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# Quality Control and Quality Assurance in Pharmaceuticals

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***Abstract*** : A component of quality management, quality assurance is the process of giving assurance that the requirements for quality will be met. One way to characterize quality control is as a component of quality management that is concerned with meeting quality standards. Quality assurance (QA), quality control (QC), and good manufacturing practice (GMP) are critical considerations in the production, distribution, and marketing of pharmaceutical products. These processes ensure the products' identity, potency, purity, pharmacological safety, efficacy, and effectiveness. The phrases quality assurance, quality control, and good manufacturing practices are defined in most international regulatory regulations, including those from the USFDA, WHO, MHRA, TGA, and others. As low-quality medications can cause harm or even death to patients, it has been determined that having an adequate supply of vital medicines is essential to any nation's ability to provide a health care system. Even trace amounts of undesirable substances can affect a medication's safety and effectiveness. In addition to the inherent toxicity of some contaminants, impurities in pharmaceutical products can have detrimental effects on the stability and shelf-life of drugs, which gives rise to significant Concerns. Impurities are undesirable substances (organic, inorganic, and residual Solvents) that are added to or emerge during the manufacture of pharmaceutical and drug Products, or that persists with the active pharmaceutical ingredients (APIs) after they have aged. The most prevalent contaminants in all APIs are organic ones, which, even with appropriate handling, naturally integrate during the multi-step synthesis process. For project managers, quality assurance (QA) and internal control (QC) are becoming more and more crucial. Large expenses could arise from construction site malfunctions or defects. Large expenses could arise from construction site malfunctions or defects. Reconstruction is also necessary and facility operations are hampered, even with little flaws. The end effect is more expenses and longer delays. Internal control and quality assurance are crucial components of any building process that raise the project's standard and consistency. Due to recent significant changes and technological advancements, the need for QA and QC in building projects has expanded significantly technological breakthroughs and high user expectations.

***IndexTerms*** - Quality Control, Quality Assurance

## INTRODUCTION: -

**Definition of QC & QA**

**Quality Control: -** "A part of quality management focused on fulfilling quality requirements" is how ISO 9000 defines quality control. This area of GMP deals with sampling, specification and testing, documentation, and release processes. It makes sure that all relevant and essential tests are carried out and that the product is only made available for use after its quality has been established.

**Quality Assurance: -** The World Health Organization defines quality assurance as a broad concept that encompasses all factors that either alone or jointly affect a product's quality. Production, distribution, quality control, development, and inspections are the main domains of quality assurance in the pharmaceutical industry. "A portion of quality management focused on providing confidence that quality requirements will be fulfilled" is how ISO 9000 describes it.

**Role of QA & QC: -** One of the production sectors with the strictest regulations is the pharmaceutical business, and the quality of the final goods is greatly influenced by the quality management system. The International Conference for Harmonization of Technical Requirements for Registration, or ICH Q10 guidelines, provides a scientific and risk-based strategy that may be applied at many stages of the product life-cycle, and this is the foundation upon which the current quality management system is perceived. It functions in tandem with the International Organization for Standardization's foundational principles (ISO). ICH Q10 connects the development and manufacturing of pharmaceuticals, opening doors for innovation and non-mandatory continuous improvement. It also focuses primarily on achieving global uniformity in the areas of quality, safety, and effectiveness of pharmaceutical products. Customer satisfaction and product quality are guaranteed by Q10 criteria. It offers recommendations on how to apply the Quality Management System in the pharmaceutical sector.

**QA & QC in the Quality Management System:**-The goal of a quality management system (QMS) is to maximize output quality, which is why a QMS's foundation is made up of both quality assurance (QA) and quality control (QC). Furthermore, QA and QC comprise the framework of the Quality Management System in addition to the industry-specific quality laws and regulations. "Continuous improvement," one of the cornerstones of ISO-9001, implies that advancements in Quality Assurance (QA) are ongoing. This means that in order to guarantee continuous improvements, you need always conduct a critical evaluation of your company's Quality Assurance (QA) System.

**QA & QC Tools in Pharmaceuticals:-** Another way of looking at Quality Assurance (QA) and Quality Control (QC) would be to recognize what type of tools those are. For example, you can perceive QA as a managerial tool for preventing various quality issues. At the same time, QC could be an operational tool, for identifying and correcting the defects before the product enters the market.

**Duration & Life Cycle of QA & QC: -** Typically, quality assurance (QA) is a medium-to-long-term process during the product design phase. In contrast, quality control (QC) is a much shorter-term activity, usually at the final stage when the output is produced. Therefore, you should plan such quality control activities during the development life cycle. Although procedures related to quality control are usually placed in the test life cycle.

Theengineering department is responsible for calibrating production equipment, sensors, measuring equipment and utilities.

The primary user department is responsible for calibrating scales installed in various departments such as warehouse, production, quality control, etc.

## Quality by Design (QBD)

A strategic strategy known as Quality by Design (QbD) is used in a number of industries, such as manufacturing, product development, and medicines, to guarantee the continuous delivery of high-quality products. It entails a methodical and proactive approach of incorporating quality considerations at every stage of the product lifecycle, from development to manufacturing.

**The Current Approach: - Quality by Design** From Development to Manufacturing

The primary user department is responsible for calibrating scales installed in various departments such as warehouse, production, quality control, etc.

1)Quality designed into products and processes based on scientific understanding.

2) Knowledge Presentation Demonstrates product knowledge and process understanding.

3) Specifications are based on product performance requirements Flexible process in design mode enables continuous improvement.

4) Focus on robustness – understanding and controlling variations.

**Potential Challenges Associated with Quality by Design**

1) All stakeholders must agree to this. **Quality Control & Quality Assurance Supporting System**:-

You can support quality assurance (QA) and quality control (QC) by implementing an electronic quality management system (eQMS).

Such a system enables the prevention, identification and control of problems as essential QMS elements such as:
Document Control
eSignatures
CAPA Management
Supplier Management
Training Management
SOP Management
Template Management
Equipment Management

**GOOD LABORATORY PRACTICES:-**

Good Laboratory Practice (GLP) is a quality system that includes the organizational process and conditions under which non-clinical laboratory tests are planned, performed, monitored, recorded, reported and archived. GLP ensures the quality and integrity of safety test data submitted to the government for research approvals.

Good Laboratory practice Guidelines:-
Below are Good Laboratory Practice guidelines for the different elements of a study:

**1) Personnel**: - Before the start of a study, the director of the testing facility must appoint a study manager who is responsible for the overall conduct of the study and its GLP compliance.

**2)FacilityEquipment:-**The test facility must organize the functions separately to avoid interference and other disturbances that threaten the research.

**3)Characterization:-**Identification, purity, composition and shelf life date received expiry date and storage instructions quantity received and quantity used.

**4) Study Plan or Protocol:-**Identification, purity, composition and shelf life date received expiry date and storage instructions quantity received and quantity used.

**5) Standard Operating Procedure:-**Each separate area of the testing facility should have standard operating procedures (SOPs), especially for routine procedures
.
**6) Final Report:-**A complete and accurate account of the conduct of the study any deviations from the planned procedure (e.g. SOP or protocol).

**7) Storage of Records:-**The study administrator is responsible throughout the study to ensure that all study-related information is collected and entered into securely maintained records.

**8) Retention of Records:-**The required retention period for archived records varies according to national GMP regulations.

## Good Manufacturing Practices:-

Good Manufacturing Practice (GMP) is a guideline that guides the regulatory standard to ensure the qualityof medicines.

**The Good Manufacturing Practices (GMPs) contents-**

The 5 Pillars of Good Manufacturing Practices are:-

**1) People (GMP Training):-**All manufacturing facilities must strictly adhere to good manufacturing practices and all employees must strictly adhere to manufacturing processes and regulations.

**2) Procedures: -** All manufacturing facilities must strictly adhere to good manufacturing practices and all employees must strictly adhere to manufacturing processes and regulations.

**3) Products and Primary Materials:-**All products are must undergo continuous testing benchmarking and quality assurance before reaching consumers.
**4) Processes: -** This is part of the requirement that every process be clearly defined, properly documented, consistent, shared with all employees and evaluated.
**5) Premises and equipment**: - This is part of the requirement that each process be clearly defined, properly documented, consistent, shared with all employees and evaluated.

## Validation:-

Authorizing documentation proof to demonstrate that a certain process, method, or action will consistently result in a product that meets preset requirements and produces the desired outcome is known as validation. Pharmaceutical companies use a variety of components for their validation programs, some of which have to do with processing, cleaning, facilities, equipment, or instruments.

## Role of validation in QA & QC Pharmaceuticals:-

1) Process parameters and controls are determined during the validation of any process or system.
2) Deep study and understanding of the system and equipment are made possible due to the validation.
3) Batch to batch variation is minimized due to the validation of processes, systems and equipment.
4) Decreases the chances of the failure of the batches.

## Calibration:-

The method by which you can ascertain whether, when compared to traceable standards of measurement, an instrument or equipment is producing accurate findings within the designated limits.

**Importance of calibration**

Instruments must be properly calibrated to ensure accurate readings. This is very important in industries where production or product standards depend on the correct adjustment of the instruments used in various stages of processing. Standardization of values is the main advantage of calibration.

**Responsibility of calibration:-**

1) A designated QC person is responsible for calibrating the QC equipment.
1) The production department is responsible for the calibration of the IPQC device
2) Corporate inertia.
3) Initial costs of new equipment and training.

## National Accreditation Board for Testing & Calibration Laboratories (NABL):-

National Accreditation Board for Testing and Calibration Laboratories (NABL) is an independent body headed an by Depts. Of Science and Technology, Govt. of India, which plans to provide accreditation for testing and calibration of clinical laboratories in the country.

The guidelines for NABL accreditation process include the following steps:
1) Application: - The laboratory submits an application for accreditation to NABL.
2) Document Review: - NABL reviews the laboratory's quality manual, procedures and other related documents to ensure compliance with international standards.
3) Pre-Assessment:- NABL conducts a pre-assessment visit to assess the laboratory's readiness for the accreditation process.
4) Assessment:-NABL will conduct an on-site evaluation of the laboratory by a team of experts.
5) Evaluation: -The assessment team prepares a report based on their findings and submits it to NABL for evaluation.
6) Corrective Actions: When nonconformities or deviations are identified, the laboratory must take corrective actions to correct them.
7) Final evaluation-Final evaluation is done after corrective actions are implemented.
8) Surveillance review and renewal: - a surveillance review is conducted annually to implement appropriate corrective actions, followed by renewal to continuously monitor the laboratory's competence and compliance with international standards.

## International Conference for Harmonization (ICH)

The International Council for Harmonization of Technical Requirements for Medicinal Products for Human Use (ICH) is unique in bringing regulatory agencies and the pharmaceutical industry together to discuss scientific and technical aspects of medicines and develop ICH guidelines.

**Goals of ICH Guidelines -**

1) Promotion of international Harmonization.
2)Strengthens the ability of pharmaceutical authorities and industry to use them.

**QSEM Guidelines –**

1) Q: Quality Guidelines: - It includes stability, impurities, testing and GMP.
2) S: Safety Guidelines: - It includes carcinogenicity, genotoxicity, and reprotoxicity.
3) E: Efficacy Guidelines: - It includes clinical pharmacy genomics.
4 M: Multidisciplinary Guidelines: - It includes medical dictionary or regulatory activities, electric standards on clinical safety studies, common technical document.

## Conclusion:-

In terms of our focus, we understand that quality control is a product-oriented process. As for quality assurance, it is a process-oriented practice. As a summary of the entire discussion, it clearly shows that quality assurance is somehow related to every department in the pharmaceutical industry and plays an important role in every department in strengthening the process of that department. Quality control (QC) and quality assurance (QA) are two key components of the pharmaceutical industry that play an important role in ensuring the safety, efficacy and quality of pharmaceutical products. These processes are essential to meet regulatory requirements, maintain consumer confidence and ultimately promote public health. In thiscomprehensive report, we discuss the importance of quality control and quality assurance in the pharmaceutical industry, exploring their roles, key principles, regulatory framework and emerging trends.

## References:-

1)https://www.microlit.com/what-are-the-guidelines-of-nabl-accreditation-process-and-why-is-it-important/
2)https://www.mt.com/in/en/home/applications/L1_AutoChem_Applications/L2_PAT/quality-by-design.html
3)https://aujmsr.com/validation-in-pharmaceutical-industry-equipment-validation-a-brief-review/
4)https://pharmapush.com/significance-of-quality-control-and-quality-assurance-in-pharmaceutical-industries/
5)https://www.blog-qhse.com/en/why-good-manufacturing-practices-gmps-are-important-in-the-pharmaceutical-industry
6)https://safetyculture.com/topics/good-laboratory-practice-glp/
7)https://www.simplerqms.com/quality-assurance-vs-quality-control/
8)https://images.app.goo.gl/h2AxLnw3AJLnLgFMA
9) QA/QC in the Pharmaceutical Science: A Review 1Sujata C.Kasar, 2Arti M. Jadhav, 3Sushant C. Kadam, 4Amruta P. Patil *Dr.Naikwadi College of pharmacy, Jamgaon, Maharashtra Corresponding Author: 1Sujata C.Kasar.*
10) QUALITY CONTROL AND QUALITY ASSURANCE IN PHARMACEUTICAL INDUSTRY Yadav Ravi, Piyush yadav, Priyanshu Maurya, Tushar Yadav, Rohit Kumar. Department of Pharmacy, Prasad Institute of Technology Jaunpur 222001, UP., INDIA.
11) Quality Assurance of Pharmaceuticals; Good Manufacturing Practices and Inspection, Volume-2, World Health Organization, Geneva, 1999.
12) Committee on Specifications for Pharmaceutical Preparations. Good Manufacturing Practices for Pharmaceutical Products. WHO Technical Report Seriesno.82.geneva: World Health Organization, 1992, pp 14-7
13) Quality Assurance in Financial Auditing, A Handbook, IDI-ASOSAI, 2009.
14) A Handbook on Quality Assurance in Performance Auditing, IDI-ASOSAI, 2011ndbook, IDI-ASOSAI, 2009

15) Ezzelle, J., Rodriguez-Chavez, I. R., Darden, J. M., Stirewalt, M., Kunwar, N., Hitchcock, R., & D'souza, M. P.Guidelines on good clinical laboratory practice: bridging operations between research and clinical research laboratories. Journal of pharmaceutical and biomedical analysis, 2008; 46(1): 18-29.

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