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Quality Assurance and Quality Control in Pharmaceutical Field: A Systematic Review

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ABSTRACT

For many years, the pharmaceutical industry has faced ongoing challenges related to product quality, compliance, and process consistency. These quality failures often result in significant economic losses, product recalls, regulatory sanctions, and potential risks to patient safety. However, these issues can be greatly minimized if the sector fully adopts a comprehensive Quality Assurance (QA) approach, similar to the systems that have proven highly effective in other regulated industries such as food manufacturing and bio technology .To support this shift, pharmaceutical manufacturers, regulatory authorities, and product stakeholders must understand the importance of quality assurance and consistently apply it throughout the drug development and production lifecycle. When integrated effectively, QA and Quality Control (QC) systems strengthen internal oversight, reduce defects, enhance regulatory compliance, and ensure that medicines delivered to patients meet the highest safety and efficacy standards.Internal Quality Control (QC) and Quality Assurance (QA) are increasingly critical components for pharmaceutical project managers and production teams. Failures in drug formulation, packaging, stability, or manufacturing processes can lead to product recalls and interruptions in supply chains, in addition to compromising patient well-being. Therefore, QA and QC represent essential frameworks for improving reliability, uniformity, and the overall quality of pharmaceutical products.

Keywords: quality assurance, quality control, compliance, pharmaceutical

I.INTRODUCTION

\When we talk about **quality** in the pharmaceutical industry, we refer to medicines that are safe, effective, and capable of meeting or exceeding regulatory and therapeutic expectations. These expectations are shaped not only by the intended medical use of the product but also by the trust patients and healthcare providers place in the pharmaceutical manufacturer.

Quality Control (QC) is a structured set of scientific and technical activities used to measure, test, and verify the quality of raw materials, intermediate products, and finished pharmaceutical goods during manufacturing. A comprehensive QC system is designed to:

- Perform continuous testing to ensure accuracy, reliability, and completeness of product data.
- Identify and correct deviations, errors, and non-conformities at early stages.
- Maintain robust documentation and data integrity to support regulatory compliance and traceability.

QC procedures include raw material inspection, in-process testing, analytical method validation, stability studies, environmental monitoring, and final product quality testing. Advanced QC activities also involve assessing batch-to-batch consistency, evaluating critical process parameters, and ensuring that all testing methods meet regulatory standards such as Good Manufacturing Practices (GMP).

Quality Assurance (QA) differs from QC in that it focuses on system-wide processes rather than individual product tests. QA encompasses planned and systematic activities performed by personnel who are not directly involved in day-to-day production or testing. Its purpose is to ensure that the overall manufacturing system consistently produces high-quality medicines.

QA activities include internal audits, validation of equipment and processes, supplier qualification, change control, risk assessment, deviation management, and continuous improvement initiatives. QA provides essential feedback to manufacturing teams, management, regulatory agencies, and stakeholders to ensure that all pharmaceutical processes meet established quality standards.

Before implementing a QA/QC program, pharmaceutical organizations must determine which methods and procedures are most appropriate for their production environments. These decisions depend on technical requirements, regulatory obligations, available expertise, manufacturing technologies, and the unique characteristics of the products being produced. By aligning quality systems with these factors, pharmaceutical companies can enhance efficiency, reduce costs, and ensure that patients receive safe and effective medications.

Figure 1. Eight quality systems contribute to the high quality of the finished pharmaceutical product.

DIFFERENCE B/W QUALITY ASSURANCE AND QUALITY CONTROL

QUALITY ASSURANCE	QUALITY CONTROL
A Managing tool /Approach	A correcting Tool / Approach
Process oriented	Product oriented
Proactive Approach	Reactive approach
Defect prevention	Defect detection
CFT(Cross functional team) is responsible	Quality term is responsible
Some tools –SPC,MSS,Process Audit Etc.	Some tools- petrol inspection,sampling inspection

ELEMENTS OF A QA/QCSYSTEM

The following are the essential factors to be viewed in the development of a QC/QA machine to be implemented in monitoring stock compilation:

A QA/QC plan

An inventory organization accountable for coordinating QA/QC activities

General QC tactics

Sources category specific QC approaches

QA evaluation procedures

Reporting, documentation, and archiving procedures

IN PROCESS QUALITY CONTROL TESTS(IPQC)

IPQC is concerned with supplying accurate, specific.

In manner Quality manipulate IPQC take a look at are normally function within manufacturing area.

They need to not lift any hazard for the first class of product.

In system checking out enables less complicated identification of problems

It sometime identifies a faulty product batch that can be corrected with the aid of rework, where as soon as that batch has been completed this may also now not be possible.

Failure to meet in system control specification shows both that technique were not accompanied or some element (S)out of manage.

IPQC TESTS FOR VARIOUS DOSAGES FORMS

Tablets:

a) Dug contents determination

b) Moisture contents of granules

c) Assay of active ingredients

d) Weight variation of uncoated tablets

Syrup and Suspension:

a) Drug contents determination

b) Assay of active ingredients.

c) pH

d) Weight per ml

e) particle size

Test for semi-solids:

a) Drug contents determination
b) Assay of active ingredients

c) Uniformity test

d) Viscosity and specific gravity test

e) Filling test

Tests for injectables:

a) Drug-contents determination

b) Clarity test

c) pH

d) Pyrogen test

e) Stability test

ISO AS A DATA MANAGEMENT SYSTEM

International Organization for Standardization (IS0) series programme provides standards for data documentation and audits as part of a quality management system, Though the IS0 series is not designed explicitly for emissions data development, many of the principles may be applied to ensure the production of a quality inventory, Inventory agencies may find these documents source material or developing QA/QC plans for greenhouse gas inventories Some countries (e.g. the United Kingdom and the Netherlands) have already applied some elements of the IS standards for their inventory development process and data management

The following standards and guidelines published under the ISO series may supplement source 150 9004-1: General quality guidelines to implement a quality system.

150 9004-4: Guidelines for implementing continuous quality improvement

within the organisation, using tools and techniques based on data collection and analysis.19

150 10005 Guidance on how to prepare quality plans for the control of specific project

1S0 10011-1: Guidelines for auditing a quality system

1S0 10011-2: Guidance on the qualification criteria for quality systems auditors

1S0 10011-3: Guidelines for managing quality system audit programmes.

1S0 10012: Guidelines on calibration systems and statistical controls to ensure Measurements are made with the intended accuracy.

150 10013: Guidelines for developing quality manuals to meet specific needs.'

CDSCO:CENTRAL DRUGS STANDARD CONTROL ORGANIZATION [INDIA]

HC:HEALTH CANADA [CANADA]

FDA:FOOD AND DRUG ADMINISTRATION [USA]

ANVISA: AGENCIA NACIONAL DE VIGILONCIA SANITARIA [BRAZIL]

EMA:EUROPEAN MEDICINES AGENCY [EUROPEAN UNION]

MHRF: MINISTRY OF HEAL, TH OF THE RUSSIAN FEDERATION [RUSSIA]

CFDA:CHINA FOOD AND DRUG ADMINISTRATION [CHINA]

PMDA: PHARMACEUTICALS AND MEDICAL DEVICES AGENCY JAPAN]

TGA:THERAPEUTIC GOODS ADMINISTRATION [AUSTRALIA]

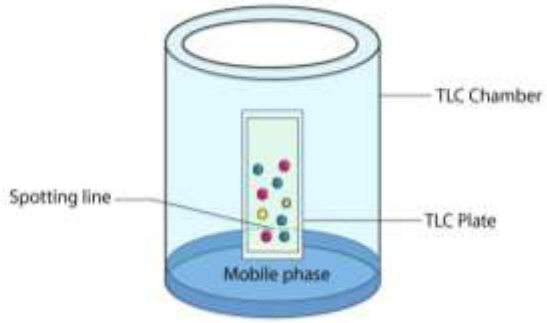
ICH Guidelines

The international Conference on Harmonization of technical requirements for registration of pharmaceutical for human use (ICH) is a special project that gathers the regulatory authorities of Europe, Japan and the United Sates and experts from the pharmaceutical industry in the three different regions to discuss scientific and technical aspects of product registration.

Instruments

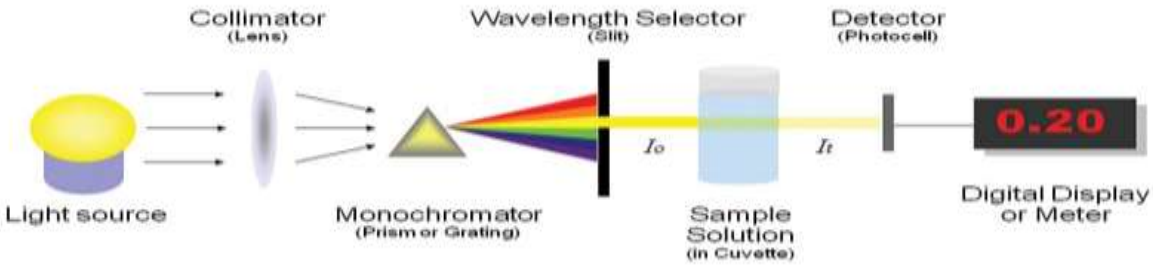
Thin Layer Chromatography:

Thin-layer chromatography is a chromatography technique used to separate non volatile mixtures, Thin-layer chromatography is performed on a sheet of an inert substrate such as glass, plastic, or aluminium foil, which is coated with a thin layer of adsorbent material, usually silica gel, aluminium oxide, or cellulose.



UV spectrophotometer

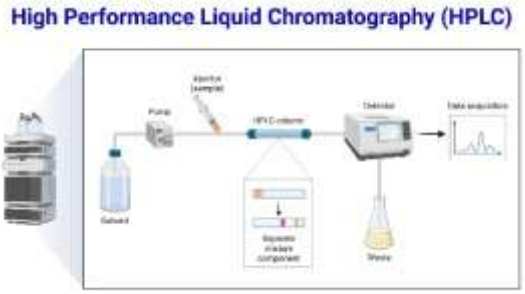
Ultraviolet-visible (UV-Vis) spectrophotometry is a technique used to measure light absorbance across the ultraviolet and visible ranges of the electromagnetic spectrum.



HPLC

High-performance liquid chromatography (or High pressure liquid chromatography, (HPLC) is a specific form

of column chromatography generally used in biochemistry and analysis to separate, identify, and quantify the active compounds.



Dissolution Test Apparatus

Dissolution is the process by which a solid solute enters a solution. Dissolution testing is an official test used by pharmacopeia's for evaluating drug release of solid and semisolid dosage forms,

pH Meter

pH meters are widely used to measure the ph of water, solutions and environmental samples

Validation

Validation is the procedure which authorizing documentary evidences that prove, the following process/method or activity will consistently produce the product which leads to the expected result (predetermined requirements)

Calibration

Calibration determines that a device or instrument is producing accurate results within the specified limits compared to those produced by a traceable standard.

Qualification

Qualification is as an action of providing that equipment or ancillary systems are properly installed, work correctly, and actually lead to the expected results.

- Design qualification
- Installation qualification
- Operational qualification
- Performance qualification

Quality by design

Quality by design is an approach that aims to ensure the quality of medicines by employing statistical, analytical and risk-management methodology in the design, development and manufacturing of medicines.

Steps involved in QBD

1.Development of new molecular entity:

Preclinical study

Clinical study

Submission for market approval

2.Manufacturing

Quality control

Analytical technology)

3.Control Strategy:

Continuous improvement

• Product performance

Process Analytical Technology (PAT)

PAT is a toolkit used to increase operational efficiencies, operational utilization and process understanding while decreasing operation operating expenses and ensuring that quality is built into the product.

Intellectual Property Rights

• Trade mark

Sign, design that identifies the product or services from a particular source.

- **Copyright**

Protection against the potential infringement of the drug discovery and development.

• Patent

Provides pharma companies exclusive rights to market drugs and prevent others to manufacture, sell and make these drugs for a period of 20 years.

II.CONCLUSION

As a conclusion on the entire discussion it clearly shows that quality assurance is somehow related to all the departments in a pharmaceutical industry, and it plays an important role in each department to enhance the process of that particular department. As how the title mentions that the quality assurance plays vital role and it is said as the backbone of a pharmaceutical industry.

Quality control (QC) is a procedure or set of procedures intended to ensure that a manufactured product or performed service adheres to a defined set of quality criteria or meets the requirements of the client or customer

Quality control is a product-oriented process.

Quality control makes sure the end product meets the quality requirements

Quality control can be noted as a reactive process

REFERENCES

1. Basavaraj K. Nanjwade, Kishor A. Bellad, Meghana S. Kamble , Teerapol Srichana, Nagi F. Idris.Development of cosmeceuticals; world journal of pharmacy and pharmaceutical sciences; Volume 6,.Issue 4, 643-691

2. Dureja, H, Kaushik D, Gupta, M, Kumar, V. and Lather, V.cosmeceuticals; An emerging concept, Indian J..Pharmacol, 1995, 37, 155-159.

3. Lawlor TM.Dental care compositions.US Patent 6685921(2004)

4. Gillbro JM1, 0lsson MI);The melanogenesis and mechanisms of skin-lightening agents--existing and new approaches. https://www.ncbi.nlm.nih.gov/pubmed/21265866

5. https://www.drugs.com/pro/skin-ightening-comple.html

6. Kadam Vaishali S, Chintale Ashwini G, Deshmukh Kshitja Pand Nalwad Digambar N; cosmeceuticals an emerging concepts ; a comprehensive review ; ISSN:2231-2781.

7. Padma PJ, Karthika: Cosmeceuticals-an evolution; International Journal of ChemTech Research CODEN(USA): IJCRGG; ISSN: 09744290.Vol.1, No.4, pp1217-1223; 2009;1(4):Dept. of Pharmaceutics, K.M.C.H College of pharmacy, Coimbatore-641 048 India.

8. https://en.wikipedia.org/wiki/Medication#Defnition

9. https://en.wikipedia.org/wiki/rCosmeceutical

10. htps://cosmeticcomposition.com/2018/04/17/what-are-nutricosmetics