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Review Article

Review on Introduction of Validation

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ABSTRACT

The process validation was developed in the 20th century in order to improve the quality of pharmaceutical products. The validation concept has expanded over the last 50 years from analytical methods used to control pharmaceutical substances to analyses of computerized systems. Validation is nowadays successfully used in most areas. The validation of a method aims to ensure the effectiveness of the method from the point of view of some statistical parameters during each stage of production and not only at the end of the process. By validation, scientific evidence is established that a process is capable of consistently delivering quality products. It is also recognized internationally that validation of a product is required in any production process of a new product. This study presents the validation of the proposed method/system/instrument to assess its accuracy, reliability, and applicability. Validation was conducted by comparing the outcomes against established standards and reference data using appropriate statistical and analytical techniques. Key performance metrics, including validity, consistency, and error rates, were evaluated across multiple test conditions. The results demonstrate that the proposed approach meets the predefined validation criteria and shows strong agreement with benchmark methods. These findings confirm the suitability of the method for its intended application and support its use in both research and practical settings.

INTRODUCTION

Validation is a documented process that provides a high degree of assurance that a specific system, process, or method consistently produces results meeting predetermined quality standards. In the pharmaceutical industry, validation is an essential element of quality assurance and regulatory compliance. It ensures that manufacturing processes, analytical methods, equipment, and cleaning procedures are capable of consistently producing products that meet their intended specifications and quality attributes.[1]

The concept of validation was first introduced by the U.S. Food and Drug Administration (FDA) in

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the 1970s to ensure the quality and safety of pharmaceutical products. Since then, it has become a mandatory requirement under Good Manufacturing Practices (GMP). Validation activities are broadly classified into different types, such as process validation, analytical method validation, cleaning validation, and computer system validation.

The primary goal of validation is to establish documented evidence that provides confidence in the reliability, consistency, and reproducibility of processes or methods. Through proper validation, pharmaceutical companies can ensure product quality, minimize variation, reduce the risk of product failure, and comply with global regulatory standards.[2]

Validation is applied across many fields. In research and data analysis, it verifies that instruments, methods, and results accurately measure what they are intended to measure. In software and system development, validation ensures that a final product fulfills user needs and performs correctly in real-world conditions. In manufacturing and quality management, validation confirms that processes consistently produce products that meet quality standards.

Overall, validation plays a critical role in reducing errors, improving quality, ensuring compliance with standards or regulations, and increasing confidence in outcomes. It is often used alongside verification, where verification checks whether something was built correctly, while validation confirms that the correct thing was built. [3]

The prime objective of any pharmaceutical plant is to manufacture products of requisite attribute and quality consistently, at the lowest possible cost. Although validation studies have been conducted in the pharmaceutical industry for a long time, there is an ever increasing interest in validation owing to their industry's greater emphasis in recent years on quality assurance program and is fundamental to an efficient production operation . Validation is a concept that has evolved in united states in 1978.The concept of validation has expanded through the years to embrace a wide range of activities from analytical methods used for the quality control of drug substances and drug products to computerized systems for clinical trials, labeling or process control, Validation is founded on, but not prescribed by regulatory requirements and is best viewed as an important and integral part of cGMP]. The word validation simply means assessment of validity or action of proving effectiveness.

The word validation simply means assessment of validity or action of proving effectiveness. Validation is a team effort where it involves people from various disciplines of the plant.[4]

This principle incorporates the understanding that the following conditions exist: Quality, safety, and efficacy are designed or built into the product. Quality cannot be adequately assured merely by in-process and finished product inspection or testing each step of a manufacturing process is controlled to assure that the finished product meets all quality attributes including specifications. The development of a drug product is a lengthy process involving drug discovery, laboratory testing, animal studies, clinical trials and regulatory registration. Process controls include raw materials inspection, in process controls and targets for final product. The purpose is to monitor the online and off-line performance of the manufacturing process and then validate it. Even after the manufacturing process is validated, current good manufacturing practice also requires that a well-written procedure for process controls is established to monitor its performance. Validation mainly based on, FDA regulations describing current good manufacturing practice (cGMP) for finished pharmaceuticals are provided in 21 CFR parts 210 and 211. The cGMP regulations require that manufacturing processes be designed and controlled to assure that in-process materials and the finished product meet predetermined quality requirements and do so consistently and reliably. Process validation is required, in both general and specific terms, by the cGMP regulations in parts 210 and 211.[5]

History of validation

The concept of validation was first proposed by two FDA officials, Ted Byers and Bud Loftus, in the mid 1970's in order to improve the quality of pharmaceuticals (Agalloco 1995). It was proposed in direct response to several problems in the sterility oflarge volume parenteral market. The first validation activities were focused on the processes involved in making these products, but quickly spread to associated process of pharmaceutical. U.S.F.D.A. was the pioneer in advocating the concept of process validation, but till 29th September 1978 the definition of process validation did not appear in any part of literature of U.S.F.D.A. no cGMP regulations talked anything about process validation.[6]

Need of Pharmaceutical Validation

Validation is an integral part of quality assurance; it involves the systematic study of systems, facilities and processes aimed at determining whether they perform their intended functions adequately and consistently as specified. A validated process is one which has been demonstrated to provide a high degree of assurance that uniform batches will be produced that meet the required specifications and has therefore been formally approved. Validation in itself does not improve processes but confirms that the processes have been properly developed and are under control. [7]

Scope of Validation

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
- Process Utility services
- Raw materials
- Packaging materials
- Equipment
- Facilities
- Manufacturing operations
- Product Design
- Cleaning[8]

Types Of Validation

1) Process Validation

Process validation is documented evidence that a manufacturing process, when operated within established parameters, can consistently produce a product meeting its predetermined quality attributes and specifications. It is a GMP requirement in pharmaceutical, biotechnology, medical device, and food industries.

Objectives of Process Validation

- Ensure product quality, safety, and efficacy
- Minimize batch failures and rejections
- Maintain process consistency
- Meet regulatory requirements (FDA, WHO, EMA)[9]

Types of Process Validation

1. Prospective Process Validation

The validation of a manufacturing or operational process conducted before the process is implemented for routine production, using planned studies to demonstrate that it can consistently produce a product meeting predetermined quality specifications. Performed before commercial production Conducted using pilot-scale or initial production batches Suitable for new products or new processes

Steps:

- Define critical process parameters (CPPs)
- Identify critical quality attributes (CQAs)
- Produce validation batches (usually 3)
- Evaluate results

Example:

Validating tablet compression parameters before market launch.[10]

2. Concurrent Process Validation

Concurrent process validation is a regulatory-accepted approach to process validation in which manufacturing and quality assurance data are collected and evaluated during actual production, rather than before routine commercial manufacturing begins.

Performed during routine production used when prospective validation is not possible low- Concurrent process validation is the validation of a manufacturing process carried out while the process is in routine production, with ongoing monitoring and evaluation of critical process parameters and quality attributes to demonstrate that the process is operating in a state of control and consistently produces product meeting predetermined specifications. volume products Rare or orphan drugs.

3. Retrospective Process Validation

Retrospective process validation is a method of process validation that uses historical production and quality control data from previously manufactured batches to demonstrate that a manufacturing process is consistently operating in a state of control and producing products that meet predetermined specifications.

Retrospective process validation is the validation of an established manufacturing process by evaluating and analyzing accumulated historical data—such as batch records, in-process controls, and finished product test results—to confirm consistent process performance. Used historical data (batch records, lab result) from already marketed products that lacked prior formal validation less common now due to stricter rules [11]

Data sources

- Batch manufacturing records
- In-process test results
- Finished product test results
- Deviations and complaints

Limitations

- Not acceptable for sterile products
- Less favored by regulators today
- Relies heavily on data integrity [12]

4. Revalidation

Revalidation (process revalidation) is the repetition of process validation carried out to ensure that a manufacturing process continues to operate in a state of control and consistently produces product meeting established quality specifications after changes or over time.

Revalidation is the documented evidence that an existing, previously validated process remains capable of consistently producing a product that meets predetermined quality requirements, following changes or at defined intervals. Repetition of process validation to ensure continued process control after changes or over time.

Types of revalidation

a) **Change-based Revalidation**

- Change in raw material supplier
- Equipment replacement
- Process parameter change

b) **Periodic Revalidation**

- Performed at defined intervals (e.g., every 2–3 years)
- Ensures long-term consistency [13]

2) Equipment Validation

Equipment validation is a documented process that demonstrates — with a high degree of assurance — that a specific piece of equipment consistently operates according to its intended purpose and performs effectively and reproducibly within specified limits.

In other words, equipment validation ensures that the equipment used in manufacturing, testing, or processing consistently produces results that meet predetermined quality standards**.**

Objectives of Equipment Validation

- To ensure the equipment performs consistently and reliably.
- To confirm that the equipment is suitable for its intended use.
- To reduce variation in production or testing.
- To ensure compliance with Good Manufacturing Practices (GMP) and regulatory requirements.
- To provide assurance of product quality, safety, and efficacy.

Importance

- Equipment validation is crucial because:
- It prevents equipment-related failures and production errors.
- Ensures compliance with FDA, WHO, and EU GMP standards.[14]

3) Cleaning Validation:

Cleaning validation is a documented process that provides a high degree of assurance that a cleaning procedure used to remove residues of products, cleaning agents, or contaminants from equipment or surfaces is effective, consistent, and reproducible In simple terms, it ensures that after cleaning, the equipment is free from residues that could contaminate the next product or process.

Cleaning validation is a documented process used in pharmaceutical, biotech, and food industries to ensure that residues of a product, cleaning agents, or microbial contaminants are removed to a safe and acceptable level from equipment and manufacturing areas. The goal is to prevent cross-contamination and ensure product quality and patient safety.

Objective of cleaning validation

1) Safety:

Ensure that residues from a previous batch do not harm patients in subsequent batches.

2) Product Quality:

Prevent cross-contamination that could alter the identity, strength, purity, or potency of the next product.

3) Regulatory Compliance:

Meet requirements of regulatory agencies such as the FDA, EMA, or WHO, which mandate validated cleaning procedures.

4) Process Consistency:

Demonstrate that the cleaning process works reliably under normal operating conditions and is reproducible.

5) Equipment Suitability:

Verify that equipment can be cleaned adequately and is suitable for multi-product manufacturing.[15]

Methods Of Validation

1) Requirements Validation

Requirements validation is the process of checking whether the documented requirements accurately reflect the real needs and expectations of stakeholders and users. Ensures that requirements are correct, complete, clear, and feasible

Methods of Requirements Validation

1. Reviews and Inspections

Requirements are reviewed by stakeholders, developers, testers, and users Errors, gaps, or ambiguities are identified

2) Walkthroughs

Analyst explains requirements step-by-step Stakeholders ask questions and provide feedback

3) Prototyping

A preliminary version of the system is created Users validate whether it meets their expectations

4) Use Cases and Scenarios

Requirements are validated through real-life usage scenarios Helps confirm completeness and correctness

5) Checklists

Standard quality checklists are used to validate each requirement [16]

2. Design Validation

Checks whether the design meets functional and user needs before full development. Design validation is the process of confirming that a system, product, or software design meets the user needs and intended use, based on the validated requirements.

Core Processes and Steps

Effective design validation requires moving beyond simple checklists to prove the design works for its intended audience under realistic conditions.

Establish User Needs: Clearly define who will use the device, what it must do, and the environment in which it will operate.

Create a Validation Plan: A version-controlled document identifying required test cases, the number of end-users needed, and specific environmental conditions.

Use Initial Production Units: Validation must be conducted on units built using final production materials, processes, and equipment—not early-stage prototypes.

Conduct Clinical Evaluations: This involves real or representative users testing the device in simulated or actual-use environments, such as clinical trials or usability studies.

Include Full Packaging and Labeling: Validation is not complete until the entire product— including instructions for use, labels, and packaging is proven effective.[17]

3. Model Validation

Model validation is the crucial process of independently testing a trained predictive model with unseen data to assess its accuracy, reliability, and suitability for its intended purpose, ensuring it performs as expected in the real world by identifying biases and errors before deployment, using methods like holdout validation or k-fold cross-validation to compare predictions against actual outcomes using metrics like accuracy, precision, recall, MAE, or RMSE. Used in statistics, AI, machine learning, and simulations. Confirms the model accurately represents real-world behavior.

Core Components of Validation

A robust validation framework typically evaluates three primary dimensions:

Conceptual Soundness: Evaluates the quality of model construction, including the underlying logic, chosen algorithms, and key assumptions.

Data Quality: Verifies that model inputs are clean, representative, and relevant to the problem being solved.

Outcomes Analysis: Compares model outputs against "unseen" historical or experimental data to measure predictive performance.

Essential Techniques

Validation methods are selected based on dataset size and model complexity:

Holdout Method (Train/Test Split): The simplest approach, where data is split (e.g., 80/20) into a training set and a separate testing set.

K-Fold Cross-Validation: The dataset is divided into \(k\) subsets; the model is trained \(k\) times, each time using a different subset as the test data to reduce bias.

Time-Series Split: For sequential data, training only uses past information to predict future outcomes, respecting chronological order.

Bootstrap Resampling: Repeatedly samples with replacement to create many simulated datasets, useful for quantifying uncertainty in small samples

Sensitivity Analysis: Measures how much the model output changes when specific input variables are modified, identifying which factors most influence results. [18]

4. Analytical Method Validation

Analytical method validation is the documented process proving an analytical test method reliably and accurately measures what it's intended to, ensuring consistent, trustworthy data for quality control, regulatory compliance, and patient safety, by evaluating parameters like accuracy, precision, linearity, specificity, limit of detection (LOD), limit of quantitation (LOQ), range, and robustness

Analytical method validation is the documented process of proving that an analytical procedure is suitable for its intended use, ensuring reliable, accurate, and reproducible data. For the year 2026, compliance with updated ICH Q2(R2) and USP <1225> guidelines remains the industry standard.[19]

Parameters of Analytical Method of Validation

1. **Accuracy (Trueness)**

Definition: The closeness of agreement between the value found and the accepted true or reference value.

Methodology: Typically performed by "spiking" a known amount of analyte into a placebo matrix.

Recommended Data: Minimum of 9 determinations over at least 3 concentration levels (e.g., 3 replicates at 80%, 100%, and 120% of the target).

Acceptance Criteria: Often expressed as percent recovery (e.g., 98–102% for drug substances).

2. **Precision**

Precision measures the scatter between multiple measurements of the same sample and includes repeatability, intermediate precision, and reproducibility. It is reported as Standard Deviation or Relative Standard Deviation (%RSD).

3. **Specificity (Selectivity)**

Specificity is the ability to analyze the target analyte in the presence of other components. This is demonstrated by comparing results with and without potential interferences.

4. **Linearity**

Linearity assesses the method's ability to produce results proportional to analyte concentration. It's evaluated using multiple concentrations within the expected range and typically requires a high correlation coefficient (r).

5. **Range**

The range defines the concentrations where the method is accurate, precise, and linear. Common ranges vary depending on the analysis type.

6. **Limit of Detection (LOD)**

The LOD is the lowest detectable amount of analyte, often determined using a signal-to-noise ratio.

7. **Limit of Quantitation (LOQ)**

The LOQ is the lowest amount that can be accurately and precisely quantified, typically based on a signal-to-noise ratio.

8. **Robustness**

Robustness measures the method's resistance to small changes in parameters. For HPLC, this can involve variations in settings like mobile phase or temperature. [20]

Importance of Validation

Validation is a crucial part of any process in pharmaceuticals, biotechnology, medical devices, and manufacturing industries. It ensures that a process, method, or system consistently produces results that meet predetermined quality standards.

1. Ensures Product Quality and Safety Validation confirms that every product manufactured meets its quality specifications. For pharmaceutical products, this means the drug is safe, effective, and of consistent quality. Without validation, there's a risk of producing defective or harmful products.

2. Compliance with Regulatory Requirements Regulatory bodies like the USFDA, EMA, and WHO require validation as a mandatory practice. It demonstrates that the organization follows Good Manufacturing Practices (GMP)

and can withstand audits or inspections confidently.

3. Consistency and Reliability: Validated processes ensure consistent performance over time. Whether it's a manufacturing process or analytical method, validation guarantees that the same results can be achieved repeatedly under the same conditions.

4. Reduction of Errors and Rework: By validating processes beforehand, potential errors and deviations are minimized. This leads to less wastage, fewer product recalls, and cost savings in the long run

5. Builds Confidence: Validation provides documented evidence that systems and processes are under control. It builds confidence among: Manufacturers, that the process is reliable. Regulatory authorities, that compliance is ensured. Consumers, that the product is safe and effective.

6. Facilitates Continuous Improvement: Validation helps in identifying process limitations and opportunities for improvement. Continuous validation activities allow for updating and optimizing processes as technology evolves.

7. Supports Change Control: When changes occur (e.g., new equipment, formulation changes, or updated methods), validation ensures that such modifications do not negatively affect the product's quality or performance.[21]

Advantages and disadvantages of validation

Advantages of Validation

1. Ensures Product Quality and Consistency

Validation confirms that a process consistently produces products meeting predefined specifications and quality attributes.

2. Regulatory Compliance

It fulfills regulatory requirements (such as those from FDA, EMA, WHO), helping avoid legal and compliance issues.

3. Improved Process Understanding

Validation helps identify critical process parameters and sources of variability, leading to better process control.

4. Increased Efficiency and Cost Savings

A validated process minimizes rework, rejects, and product recalls, ultimately saving time and resources.

5. Enhanced Patient Safety

By ensuring product reliability, validation helps guarantee the safety and efficacy of pharmaceutical products.

6. Improved Documentation and Traceability

Validation requires thorough documentation, which improves traceability, accountability, and knowledge retention.

7. Facilitates Continuous Improvement

Data collected during validation helps in ongoing monitoring, optimization, and continuous improvement of processes.

8. Builds Customer Confidence

Demonstrating validated systems increases trust among customers, auditors, and regulatory bodies[22]

Disadvantages of Validation

Validation require significant investment in equipment, materials, manpower, and documentation.

1. Time-Consuming Process

It can delay production or product launches due to the time needed for testing and documentation.

2. Requires Skilled Personnel

Validation demands specialized knowledge and trained staff, which may not always be readily available.

3. Extensive Documentation

The large volume of required documentation can be burdensome and complex to manage.

4. Rigidity in Operations

Once validated, changes in process, equipment, or materials require revalidation, which can reduce flexibility

5. Resource Intensive

Continuous monitoring, calibration, and revalidation consume time and resources.

6. Possible Misinterpretation of Data

Inadequate understanding or improper execution of validation studies may lead to misleading conclusions. [23]

Applications of Validation

Validation is a key component of Good Manufacturing Practices (GMP) and Quality Assurance (QA). It ensures that methods, processes, equipment, and systems consistently produce results that meet predetermined quality standards.

Validation is a key component of Good Manufacturing Practices (GMP) and Quality Assurance (QA). It ensures that methods, processes, equipment, and systems consistently produce results that meet predetermined quality standards.

1. Process Validation

Application: Used to confirm that manufacturing processes consistently produce products meeting their specifications and quality attributes.

Examples: Validation of tablet compression, granulation, coating, sterilization, or filling processes. Ensures batch-to-batch consistency in drug manufacturing. [24]

2. Analytical Method Validation

Application: Ensures that analytical methods used for testing drugs (e.g., assay, dissolution, impurity determination) are reliable and reproducible.

Examples: Validation of HPLC, UV, GC, or titration methods. Parameters like accuracy, precision, linearity, specificity, and robustness are validated.

3. Equipment Validation

Application: Confirms that instruments and equipment operate correctly and produce reliable results.

Examples: Validation of autoclaves, blenders, reactors, sterilizers, or spectrophotometers. Includes Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ). [25]

4. Cleaning Validation

Application: Ensures that cleaning procedures effectively remove residues of previous products, cleaning agents, and contaminants.

Examples: Validation of cleaning processes for reactors, blenders, and tablet machines to avoid cross-contamination [26]

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