation.
- QC Inspector: Inspects products, materials, and equipment to ensure compliance.

- QA Manager: Oversees QA processes, ensuring standards are maintained and continuously improved.
- In each industry, QA plays a critical role in ensuring customer satisfaction, safety, compliance, and efficiency.

❖ ICH Guidelines: -

ICH Q10 is a comprehensive concept of an effective pharmaceutical quality system based on ISO standards. Quality concepts that incorporate practical good practice (GMP) principles, as well as compliance. Implementing ICH Q10 throughout the product life cycle promotes ongoing innovation and strengthens the link between drug development and manufacturing.

The **International Conference on Harmonisation (ICH)** has developed several guidelines that cover various aspects of pharmaceutical development and regulatory affairs. Here's an overview of ICH guidelines Q1 to Q11, which focus on Quality topics:

1. ICH Q1 : Stability Testing

These guidelines deal with the stability testing of new drug substances and products to ensure they maintain their quality throughout their shelf life.

Q1A(R2) : Stability Testing of New Drug Substances and Products

Q1B: Photostability Testing of New Drug Substances and Products

Q1C : Stability Testing for New Dosage Forms

Q1D : Bracketing and Matrixing Designs for Stability Testing

Q1E : Evaluation of Stability Data

Q1F : Stability Data Package for Registration in Climatic Zones III and IV

2. ICH Q2 : Validation of Analytical Procedures

This guideline outlines the validation of analytical methods used in drug testing to ensure accuracy, precision, specificity, and sensitivity.

Q2(R1) : Validation of Analytical Procedures: Text and Methodology

3. ICH Q3: Impurities



These guidelines deal with impurities in new drug substances and products, including their identification, qualification, and control.

Q3A(R2) : Impurities in New Drug Substances

Q3B(R2) : Impurities in New Drug Products

Q3C(R8) : Impurities: Guideline for Residual Solvents

Q3D(R2) : Guideline for Elemental Impurities

4. ICH Q4: Pharmacopoeias

This guideline harmonizes pharmacopoeias standards across different regions to ensure consistency.

Q4B : Evaluation and Recommendation of Pharmacopoeias Texts for Use in the ICH Regions

5. ICH Q5: Biotechnological Products

These guidelines cover the quality aspects of biotechnological and biological products.

Q5A(R1): Viral Safety Evaluation of Biotechnology Products

Q5B : Quality of Biotechnological Products: Analysis of the Expression Construct

Q5C : Stability Testing of Biotechnological/Biological Products

Q5D : Derivation and Characterization of Cell Substrates

Q5E Comparability of Biotechnological/Biological Products

6. ICH Q6: Specifications

This guideline addresses the development of specifications for drug substances and products, including the criteria for testing.

Q6A : Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances

Q6B: Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products

7. ICH Q7: Good Manufacturing Practice (GMP)

This guideline provides a framework for Good Manufacturing Practice (GMP) for the active pharmaceutical ingredient (API).

Q7: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients

8. ICH Q8: Pharmaceutical Development

This guideline introduces the concept of Quality by Design (QbD), focusing on a more thorough understanding of the product and the manufacturing process.

Q8(R2) : Pharmaceutical Development

9. ICH Q9: Quality Risk Management

This guideline provides principles for risk management related to product quality and establishes a systematic process for assessing, controlling, and reviewing risks.

Q9: Quality Risk Management

10. ICH Q10: Pharmaceutical Quality System

This guideline introduces a comprehensive pharmaceutical quality system that emphasizes a proactive approach to ensure product quality throughout its lifecycle.

Q10: Pharmaceutical Quality System

11. ICH Q11: Development and Manufacture of Drug Substances

This guideline addresses the development and manufacture of drug substances, including process design, development, and control.

Q11: Development and Manufacture of Drug Substances

These guidelines are crucial for ensuring the safety, quality, and efficacy of pharmaceutical products across different regions.

12. ICH Q12: Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management

Objective: Q12 provides a framework for managing post-approval changes in a more flexible and efficient manner. It introduces tools for pharmaceutical companies to gain regulatory flexibility while maintaining product quality throughout its lifecycle.

Key Points:

-Defines established conditions (ECs) for a product, which outlines the critical elements that assure the product's quality.

-Introduces tools like Product Lifecycle Management (PLCM) document and Post-Approval Change Management Protocol (PACMP).

- Aims to encourage innovation and continuous improvement by streamlining the regulatory process for post-approval changes.

- Harmonizes global approaches to lifecycle management, reducing the need for repetitive submissions.

13. ICH Q13: Continuous Manufacturing of Drug Substances and Drug Products

Objective: Q13 provides guidance on continuous manufacturing (CM) of drug substances (active ingredients) and drug products (finished dosage forms). CM is an alternative to traditional batch manufacturing, offering improvements in efficiency, flexibility, and consistency.

Key Points:

- Provides principles for the design, development, and implementation of continuous manufacturing systems.

- Discusses regulatory expectations for the submission of applications involving CM.

- Focuses on critical process controls, real-time monitoring, and feedback systems in CM.

- Harmonizes regulatory standards to support the adoption of CM globally, thereby fostering innovation and efficiency.

14. ICH Q14: Analytical Procedure Development

Objective: Q14 focuses on providing guidelines for the development of analytical procedures for drug substances and drug products, ensuring they are fit for purpose.

Key Points:

- Provides a structured approach to analytical procedure development, including method selection, validation, and lifecycle management.

-Encourages the use of modern analytical technologies, such as Process Analytical Technology (PAT) and multivariate analysis, to improve the understanding of methods.

-Introduces the concept of a "control strategy" for the analytical procedures, aimed at maintaining consistent performance.

-Complements the principles from ICH Q8 (Pharmaceutical Development) and Q9 (Quality Risk Management).

These guidelines aim to improve efficiency and flexibility in pharmaceutical development and lifecycle management while maintaining high-quality standards.

CONCLUSION:

"Quality assurance (QA) and quality management (QM) are integral to ensuring the safety, efficacy, and consistency of pharmaceutical products. By implementing robust QA systems and adhering to internationally recognized quality standards, the pharmaceutical industry can safeguard public health, build trust, and meet regulatory requirements. Continuous improvement, driven by advanced quality management practices, fosters innovation while maintaining compliance, thus enabling the industry to address evolving challenges and deliver high-quality medicines globally."

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