International Journal of Pharmaceutical Research and Development

ISSN Print: 2664-6862
ISSN Online: 2664-6870
Impact Factor: RJIF 8.55
IJPRD 2025; 7(2): 688-698
www.pharmaceuticaljournal.net
Received: 06-10-2025
Accepted: 04-11-2025

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The review on a validation

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DOI: https://www.doi.org/10.33545/26646862.2025.v7.i2h.232

Abstract
Validation means making sure every step in a manufacturing process is planned properly and carried out exactly as intended, with clear documentation. It is an essential part of CGMP because it helps guarantee the quality and safety of the final product. Validation and quality assurance always support each other to maintain consistent product standards. In this article, we explain what validation is and why it is important. We discuss different types of validation, including process, equipment, cleaning, and analytical method validation. When each step of production is validated, we can trust that the final product will meet high-quality requirements. Process validation focuses on checking each stage of manufacturing to ensure it works correctly. Since different dosage forms are produced in different ways, each one needs its own specific validation method. The purpose of this review is to give a clear and detailed overview of validation with special emphasis on its role in maintaining product quality.

Keywords: CGMP, validation, quality, process validation, equipment validation, validation protocols

Introduction
Validation is a process used across many disciplines, including medicine, economics, psychology, sales, chemistry, and biology. In reality, the idea of validation can be applied to almost any professional or scientific field. When a new method is developed or an existing one is improved, validation is necessary to confirm that the method is reliable. It must demonstrate that the method meets essential quality parameters such as accuracy, precision, detection limits, quantitation limits, selectivity, linearity range, and the ability to transfer the method successfully to another setting. In simple terms, validation refers to "assessing validation activities or demonstrating that a method works effectively" [1]. "According to European community for medicinal merchandise validation is movement of proving according with the concept gimp that any procedure, method, requirement, material, activity or system actually lead to expected result" [2].

Validation refers to the process of confirming that any procedure, operation, material, system, or piece of equipment consistently delivers the expected outcome. Over time, the idea of validation has broadened to cover many activities, ranging from analytical techniques used in the quality control of drug substances and finished products to computerized systems involved in clinical trials, labeling, and process monitoring. Although validation is supported by regulatory expectations, it is not dictated solely by them; instead, it is recognized as an essential and permanent component of cGMP. In simple terms, validation means evaluating whether something is valid or demonstrating that it functions effectively. It is a collaborative effort, requiring the combined expertise of professionals from different departments within a manufacturing facility [3].

History of validation
The idea of validation was initially introduced in the mid-1970s by two FDA experts, Ted Byers and Bud Loftus, with the aim of improving the overall quality of pharmaceutical products (Agalloco, 1995). Their proposal came as a response to recurring issues related to the sterility of large-volume parenteral preparations. Early validation efforts concentrated mainly on the manufacturing steps of these sterile products, but the concept soon extended to other pharmaceutical processes as well. Although the U.S. FDA played a leading role in promoting process validation, the term itself did not appear in official FDA documents until September 29, 1978. Prior to that time, none of the existing cGMP guidelines mentioned process validation, nor did they provide any formal definition of it [4].

Definition of validation [5-7]

- **US FDA:** "The process validation is the establishment of evidence to ensure a high degree of certainty for a specified process to consistently produce a product that meets its predefined specifications and documented quality characteristics".
- **ICH:** "Process validation represents the means of ensuring and providing supporting documents specifying their design parameters by whom they are capable repeatedly and reliably produce a finished product of the required quality."
- **WHO:** "The documented document proving that any procedure, process, equipment, material, activity or system can lead to the expected result".
- **European Commission 1991:** Validation-"Act of proving in accordance with GMP that any process actually needs to expected result".
- **European Commission 2000:** "Evidence that this process, operated within established parameters, can perform efficiently and reproducibly to produce a drug substance meeting its predetermined specifications and quality attributes.

Scope of Validation [8]

Pharmaceutical Validation is a vast area of work and it practically covers every aspect of pharmaceutical processing activities, hence defining the Scope of Validation becomes a really difficult task. However, a systematic look at the pharmaceutical operations will point out at least the following areas for pharmaceutical validation;

- Analytical
- Instrument Calibration
- Raw materials
- Packaging materials
- Equipment
- Facilities
- Manufacturing operations
- Product Design
- Cleaning
- Operators
- Process Utility services

Importance of Validation [9, 10]

- **Assurance of quality:** Validation confirms that a process, method, or system performs consistently every time. It reduces variability and ensures that all operations yield the same expected outcomes. This consistency is essential for maintaining overall product quality. It Protects patients and end users by ensuring the product is safe, effective, and free from defects.
- **Time bound:** Time-bound validation is critical because it maintains regulatory compliance, ensures continuity of production, prevents quality risks, and maintains data integrity. Validation without strict timelines can jeopardize patient safety, product quality, and business competitiveness. Thus, integrating clear timelines into validation planning, execution, and documentation is an essential element of Quality Assurance.
- **Process optimization:** Process optimization is a foundational requirement for successful validation. It ensures that the process is efficient, scalable, reproducible, and aligned with regulatory expectations. Without optimization, validation becomes unreliable, inefficient, and costly. Optimized processes lead to high-quality products, improved compliance, reduced risk, and sustainable lifecycle performance.
- **Reduction of quality cost:** It is a major benefit of validation. A well-designed validation program lowers failure costs, reduces rework, improves efficiency, supports compliance, and stabilizes operations. Ultimately, validation is not a cost it is an investment that prevents far greater losses in production, quality, and regulatory performance.
- **Nominal mix-ups, and bottle necks:** Addressing nominal mix-ups and bottlenecks is crucial in validation because it ensures correct identification, reduces errors, enhances efficiency, supports data integrity, prevents delays, lowers costs, and ensures compliance. A robust validation process must proactively identify and eliminate these issues to guarantee consistent, high-quality, and reproducible results.
- **Minimal batch failures, improved efficiently and productivity:** Validation is designed to ensure that manufacturing processes, analytical methods, equipment, and cleaning procedures produce consistent and reliable results. One of its greatest benefits is the ability to reduce batch failures, improve operational efficiency, and enhance overall productivity. These outcomes strengthen quality, reduce cost, and ensure regulatory compliance.
- **Reduction in rejections:** Reducing batch rejections is one of the most critical outcomes of any validation activity. Validation ensures that processes, methods, equipment, and cleaning procedures operate within defined and controlled parameters so that the final product consistently meets quality specifications. Fewer rejections lead to improved efficiency, cost savings, and regulatory compliance.
- **Increased output:** Increasing output (higher productivity, greater batch throughput, more consistent yield) is one of the major benefits of effective validation. Validation ensures that processes, equipment, methods, and systems function in a controlled, reproducible manner, which directly contributes to increased operational output.
- **Avoidance of capital expenditures:** Validation not only ensures product quality and regulatory compliance, but it also helps organizations avoid unnecessary capital expenditures (CapEx) by ensuring existing systems, equipment, and processes function properly and efficiently. This financial benefit is often overlooked but is highly significant for pharmaceutical, biotech, and healthcare manufacturing units.
- **Reduced testing in process and in finished goods:** Validation ensures that manufacturing processes consistently produce products that meet predetermined quality standards. Once a process is validated, it becomes predictable, controlled, and scientifically understood. This allows manufacturers to reduce the amount of in-process testing (IPT) and finished product testing (FPT) without compromising safety or quality. Reduced testing is not about skipping tests, it is about needing fewer tests because the process is proven reliable.
- **More rapid and reliable start-up of new equipment's:** Validation plays a critical role in

ensuring that new equipment introduced into a pharmaceutical or healthcare manufacturing environment operates reliably, safely, and consistently from the very beginning. A validated start-up minimizes delays, prevents deviations, ensures compliance, and accelerates the achievement of commercial productivity.

More rapid and reliable start-up of new equipment is a major benefit of validation. By ensuring proper installation, operation, and performance before production begins, validation minimizes early failures, accelerates operational readiness, enhances compliance, reduces costs, and ensures consistent product quality.

- **Easier scale-up form development work:** Scale-up refers to the process of transferring a product or process from laboratory or pilot scale to full commercial manufacturing. Validation plays a critical role in ensuring that this scale-up is smooth, reliable, and compliant. When validation activities support easier scale-up, organizations achieve several key benefits.
- **Easier maintenance of equipment:** Equipment validation (IQ/OQ/PQ) ensures that machines operate consistently within predetermined parameters. One important benefit of proper validation is easier, more efficient maintenance of equipment throughout its lifecycle.
- **Improved employee awareness of processes:** Validation activities require thorough documentation, defined procedures, and scientific understanding of each process. This naturally leads to greater awareness, competence, and accountability among employees involved in manufacturing, quality, and maintenance.
- **More rapid automation:** Validation provides a structured, scientific understanding of processes and equipment. This strong process knowledge enables faster, safer, and more effective implementation of automation technologies in pharmaceutical and manufacturing environments.
- Government regulation (Compliance with validation requirements is necessary for obtaining approval to manufacture and to introduce new products)

  Government regulations (FDA, EMA, CDSCO, MHRA, WHO, ICH, etc.) form the backbone of pharmaceutical validation. These regulations ensure that all processes, equipment, and systems consistently produce products that are safe, effective, and of high quality.

  Thus, regulatory oversight is essential to the entire validation lifecycle.
- **Enhance patient Safety:** Validation ensures that every manufacturing process, analytical method, equipment, and system consistently performs as intended. One of the most critical outcomes of validation is enhanced patient safety, because pharmaceutical products directly affect human health.
- **Ensures consistently product quality:** Validation ensures consistent product quality by controlling process parameters, reducing variability, preventing errors, and maintaining uniform performance of materials, equipment, and methods.
- **Provides process assurance & reduce risk:** Validation ensures that every manufacturing process, method, and equipment performs consistently and reliably under defined conditions. This provides strong process assurance and significantly reduces risks related to product quality, safety, and compliance.

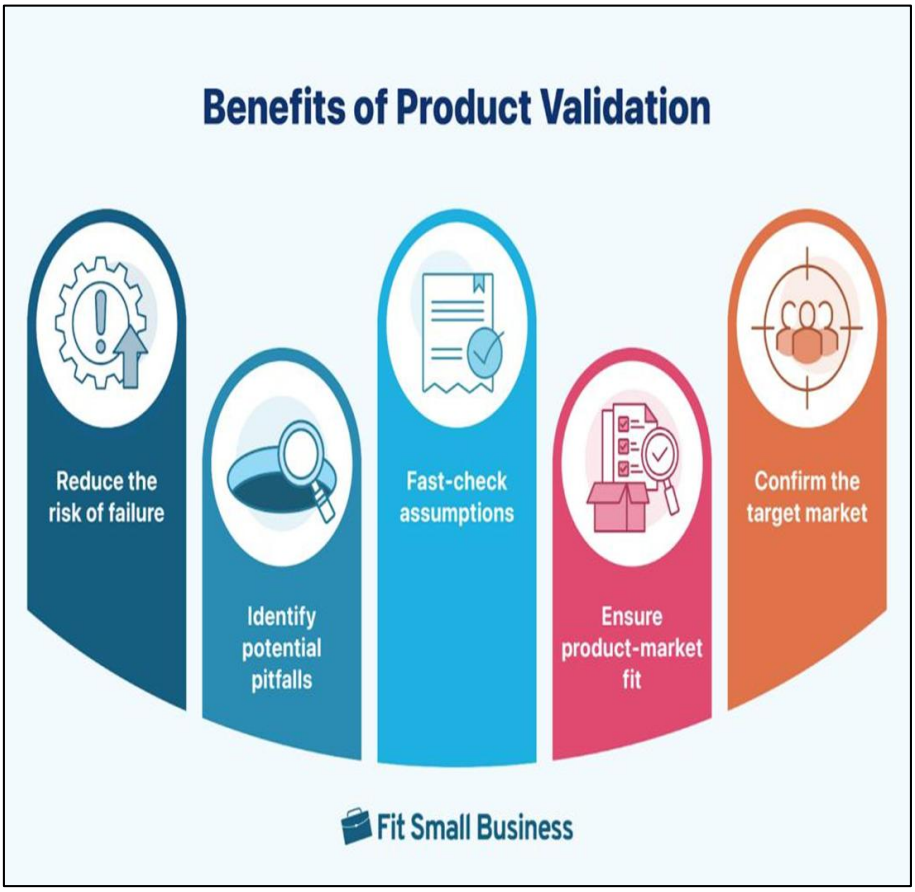

Fig 1: Importance of validation

Types of validation

There are mainly four types of major types of validation as follows.

- Process validation
- Equipment validation
- Analytical method validation
- Cleaning validation

Process validation

The process validation is a component of the coherent prerequisites of a quality management system. Process validation is the most essential and perceived parameters of current good manufacturing practices. The objective of a quality system is to produce items that are matched with their proposed use uniformly. Process approval is a key component in guaranteeing that these standards and objectives are met [11].

Pharmaceutical Process Validation is the most important and recognized parameters of cGMPs. The requirement of process validation appears of the quality system (QS) regulation. The goal of a quality system is to consistently produce products that are fit for their intended use [12].Process validation is a key element in assuring that these principles and goal are met. The process validation is standardization of the validation documents that must be submitted with the submission file for marketing authorization. The process validation is intended to assist manufacturers in understanding Quality Management System (QMS) requirements concerning process validation and has general applicability to manufacturing process. According to FDA, Assurance of product quality is derived from careful and systemic attention to a number of importance factors, including: Selection of quality process through in-process and end product testing [13].

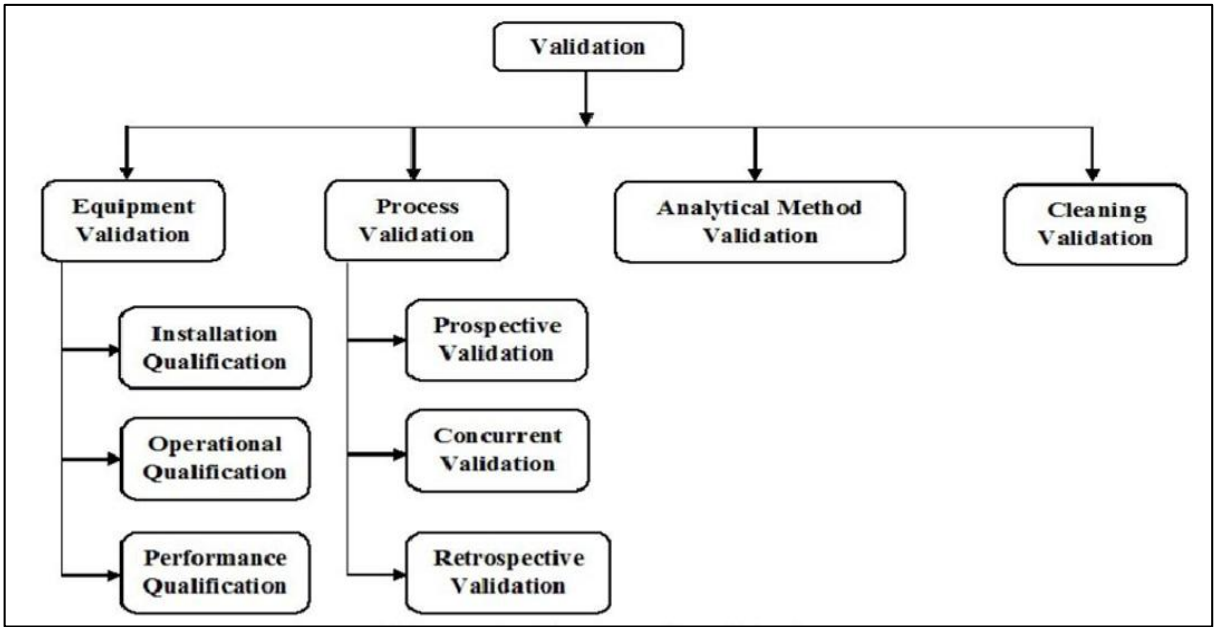

Fig 2: Types of validation

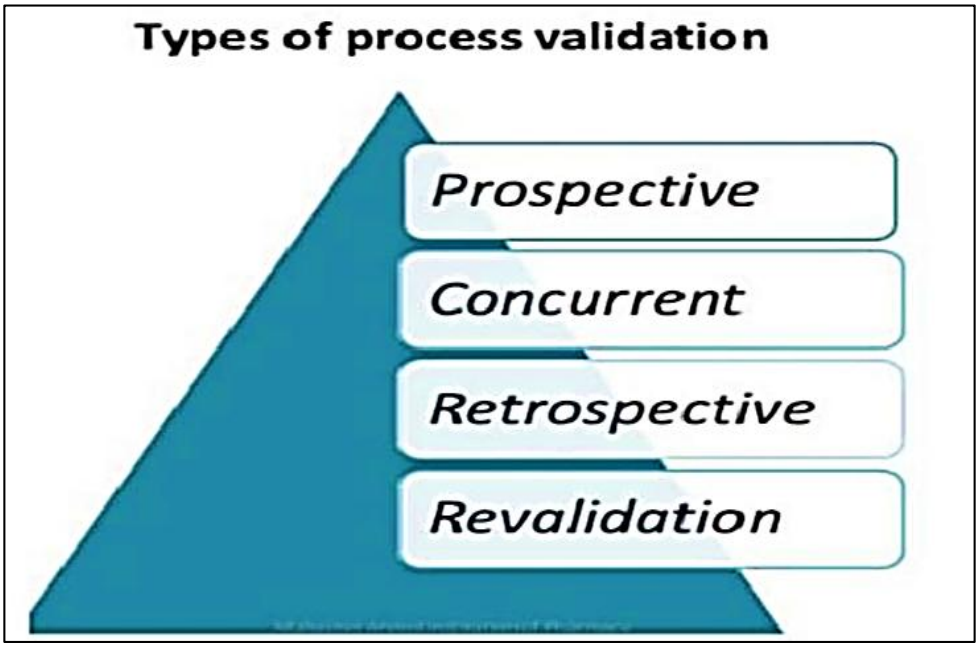

Fig 3: Types of process validation

A) Prospective Validation

It is used for facilities, processes, and process controls in operation use that have not undergone a formally documented validation process. Validation was conducted prior to the distribution of either a new product or a product made under a revised manufacturing process. Validation is completed, and the results are approved prior to any product release establishing documented evidence prior to process implementation that a system does what it proposed to do based on pre-planned protocols. Each prospective validation step will be described in the qualification/validation documents [14].

In Prospective Validation, the validation protocol is executed before the process is put into commercial use during the product development phase, the production process should be categorized into individual steps. Each step should be evaluated on the basis of experience or theoretical considerations to determine the critical parameters that may affect the quality of the finished product. A series of experiment should be designed to determine the criticality of these factors. Each experiment should be planned and documented fully in an authorized protocol. All equipment, production environment and the analytical testing methods to be used should have been fully validated. Master batch documents can be prepared only after the critical parameters of the process have been identified and machine settings, component specifications and environmental conditions have been determined [15].

Prospective validation should include, but not to be limited to the following:-

- Short description of the process.
- Summary of the critical processing steps to be investigated.
- List of the equipment/facilities to be used (including measuring, monitoring/recording equipment) together with its calibration status.
- Finished product specifications for release.
- List of analytical methods, as appropriate.
- Proposed in-process controls with acceptance criteria.
- Additional testing to be carried out, with acceptance criteria and analytical validation, as appropriate.
- Sampling plan.
- Methods for recording and evaluating results.
- Functions and responsibilities.
- Proposed timetable.

B) Retrospective Validation

Establishing documented evidence prior to process implemen-tation that a system does what it proposed to do based on pre-planned protocols. This approach to validation is normally undertaken whenever the process for a new formula must be validated before routine pharmaceutical production commences. Validation of a process by this approach often leads to the transfer of the manufacturing process from the development function to production. The retrospective validation is used for facilities, processes, and process controls in operation use that have not undergone a formally documented validation process. Retrospective validation is only acceptable for well-established processes and will be inappropriate where there have been recent changes in the composition of the product, operating procedures or equipment.

- Gather the numerical information from the completed clump report and comprise measure esteems, final result che and in-technique facts,
- Organize this information in a sequential grouping as indicated by bunch fabricating information, utilizing a spreadsheet organize.
- Include information from at any charge the final 20-30 fabricated bunches for research.
- In the occasion that the bunches is under 20, comprise all fabricated clusters and remedy to gather the required range for research
- Trim the information by wiping out check effects from noncritical preparing steps and erase all unwarranted numerical data.
- Subject the ensuing facts to measurable research and assessment.
- Draw ends as regards to the circumstance of manipulate of the assembling technique depending on the examination Review validation information.
- Issue a report of your discoveries (documented proof).
- Batch measure/quality/maker/year/time span.
- Master fabricating/bundling records.
- Current particulars for dynamic materials/finished items.
- List of technique deviations, remedial activities and modifications to assembling records. Data for safety testing for some clumps.[16]

C) Concurrent Validation

It is a combination of retrospective and prospective validation. Performed against an approved protocol, but the product is released on a lot-by-lot basis, usually used on an existing product not previously validated or insufficiently validated. Concurrent validation is used for establishing documented evidence that a facility and processes do what they purport to do, based on information generated during actual imputation of the process.

Building up reported proof that the method is in a situation of manage amid the real utilization of the procedure. This is in standard performed through leading in-process testing as well as gazing essential activities amid the manufacture of every generation Batch, [17]

- This validation consists of in-process checking of basic preparing steps and item testing.
- In great situations it might be worth not to complete a validation program earlier than routine creation begins.
- This creates and recorded evidence to illustrate that the generation method is in a situation of the control.
- The preference to do simultaneous validation must be advocated, reported and affirmed by the approved work force.
- Documentation requirements for simultaneous validation are equal to indicated for imminent validation.
- In-process checking of basic preparing steps and final result testing of modern-day creation can supply archived evidence to illustrate that the assembling procedure is in a condition of the control.

D) Revalidation

Re-validation provides the evidence that changes in a process and/or the process environment that are introduced do not adversely affect process characteristics and product

quality. Documentation requirements will be the same as for the initial validation of the process. Facilities, systems, equipment and processes, including cleaning, should be periodically evaluated to confirm that they remain valid. Where no significant changes have been made to the validated status, a review with evidence that facilities, systems, equipment and processes meet the prescribed requirements fulfils the need for revalidation [18].

Revalidation becomes necessary in certain situations. Some of the changes that require validation are as follows:

- Changes in raw materials (physical properties such as density, viscosity, particle size distribution and moisture etc. that may affect the process or product).
- Changes in the source of active raw material manufacturer.
- Changes in packaging material (primary container/closure system).
- Changes in the process (e.g., mixing time, drying temperatures and batch size).
- Changes in the equipment (e.g., addition of automatic detection system). Changes of equipment which involve the replacement of equipment on a "like for like" basis would not normally require re-validation except that this new equipment must be qualified.
- Changes in the plant/facility.

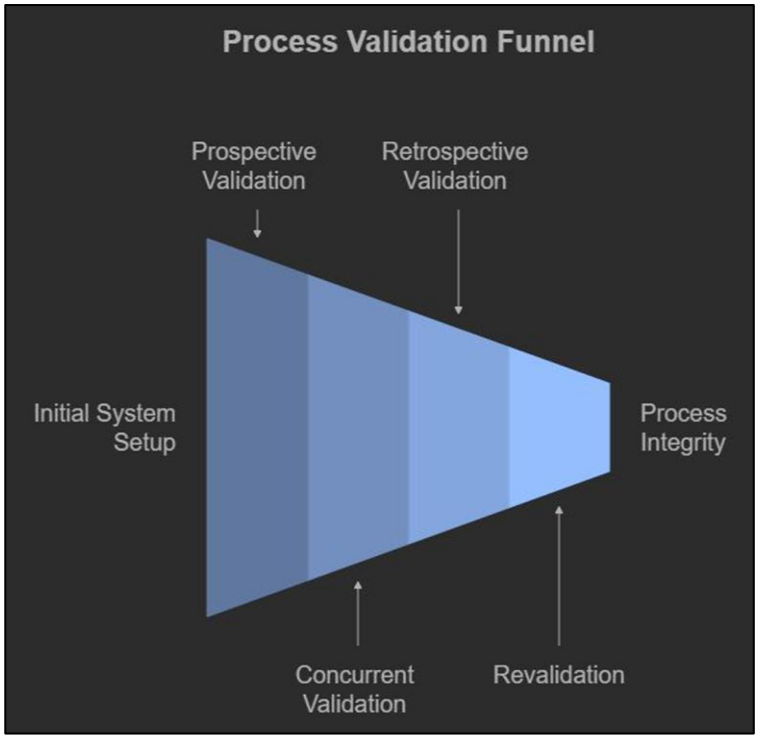

Fig 4: Process Validation

Reason for Process Validation [19]

The possible reason of performing process validation may include:

- New product or existing products as per SUPAC changes.
- Change in site of manufacturing.
- Change in batch size.
- Change in equipment.
- Change in process existing products.
- Change in composition components. Or
- Change in the critical control parameters.
- Change in vendor of API or critical excipient.
- Change in specification on input material.
- Abnormal trends in quality parameters of product through review during Annual Product Review (APR).
- Trend of Out of Specification (OOS) or Out of Trend (OOT) in consecutive batches.

Benefits of Process Validation [20]

- Consistent through output.
- Reduction in rejections and reworks.
- Reduction in utility cost.
- Avoidance of capital expenditures.
- Fewer complaints about process related failure.
- Reduced testing in process and finished goods.
- More rapid and accurate investigations into process deviation.
- More rapid and reliable start-up of new equipment.
- Easier scale-up from development work.
- Easier maintenance of equipment.
- Improve employee awareness of processes.
- More rapid automation.

Equipment Validation [21, 22]

A) Installation Qualification (IQ)

Establishing by objective evidence that all key aspects of the process equipment and ancillary system installation adhere to the manufacturer's approved specification and that the recommendation of the supplier of the equipment are suitably considered.

IQ considerations are:

- Equipment design features (i.e. material of construction clean ability, etc.)

- Installation conditions (wiring, utility, functionality, etc.)
- Calibration, preventative maintenance, cleaning schedules.
- Safety features.
- Supplier documentation, prints, drawings and manuals.
- Software documented.
- Spare parts list.
- Environmental conditions (such as clean room requirements, temperature, and humidity).

B) Operational Qualification (OQ)

Establishing by objective evidence process control limits and action levels which result in product that all predetermined requirements.

OQ considerations include

- Process control limits (time, temperature, pressure, line speed, setup conditions, etc.)
- Software parameters.
- Raw material specifications
- Process operating procedures.
- Material handling requirements
- Process change control.
- Training.
- Short term stability and capability of the process, (latitude studies or control charts).
- Potential failure modes, action levels and worst-case conditions.
- The use of statistically valid techniques such as screening experiments to optimize the process can be used during this phase.

B) Performance Qualification (PQ)

Establishing by objective evidence that the process, under anticipated conditions, consistently produces a product which meets all predetermined requirements.

PQ considerations include:-

- Actual product and process and procedures parameters established in OQ.
- Acceptability of the product.
- Assurance of process capability as established in OQ.
- Process repeatability, long term process stability.

Analytical Method Validation

Validation of an analytical approach is established through laboratory research, that the execution attributes of the procedure meet the requirements for the proposed scientific application. Validation is required for any new or altered procedure to verify that it is fit for giving predictable and dependable outcomes, once used by various administrators by the usage of comparable instrumentation inside the similar or absolutely distinct laboratories. Method validation is a reported program that offers that the processing system will give a high level of affirmation to meet its predicated acceptance basis [23, 24].

It consists of mainly five different steps which are as follows:

- Qualification of the system
- Sampling
- Preparation of sample
- Analysis of sample
- Assessment of data [25]

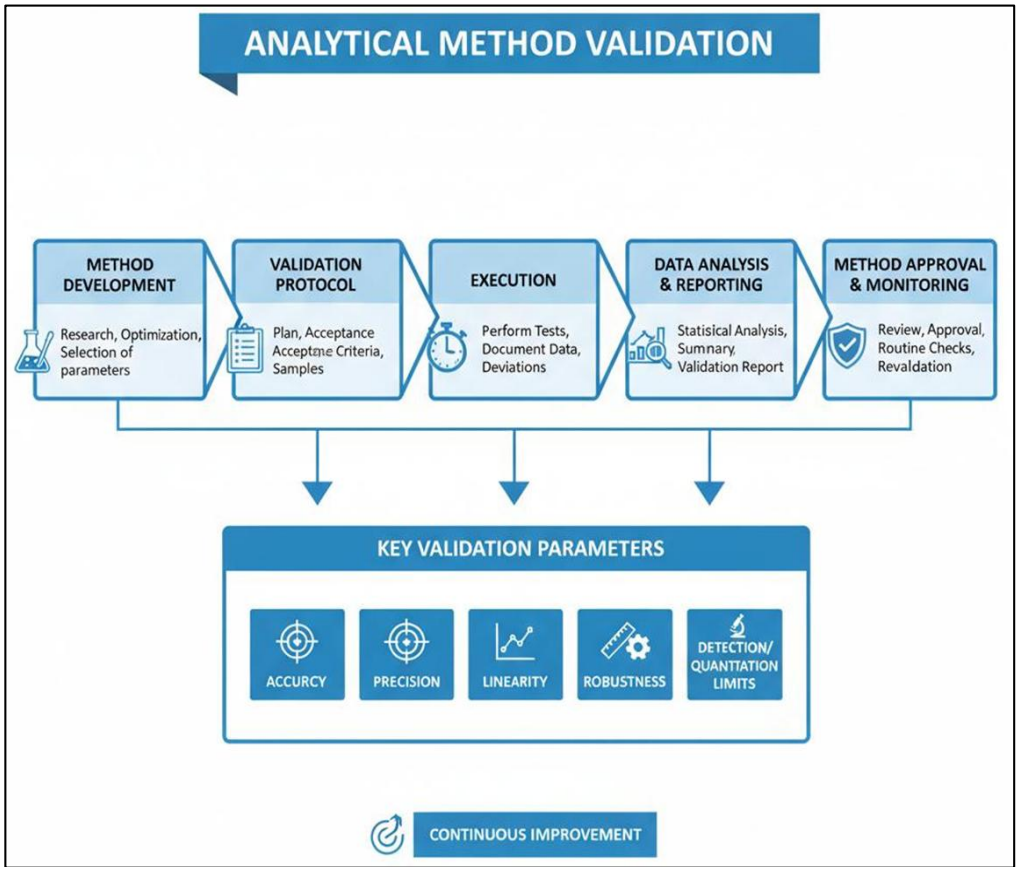

Fig 5: Analytical Method Validation

The main aim of method validation is to produce proof that the method will do what it is supposed to do, accurate, reliable. And consistent. The validation parameters as per International Conference on Harmonization (ICH) guidelines are described below: [26-32]

- **Accuracy:** Accuracy is expressed as the nearness of agreement between the values found and values that are already available. It can also be defined as the closeness between the true value and the observed value. It is sometimes called as trueness, and it could be determined by using at least nine determinations over a minimum of three concentrations over the specified range.
- **Precision:** The exactness of an analytical procedure expresses the nearness of agreement (degree of scatter) between a group of measurements obtained from the different sampling of a uniform sample underneath the prescribed conditions."
- **Specificity:** At each stage of method development, the analytical procedure must clearly demonstrate specificity. This means the method should be capable of accurately identifying and measuring the target analyte even when other expected components are present. These may include degradants, excipients, matrix components, or peaks from the blank sample. The technique must distinguish the analyte without interference.
- **Limit of detection (LoD):** The limit of detection refers to the smallest amount of analyte that can be detected, though not necessarily quantified with accuracy. To determine LoD, a blank solution is injected, and the peak-to-peak noise is measured from the baseline or chromatograms. The LoD is then calculated at a signal-to-noise ratio of approximately 3:1.
- **Linearity:** Linearity describes the ability of an analytical method to produce results that are directly proportional to the concentration of the analyte in the test or standard solutions. In other words, as the concentration increases, the response should increase in a predictable manner.
- **Range:** Range is defined as the span between the lowest and highest concentrations of analyte that can be accurately measured by the method. For assay procedures, this range usually covers 80% to 120% of the target test concentration.
- **Ruggedness:** Ruggedness refers to how well an analytical method can maintain consistent results when tested under varied conditions. These conditions may include different analysts, laboratories, instruments, environmental factors, or operating parameters. It reflects the robustness of the method when minor, intentional variations are introduced. In HPLC, such parameters may include slight changes in pH, flow rate, column temperature, or mobile phase composition.

Cleaning validation

It refers to the confirmation that cleaning procedures are capable of consistently removing residues from manufacturing equipment to levels that meet predetermined safety limits. It is mainly applied to the cleaning of process equipment used in pharmaceutical production. The term encompasses the analytical evaluation of cleaning methods and cycles. It also includes establishing acceptance criteria both chemical and microbiological determining detection limits, and choosing appropriate sampling techniques.

Reasons for validating cleaning procedures

- It fulfills customer expectations for product quality and safety.
- It ensures that the final product remains safe, pure, and uncontaminated.
- It is a regulatory requirement in the manufacturing of active pharmaceutical ingredients (APIs).
- It helps prevent contamination of pharmaceutical products or APIs by residues from other products, cleaning chemicals, or microorganisms.

Validation Protocol [33]

"A validation protocol is a formal, written plan that outlines the methodology, responsibilities, acceptance criteria, and documentation required to perform validation activities for a process, equipment, analytical method, or system." The protocol also includes prerequisites such as calibration status, training requirements, and environmental conditions that must be verified before execution. By providing a standardized framework for conducting validation, the protocol ensures traceability, regulatory compliance, consistency, and scientific justification for all decisions made during the validation exercise.

A validation protocol serves as an essential quality document that ensures all validation activities are executed in a controlled, reproducible, and auditable manner. It acts as a roadmap that links regulatory expectations with operational practices by defining the rationale for validation, identifying critical quality attributes and parameters, and describing how risks will be assessed and mitigated during the study. The protocol lays out a step-by-step sequence of operations, including equipment setup, operational checks, test conditions, and data recording formats, to guarantee uniform execution across batches or trials. It additionally specifies change control requirements, deviation handling procedures, and criteria for review and approval, ensuring that any discrepancies are appropriately evaluated. This structured approach enhances product quality assurance and strengthens compliance with GMP and international guidelines.

The validation protocol must have a unique identification number, include the required signatures, and be properly dated. At the very least, it should also include the following details:

- Title
- Objective & Scope
- Responsibility
- Protocol Approval
- Documentation
- Acceptance Criteria
- Validation Team
- Review of Process Parameters Validation Procedure
- Product Composition
- Process Flow Chart
- Manufacturing Process
- Review of Equipments/Utilities
- Review of Raw Materials and Packing Materials Review of Analytical and Batch Manufacturing Records

- Review of Batch Quantitles for Validation (Raw release for the next Materials)
- Review of Batch Quantities for Validation (Packing Materials)
- HSE Requirements
- Sampling Location
- Summary
- Conclusion

Fig 6: Validation Protocol

Validation master plan

A Validation Master Plan (VMP) is a document that outlines the company's general philosophy, strategies, and methods for confirming that systems and processes perform as intended. It must be reviewed and approved by management. Effective validation requires detailed preparation and thoughtful planning for every stage of the process. All activities should be carried out in an organized manner, following formally approved standard operating procedures. Every observation must be documented, and whenever possible, results should be recorded as exact numerical values. The VMP should present a clear overview of the entire validation program, including its scope, structure, and scheduling. One of its key components is an inventory of all equipment, systems, and processes that require validation, along with a timeline for completing them. Any validation work associated with critical technical processes, product controls, or manufacturing operations must be included in the plan. It should cover all types of validation prospective, concurrent, retrospective as well as revalidation activities. Since the VMP serves as a summary document, it should be straightforward, concise, and easy to follow. It should not duplicate information already available elsewhere but should reference supporting documents such as quality policies, SOPs, validation protocols, and validation reports [34].

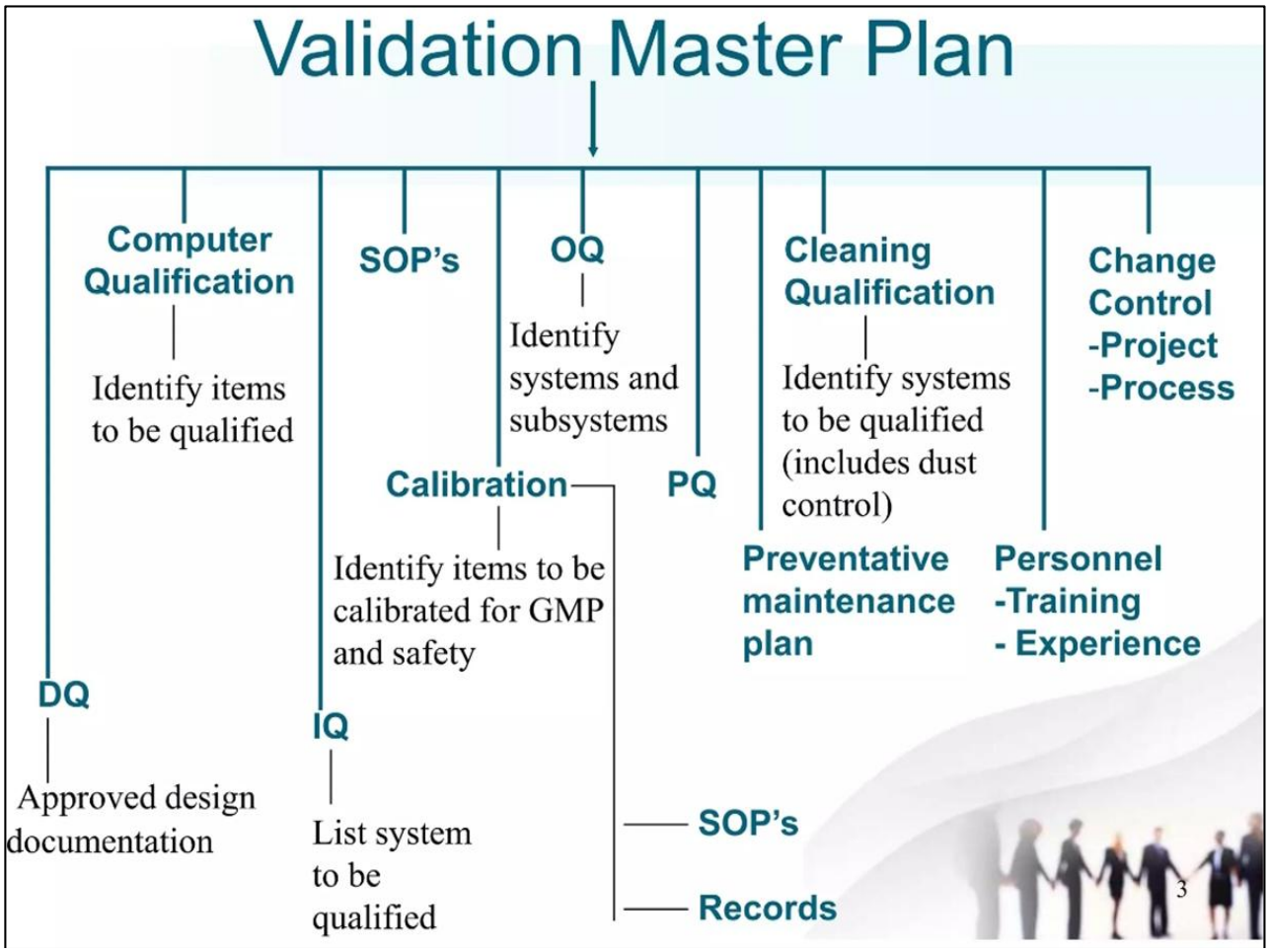

Fig 7: Validation master plan

The key phases of validation master plan are as follows:-

- Conceptualition
- Development
- Implementation

Fig 8: Validation Master Plan

Validation Report

A validation report is an official document that demonstrates that a process, system, or procedure consistently performs as expected. It provides a complete summary of the validation activities, including all tests carried out, any deviations observed, and how those deviations were addressed. The report typically covers the scope of the project, detailed test outcomes, defined acceptance criteria, and, where appropriate, the accuracy of the measurements taken.Once the validation work is completed, a written report must be prepared. If the results meet the required standards, the report must be reviewed, approved, and signed with the appropriate date. At minimum, the report should include the following elements:

- The title of the study and its objective
- A reference to the validation protocol
- Information on the materials used
- The equipment involved
- The programs and cycles applied
- A description of the procedures and test methods [35]

Fig 9: Validation Report

Documentation [36, 37]

A written protocol must be created to define the manner in which qualification and validation activities will be carried out. This protocol must be reviewed and approved before implementation. It should outline the critical steps of the process and set the acceptance criteria. After executing the qualification or validation work, a report should be prepared that includes references to the protocol, summarizes the results, explains any deviations, and provides conclusions along with recommended corrective actions if needed. Any modifications to the original plan must be documented with proper justification. Once the qualification stage is successfully completed, formal written approval should be issued to authorize progression to the next phase of qualification or validation. The lifecycle approach is crucial for ensuring clear and effective communication throughout every stage of process validation, which often involves complex, lengthy, and multidisciplinary activities. Proper documentation is necessary so that the knowledge gained about the product and its manufacturing process can be easily understood and accessed by everyone involved at each phase of the lifecycle. Transparency and availability of information are core principles of scientific practice and are vital in helping responsible organizational units make informed, science-based decisions that support the final release of a product to the market.

Conclusion

This article provides a clear understanding of what validation is, the various forms it takes, and why it plays such an essential role. Validation has proven to be a dependable method for confirming the strength and efficiency of processes, making it a vital quality-assurance tool within the pharmaceutical industry. It is one of the most frequently used terms in drug development, manufacturing, and establishing finished-product specifications. In simple

terms, validation is the creation of documented proof showing that a process or system can reliably and repeatedly produce a product with consistent characteristics. It stands as one of the key requirements of cGMP, as it involves generating written evidence about the performance of a process, a piece of equipment, or a facility.

Validation includes gathering and assessing data throughout different processing stages to provide scientific confirmation that a procedure can consistently deliver a product of the same quality demonstrated during correlation or development studies. Using validated methods is crucial for researchers because it helps establish the reliability and capability of new products. This encompasses different types of validation such as prospective, concurrent, retrospective, and revalidation. Overall, validation is essential in the pharmaceutical field as it ensures that quality is built into every step of drug development and manufacturing.

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