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Review Article

Quality Control And Quality Assurance In Pharmaceuticals

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ABSTRACT

Quality Assurance can be defined as a part of quality management focused on providing confidence that quality requirements will be fulfilled. Quality Control can be defined as a part of quality management focused on fulfilling quality requirements. When manufacturing, distributing, and marketing pharmaceutical products, quality assurance (QA), quality control (QC), and good manufacturing practice (GMP) are crucial factors to take into account in order to guarantee the products' identity, potency, purity, pharmacological safety, efficacy, and effectiveness. The majority of international regulatory documents, such as those from the WHO, USFDA, MHRA, TGA, and others, define the terms quality assurance, quality control, and good manufacturing practices. The quality of the final product is closely linked to in-process quality control (IPQC) testing because good pharmaceutical dosage forms depend on checks made during manufacturing to monitor and, if needed, change the process to ensure that the product conforms to its specifications. A few of its components are identified and quality by design is explained in the overview. The foundation for this is the Q8 ICH guidelines for pharmaceutical development.

INTRODUCTION

Concept and Scope of Quality Control and Quality Assurance.

ISO 9000 Definition:

Quality Control:

"A part of quality management focused on fulfilling quality requirements."

It involves monitoring aspects of producing and testing the output to ensure identify and classify any defects that have occurred.

Quality Assurance:

"A part of quality management focused on providing confidence that quality requirements will be fulfilled."

It involves planning, documenting, and agreeing on a set of standards to assure quality.

Difference between Quality Control and Quality Assurance:

Quality Control	Quality Assurance
Product	Process

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Reactive	Pro-active
Line Function	Staff Function
Find the defects	Prevent the defects
Walk through	Quality Audit
Testing	Defining Process
Inspection	Selection of tools
Checkpoint Review	Training

Sr. no.	Quality Control	Quality Assurance
1.	**ISO 9000 Definition**	**ISO 9000 Definition**
	A part of quality management focused on fulfilling quality requirements.	A part of quality management focused on providing confidence that quality requirements will be fulfilled
2.	**Other Definition**	**Other Definition**
	Is characterized as The operational strategies and activities used to fulfill requirements for quality".	Is defined as "All the plannedand systematic activities implemented inside the quality framework that can be exhibited to give confidence that a product or service will fulfill requirements for quality".
3.	Quality Control on the otherhand is the physical verification that the product	Quality Assurance is fundamentally focused on

Responsibility of Quality Assurance:

- To ensure that a company's quality policies are implemented, the QA department is in charge.
- It aids in locating and creating the essential SOPs for quality control.
- It must establish that the product complies with all relevant requirements and that it was produced in accordance with GMP internal standards.
- The QA department is also in charge of quality control or auditing. The purpose of QA is to continuously evaluate activities and to counsel and direct them toward full compliance with all relevant internal and external regulations.

Responsibility of Quality Control:

- QC is in charge of overseeing daily quality control within the organization.
- Analytical testing of incoming raw materials and inspection of packaging elements, including labeling, are under the purview of this department. When necessary, they carry out in-process testing, monitor the environment, and check operations for compliance.
- Additionally, they perform the necessary testing on the finished dosage form.
- The choice of qualified vendors from whom raw materials are acquired is significantly influenced by QC. Before a vendor is approved, their suitability and level of compliance with GMPs must be determined through testing of representative samples and, in many cases, through an audit of their operations.
- The environmental areas for manufacturing of various dosage forms are tested and inspected by the QC department.(2)

Good Laboratory Practice:

The term "GLP" stands for "Good Laboratory Practices," which accurately refers to the quality arrangement of organized control for research facilities and organizations to ensure the stability, dependability, reproducibility, consistency quality and synthetic substances containing pharmaceuticals non-clinical security tests; from physioconcoction properties through intense to continuous poisonous quality tests.(3)

Good Manufacturing Practice:

WHO definition of GMP:

Good Manufacturing Practice (GMP) is collectively termed as pharmaceutical regulations, directives and guidance which a manufacturer must follow when making medicinal products.

GMP is that part of quality assurance which ensure that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization. GMP concept is so high that it's desired level is infinitive. But all pharmaceutical manufacturers must follow the basic guidelines of GMP; more specifically cGMP. GMP rules are directed primarily to diminishing the risks that cannot be prevented completely through the testing of final products, such as, cross-contamination and mix-ups (confusion) caused by false labels being put on containers.

Types of GMP:

1. British GMP:

- "The Orange Guide"—the first document defining British Good Manufacturing Practice (GMP)—was created in the UK.
- In 1977, the entire text was rewritten with new sections.
- Published in 1983 as a handbook to Good Pharmaceutical Manufacturing Practice, it was reorganized, expanded, and restructured into three main portions.
- Replaced by the EEC Guide, titled "Guide to Good Manufacturing Practice for Medicinal Products in the European Community" and first published in 1989 before receiving a 1992 partial revision and new annexes.
- Adopted in 1993 along with new annexes.
- The Current Guide, which was updated in 1997.

2. WHO GMP: Good Practices in the Manufacture and Quality Control of Drugs.

- A team of advisors created the first draft in 1967 at the request of the 20" WHO.
- Text updated in 1968 by the WHO Expert Committee on Pharmaceutical Preparations Specifications.
- The text was changed once more and reprinted in the 1971 International Pharmacopeia Supplement.
- The GMP text was updated in 1975.
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- The PIC standards for GMP Guidelines for the Manufacturing of Bulk Pharmaceutical Chemicals first appeared in 1987.
- In 1992, a revised version of the GMP manual was released as a guide to Good Manufacturing Practice for Pharmaceutical Products.
- The "WHO Expert Committee on Specifications for Pharmaceutical Preparations" published the GMP text in 1992.
- Additional rules were adopted in 1996 and 1999.

3. United States GMP: Current Good Manufacturing Practices (cGMP) for Finished Pharmaceuticals.

- In 1963, the USFDA issued the GMP standards for finished pharmaceuticals.
- In 1971, criteria were updated.
- Updated and revised in 1978, it was formally adopted in 1979.
- In 1978, GLP was introduced.

4. ASEAN GMP: ASEAN Good Manufacturing Practice of Drugs.

- ASEAN GMP guidelines adopted in 1984.
- Revised in 1988.

Basic requirements of GMP (WHO guidelines):

The following are the basic requirements of GMP and there are clear guidelines and instructions in Good Manufacturing Procedures (GMP) about the requirements:

1. Quality Management
2. Personnel and Training
3. Personal Hygiene and Sanitation
4. Premises and Equipment
5. Documentation (batch documentation and others)
6. Production (including contamination control)
7. Quality Control (including GLP, Retained samples, Stability study etc.)
8. Contact Manufacturing and Analysis

9. Product Complaints, Product Recall and Returned Products
10. Self-inspection and Quality Audits
11. Validation (4)

Current Good Manufacturing Practice (cGMP):

- Current Good Manufacturing Practice (CGMP) laws are ones that the US FDA enforcing.
- In order to ensure that a drug complies with the requirements of the act, has the identity and strength, and meets the quality and purity characteristics that it is claimed to possess, current good manufacturing practices are the procedures to be used, the facilities to be used, or the controls to be used.

Objectives

- A product's quality is determined by its raw ingredients, manufacturing and quality control procedures, building, machinery, and employees.
- Ensure that goods are regularly produced and held to the required standards of quality.
- Interested in every facet of production and quality assurance.
- General supervision and control in cosmetics manufacturing
- Assure the consumer receives goods of the required caliber.
- The identity, strength, quality, and purity of drug items are guaranteed by cGMP requirements.(5)

Overview of ICH guidelines – QSEM, with special emphasis on Q - series guideline:

The International Conference on Harmonization of technical requirements for registration of pharmaceuticals for human use (ICH) is a special project that gathers the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry in the three different regions;to discuss scientific and technical aspects of product registration.The objective of such harmonization is a more efficient use of human, animal and material resources, and the removal of any delay that is not essential in the global development and availability of new medicines while maintaining safeguards on quality, safety and efficacy, and regulatory obligations to protect public health.

Q : Quality guidelines S : Safety guidelines

E : Efficacy guidelines

M : Multi-Disciplinary guidelines

1. Quality: Quality topics

Those relating to chemical and pharmaceutical Quality Assurance.

2. Safety: Safety topics

Those relating to in vitro and in vivo pre-clinical studies.

3. Efficacy: Efficacy topics

Those relating to clinical studies in human subject.

4. Multidisciplinary: Multidisciplinary topics

They are Cross-cutting topics, which do not fit uniquely into one of the above categories.(6)

Q – series guideline: (Quality Guideline)

Q1: Stability (Q1A – Q1F)

Q1A – Stability testing of new substances and products.

Q1B – Photostability testing of new drug substance and product. Q1C – Stability testing for new dosage forms.

Q1D – Bracketing and matrixing designs of stability testing of new drug substances and products.

Q1E – Evaluation of Stability data.

Q1F – Stability data package for registration application in climate zone III & IV. Q2 : Analytical Validation

Q3 : Impurities (Q3A – Q3D)

Q3A – Impurities in new drug substance. Q3B – Impurities in new drug products.

Q3C – Impurities- guidelines for residual solvents.

Q3D – Impurities- guidelines for elemental impurities. Q4 : Pharmacopoeias (Q4A -Q4B)

Q4A – Pharmacopoeial harmonization.

Q4B – Evaluation & recommendation of pharmacopoeial texts for use in the ICH regions.
Q5 : Quality of Biotechnological products (Q5A – Q5E)
Q5A - Viral Safety Evaluation. Q5B – Genetic Stability
Q5C – Stability of Biotechnological products. Q5D – Cell substrates
Q5E – Comparability of biotechnological products. Q6 : Specification (Q6A – Q6B)
Q6A – Test procedures & acceptance criteria for new drug substances & new drug products – chemical substance.
Q6B – Test procedures & acceptance criteria for biotechnological products. Q7 : GMP for Active Pharmaceutical Ingredient.
Q8 : Pharmaceutical development. Q9 : Quality risk management.
Q10 : Pharmaceutical quality system.

Good Warehousing Practice:

Good warehousing practices (GWP) entail stocking supplies in a way that keeps goods accessible, constant, and in good shape.Therefore, pharmaceutical warehousing encompasses much more than just product storage. It is a business that protects the purity of medicines.Storage and sorting of finished items for maximum efficiency at the lowest cost is referred to as warehousing and storage. The main tasks involved in warehousing are:

- Receiving
- Identifying
- Holding
- Assembling and processing of the orders to meet the demand.

Importance of Good Warehousing Practice:

- To specifically optimize the resources available for large-scale storage.
- Being an essential link in the supply chain.
- Making the most of real-time data for efficient supply chain management, stock put away optimization, and bin utilization.
- To make the process of finding and recognizing things quicker and easier.

Functions of Warehousing:

1. Receiving and Recording of goods.
2. Storage.
3. Order Picking.
4. Distribution.(7)

Analysis of raw materials, finished products, packaging materials and In process quality control (IPQC):

1. Raw Materials

Additionally, QC is in charge of sampling and analyzing the batches of raw materials used to make a batch of final goods, including packaging components. Raw materials are examined using gas chromatography and TOC (Total Organic Carbon).

2. Finish Products

It is a part of Quality Control where a pharmaceutical product goes through all production stages, including packaging in its final container and labeling. The specifications for producing finished goods could be different from those for a medicine that is about to expire.

3. Packaging Materials

Pharmaceutical packaging is designed to offer convenience, protection, performance, identity, and information to promote adherence to a course of therapy. Carton closures, shippers, and other packaging materials are frequently utilized in the pharmaceutical industry.

4. In-process Quality Control (IPQC)

During the production process, before packaging, medications are subjected to quality control. It keeps track of all the different manufactured goods varieties that have an impact on quality and place limitations on liability throughout production. This aids in maintaining the quality of raw resources as well as completed goods. A range of tests, including mechanical, physical, chemical, and biological ones, are involved. It is uneasy about giving precise, conclusive, and correct

explanations of the steps that must be taken, from the raw components to the finished compositions.(3)

In-process & Finished Product quality control test for Pharmaceutical dosage form based on Pharmacopoeias (Indian, US., British Pharmacopoeias) IPQ:

IPQC testing are conducted often throughout the manufacturing process (typically every hour). Monitoring and, if necessary, modifying the manufacturing process as part of IPQC's goals for specification compliance. A component of in-process control (IPC) may also include the regulation of the surroundings or of the machinery. They shouldn't be at danger for the product's quality. Testing in-process makes it simpler to find issues. It occasionally reveals a batch of defective products that may be fixed through rework, but this may not be possible once that batch has been finished. It's possible that such procedures weren't followed or that some variables were out of control if the product didn't fulfill IPC specifications. SOPs, or standard operating procedures, should be formed in the pharmaceutical sector and practices that test and define the IPQC.

FPQC:

FPQCs are tests that are performed when the manufacturing process is completed in order to check qualitative and quantitative characteristics along with test procedures and their acceptable limits by which the finished product must comply throughout its valid shelf-life.In order to determine the specifications of the finished product, the quality characteristics. related to the manufacturing process should be taken into account. An appropriate specification for each aspect of quality studied during the phase of development and during the validation of the manufacturing process should be determined. At least those aspects considered to be critical should be the object of specifications routinely verified. The marketing authorization applicant sets the finished product's specification limits at the time of batch release so that the specifications proposed at the end of shelf life are guaranteed. These limits are established on the basis of a critical, in-depth review of the information gathered from the batches analyzed.

Pharmacopoeias:

Pharmacopoeias are called drugs standard. There are various types of pharmacopoeia such as Indian Pharmacopoeia (IP), British Pharmacopoeia (BP), United States Pharmacopoeia (USP), European Pharmacopoeia (PhEur), International Pharmacopoeia (PhInt) and Japanese Pharmacopoeia (JP) in different parts of the world and they have laid down the specified limits within which the value should fall in order to be compliant as per the standards. The objective of this study is to show the quality parameters for Pharmaceutical tablets according to pharmacopoeias that are part of in-process and finished product quality control tests.(8)

1. IPQC test for the Pharmaceutical Tablet:

• Non-compendial standards

1. General appearance
2. The moisture content of granules
3. Size and shape
4. Thickness
5. Unique identification marking
6. Organoleptic properties (colour, odour and taste)
7. Hardness

Pharmacopoeial standards

1. Friability
2. Disintegration test
3. Uniformity of dosage units
   a) Weight variation test
   b) Uniformity of content
4. Content of active ingredients
5. Assay
6. Dissolution(9)

2. IPQC & FPQC test for the Pharmaceutical Capsule:

1. Appearance
2. Size & Shape
3. Content Uniformity test
4. Unique identification marking
5. Assay
6. Content of Active Ingredient
7. Mass Variation test
8. Uniformity of Mass (Weight)
9. Disintegration test
10. Dissolution test
11. Moisture permeation test
12.Stability test(10)

3. IPQC test for Pharmaceutical Syrups and Suspension:

1. Drug content determination
2. assay of active ingredients
3. weight per ml
4. particle size

4. IPQC test for Pharmaceutical Semisolids:

1. Drug contents determination
2. Assay of active ingreadients
3. uniformity and homogeneity test 4.viscosity and specific gravity test 5.filling test

5. IPQC test for Pharmaceutical Parenteral:

1. Drug contents determination
2. clarity test
3. pH
4. pyrogen test
5. stability test
6. leakage test
7. check up of particulate matters (11)

Regulatory Authority:

1. FDA

The Food and Drug Administration (FDA) is responsible for protecting public health by ensuring the efficacy, safety, and security of human and veterinary drugs, medical devices, biological products, our nation's food supply, cosmetics, and products that emit radiation. .The Food and Drug Administration(FDA) was established in 1906 and is a government agency subject to the approval of the Federal Food and Drug Act. It is the oldest broad consumer protection agency. FDA certification is mandatory for product placement in the US.Drug manufacturers must conduct laboratory, animal, and human clinical trials and submit their data to the FDA to obtain FDA approval. After reviewing the information, the FDA may decide to approve the medicine if it finds that it is safe for use as intended.

2. USFDA

The United State Food and Drug Administration (USFDA) provides sterile and non-sterile pharmaceutical guidelines for industries. FDA updates guidance for industry from time to time. All FDA-approved facilities must follow these FDA guidelines worldwide.

3. WHO

On April 7, 1948, the WHO was founded. The first meeting of the World Health Assembly (WHA) was held on 24 July of that year by the agency's governing body. WHO incorporated the assets, personnel and responsibilities of the Health Organization of the League of Nations and the Office for International Hygiene, including the International Classification of Diseases (ICD). WHO has played a leading role in several public health successes, notably the eradication of smallpox, the near eradication of polio, and the development of the Ebola vaccine.

4. MHRA

Medicines and Healthcare Products Regulatory Agency Ensure that drugs, medical devices and blood components for transfusion meet applicable safety, quality and efficacy standards. Ensure a safe and secure supply chain for drugs, medical devices and blood components. Ensure the efficacy and safety of biological medicines by promoting international standardization and harmonization, ensure the effectiveness and safety of biological therapies.

5. TGA

The Australian Government's regulatory body for drugs and therapies is called the Therapeutic Goods Administration. Under the Ministry of Health and Aged Care, the TGA controls the quality, supply, and marketing of drugs, pathological equipment, medical devices, blood products, and the majority of other therapeutics(12).

Documentation in Pharmaceutical Industry:

- A document is any written, printed, or electronic material that offers details or proof on a process, testing, or equipment handling.
- An important component of the QA system is good documentation. (13)

- **Procedure**

Its formats and architectures are flexible. They can be narrative, with text serving as the description, more structured with tables, more illustrated with flowcharts, or any combination of the above.The following components should be present in good procedures:

- Title – used to identify the procedure.
- Responsibilities and authorities of all people/functions included in any section of the procedures;
- Purpose—outlining the justification for the procedure;
- Scope—outlining what parts will be addressed in the procedure and which aspects will not be covered.
- The results of the actions outlined in the method should be defined and reported in the records.
- Document control – in accordance with accepted practice for document control, identification of modifications, date of review, approval, and version of the document should be included.
- Description of activities - this is the main section of the procedure, it relates all the other elements of the procedure and describes what should be done, by whom and how, when and where. In some cases, "why" should be clarified as well. Additionally, the input and the outputs of the activities should be explained, including the needed resources.
- Description of actions – this is the procedure's core portion; it connects all the other components and outlines what needs to be done, by whom, when, and where. In some circumstances, it's also important to explain "why". The input and output of the activities, as well as the resources required, should also be explained.

Work Instructions

It might be a step in a process. They might also be mandated by a procedure. Work instructions often follow a similar format to procedures and cover the same topics, but they also provide more specific information on the tasks that must be completed, with an emphasis on the order of the processes, the tools and techniques that must be used, and correctness. The utilization of competent employees and employee training reduces the requirement for extremely comprehensive work instructions. Many of the following specifics may be included in work instructions:

Work Instructions may cover many of the following details:

- The manner in which the work will be done.
- The equipment and tools that will be used.
- The environment or location associated with the work
- Material handling requirements.
- Safety alerts for the employees.
- Across-reference to any other required processes or work instructions.
- The critical process parameters to be monitored and the instructions on how to monitor.
- Equipment maintenance procedures.
- Methods for verifying that the product meets specification.
- Other non-product related criteria for the final product.

Records

The Quality Documentation System's last rung. All of the material is archived, including documents, forms, and data. The objective proof that the Quality System is being followed precisely is provided by the quality records. The quality of the final product was confirmed to have met the requirements and then the customer's demands and expectations, according to the quality records.

Records include the following sources:

- Non-Conformance Investigations.
- CAPA's *Audit Results
- Supplier Documentation
- Calibration Results (14)

Basic Principles – How to maintain, retention, & retrieval etc.

How to maintain:

Documents should be approved, signed & dated by the appropriate responsible persons. No documents should be changed without authorization& approval. Each specification for raw materials, intermediate, final product, and packing materials should be approved and maintained by the quality control department.

The right accountable parties should approve, sign, and date all documents. No document should be altered without permission and authority. The quality control department should approve and maintain each specification for raw materials, intermediate, final product, and packing materials.

How to retention:

Document storage and retention: Each batch's completed paperwork should be kept on file for at least a year beyond the batch's expiration date, and if no expiration date is specified, it should be protected from theft, loss, or information change. Even document and record archiving and retention can be done in electronic format using photo-reduced copies called microfilm and microfiche.

How to retrieval:

It is important to save documents in a way that makes it simple to retrieve them. To do this, a system is used in which a list of documents is compiled according to their name, location, and contact information. Master papers should be retrievable with the right QA authorization.(13)

Standard operating procedures:

- To comply with the aforementioned standards, the documentation and practices listed below should be prepared. To demonstrate compliance with the aforementioned standards, the data produced by these procedures should be kept.
- Prepare apex documents like Quality Policy, Quality Manual, Site Master File, Validation Master Plan, etc. to describe the quality commitments of the management.
- Define the roles and responsibilities of all personnel working in the organization.
- Prepare policy for periodic review of documents; Ensure that the current industrial practices and pharmacopoeial requirements are fulfilled by the current versions of documents.
- SOP for document (SOPs, MPCR, BPCR, validation/ qualification protocols, formats) preparation, review, approval, training, distribution, control, and its retention.
- Procedure for maintaining revision history.
- Management, control, and retention of superseded or obsolete documents.
- Document archival and retrieval procedure.
- Handling, archival, retrieval, and retention of electronic records/documents.
- Procedure for control of electronic signatures.
- Equipment cleaning and sanitation procedure.
- Issuance and control of equipment logs

Master Batch Record:

A document or set of documents specifying the starting material with their quantities and the packaging materials, together With a description of the procedure and precautions required to produce a specified quantity of a finished product as well as the processing instructions, including the in-process controls.

Batch Manufacturing Record:

Batch manufacturing record is a written document of the batch, prepared during pharmaceutical manufacturing process. It contains actual data and step by step process for manufacturing each batch. Batch manufacturing record is like a proof that batches were properly made and checked by quality control personnel.(14)

Introduction to principles of Drug discovery & development:

When one lead molecule for a drug candidate is discovered, the drug discovery phase comes to a conclusion, and the drug development process starts. Preclinical testing to ascertain the medicine's safety and efficacy is the first step in the drug development process after a lead molecule is identified.

Principle:

"Basic principles of drug discovery and development provide a thorough explanation of enabling technologies like high-throughput screening, structured drug design, molecular modeling, pharmaceutical profiling, and translational medicine. They also represent the multifaceted process of new drug identification in the modern era. regions that have developed into essential phases in the productive creation of marketable medicines.

Investigational New Drug Application (INDA)

An Investigational New Drug Application (IND) is a request by a clinical trial sponsor to obtain approval from the Food and Drug Administration (FDA) to administer an investigational drug or biological product to humans.

New Drug Application (NDA)

A New Drug Application (NDA) provides complete information about a new drug molecule. The purpose of an NDA is to demonstrate that a drug is safe and effective for its intended use in a large population study.

Abbreviated New Drug Application (ANDA)

An Abbreviated New Drug Application (ANDA) contains data that is submitted to the FDA for review and eventual approval of a generic drug. Once approved, the applicant can manufacture and market the generic drug to provide a safe, effective and cheaper alternative to the brand- name drug it refers to.

Central Drug Standard Control Organization (CDSCO)

It performs regulatory oversight on the caliber of medicines, cosmetics, and recognized medical gadgets in the nation. The Central Narcotics Bureau is in charge of carrying out the duties entrusted to it by the Drugs and Cosmetics Act (12).

- **Validation:**

Validation is a concept that developed in the United States in 1978. The concept of validation has expanded over the years to encompass a wide range of activities from analytical methods used for quality control of medicinal substances and medicinal products to computerized systems for clinical trials, labeling or management process, validation is based on regulatory requirements but is not mandated and is best considered an important and integral part of cGMP. The word validation simply means an assessment of validity or an action demonstrating effectiveness. Validation is a team effort involving people from different areas of the plant. This principle includes the understanding that the following conditions exist: Quality, safety and efficiency are designed or built into the product. Continuous inspection and final product inspection or testing cannot fully guarantee quality; thus, each stage of the production process is under control to guarantee that the end product satisfies all quality requirements, including specifications.

- **Scope of Validation**

It is challenging to define the scope of validation because pharmaceutical validation encompasses almost every component of pharmaceutical processing activities. The following areas of pharmaceutical validation will be highlighted, at

the very least, by a systematic assessment of pharmaceutical operations:

- Analytical
- Device calibration
- Process Utility services
- Raw materials
- Packaging materials
- Equipment
- Manufacturing process
- Product design
- Cleaning
- Operators

Quality By Design

- The process is designed to consistently achieve product quality features.
- The product is designed to suit patient needs and performance criteria.
- It makes sense that process settings and raw materials have an impact on product quality.
- The most important sources of process variability are found and managed.
- To ensure continual quality throughout time, the procedure is continuously reviewed and modified.

Definition [ICH Q 8(R1)]

A systematic approach to development that starts with predefined goals and emphasizes product and process understanding and process management, based on sound science and quality risk management.

Definition[FDA PAT Guidelines, Sept. 2004]

A system for designing, analyzing and controlling production through timely measurements (i.e. during processing) of critical quality and performance attributes of new and developed materials and processes to ensure the safety of the final product. The concept of "Quality by Design" (QbD) has been defined as an approach that includes a better scientific understanding of critical process and product qualities, designing controls and tests based on the scientific limits of understanding during the development phase and using the knowledge gained during the Product life cycle to work on continuous improvement Environment. QbD describes a pharmaceutical development approach referring to formulation design and development and manufacturing processes to maintain prescribed product quality(12).

CONCLUSION

The results of this study make it abundantly evident that, despite the fact that different pharmacopoeias suggest distinct types of IPQC and FPQC tests for pharmaceutical dosage form, the primary goal of all pharmacopoeias worldwide is to deliver high-quality pharmaceuticals for human health. The IPQC test is required to reduce the time-consuming instrument utilization. The Preservation of the product's quality, safety, and efficacy is aided by the completion of all the tests that are indicated for both final doses and raw ingredients. In terms of the sector in which we specialize, we are aware that quality assurance is a technique that is focused on the cost while quality control is a procedure that is focused on the product, quality control is a reactive process, whereas quality assurance is proactive.

Prior to their release onto the market, they are subjected to a number of finished product and in-process quality control tests based on several compendial and non-compendial quality attribute criteria. The foundation of quality assurance, which is also based on enacted laws, is customer happiness. Pharmaceutical companies can guarantee the quality of pharmaceutical products by adhering to GMP criteria (either WHO-GMP, British GMP, USFDA-GMP, etc.) and by keeping a well-established quality assurance department and operations. The assessment variability of the method in relation to the specification limits, which is incorporated in QbD, is one of the most important method features to take into account when assessing whether a technique is acceptable for the circumstance.

REFERENCES

1. Md. Mazher Ahmed;Quality Assurance & Quality Control in laboratories;Research and Reviews Journal of Pharmaceutical Quality Assurance;page no.26,27.
2. Gargi Nanda; Responsibility of QA/QC (module);page no.9 - 11.
3. Pragyandip Parthasarathi Dash, Ruchika Raj ;Methodical Review on Industrial Manufacturing and In-process Quality Control of Injectables; International Journal of Pharma Research & Health Sciences, page no.3172 – 3173.
4. Md.Moklesur Rahman Sarker; Comparative study of In-process and finished products quality control test for tablet and capsules according to pharmacopoeias;https://www.researchgate.net /publication/327205931; ; page no.32,33.
5. S.Gokhula Krishnan; Research Institute of Health Sciences; page no.3,4.
6. Reham M. Haleem , Maissa Y. Salem , Faten A. Fatahallah,Laila E. Abdelfattah;Quality in the pharmaceutical industry;Saudi Pharmaceutical Journal;page no.466 - 467.
7. Sayed Tabraizullah Hussaini; Good Warehousing Practice; Pee Vee book of Pharmaceutical Quality Assurance by Dr. Swarnali Das Paul, Mrs. Gunjan Jeswani, page no: 255 – 275.
8. Pooja Rajan, P. Sindhuja, M. V. Nagabhushanam, Brahmaiah Bonthagarala,D. Nagarjuna Reddy and G. Ramakrishna; A Review on In processes and Finished Products Quality Control Test for tablets according to Pharmacopoeias ;World Journal of Pharmacy and Pharmaceutical Sciences ;page no.306 – 307.
9. Ghimire Prakash, Shrestha Abinash Chandra , Pandey Sandhya , Chapagain Bidur and Dhakal Samir;Pharmacopoeial comparison of in-process and finished product quality control test for pharmaceutical tablets ;GSC Biological and Pharmaceutical Sciences; page no.157 - 162.
10. Harishchandra Chavan,Chhabra Gurmeet,Gujarathi Nayan,Jadhav Anil; Asian Journal of Pharmaceutical Research & Development ; page no.63 – 67.
11. Sujata C.Kasar,Arti M. Jadhav, Sushant C. Kadam, Amruta P. Patil;QA/QC in the Pharmaceutical Science;International Journal of Pharmaceutical Research and Applications;page no.313.
12. Gouri Mahesh Sontakke, Shrutika Shriprasad Sakhare, Rasika Dhanaji Chavan Ganesh Sugriva Dhakne, Vedant Gopichand Hamand;Quality Control and Quality Assurance in Pharmaceutical Industry;International Journal of Advanced Research in Science, Communication and Technology (IJARSCT);page no.503 - 507.
13. Yadav-Pooja-S;https://www.scribd.com/presentation/518191480/Documentation-in- Pharmaceutical-Industry.
14. Darshani D. Taral, Shreya B. Kolhe, Yogesh K. Jadhav S.P. Kokane, Dr. M. S. Kondawar;Review of Pharmaceutical Documentation System;International Journal of Creative Research Thoughts; page no.743 – 751.

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