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Review Article

Pharmaceutical Validation: A Review

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ABSTRACT

The practice of validating documentation that demonstrates a process will consistently result in a product that meets expectations is known as validation. Validation studies, according to GMP, are an essential component of GMP; they must be carried out in accordance with predetermined protocols. Process, testing, and cleaning are the bare minimum that need to be validated in order to establish control procedures that monitor output and validate manufacturing processes that might be causing variability in drug products. One of the key components in obtaining and preserving the final product's quality is validation. The accuracy, sensitivity, specificity, and repeatability of the test procedures used by the companies are provided by the validation research, which must be established and recorded. The method used in the pharmaceutical business to increase the dosage form's quality and safety is called process validation. According to cGMP, process validation is a crucial component of quality assurance. Together, validation and quality assurance will guarantee the product's complete quality. Process validation is essential to the pharmaceutical manufacturing process because it provides a high level of assurance and proof that the procedure is producing consistent results, meaning the necessary specifications have been met with accuracy. This article aims to provide a general overview and introduction to validation in the pharmaceutical business.

INTRODUCTION

The process, activity, or technique utilized in production that is used for testing has to be validated in order to produce documentation demonstrating that it continuously upholds the required level of compliance across all phases. In an effort to raise the caliber of medications, Ted Byers and Bud Loftus, two Food and Drug Administration (FDA) officials, originally put out the idea of validation in the middle of the 1970s. Validation's main goal is to make sure that quality is ingrained in the system from the beginning and

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isn't only checked at the conclusion [1]. The primary objective of every pharmaceutical plant is to continuously create items with the necessary characteristics and attributes at the most affordable prices. Even though the pharmaceutical industry has long conducted validation studies, a variety of viewpoints are currently of interest to the industry in order to achieve such a quality. In the US, the word "validation" originally surfaced in 1978. Over time, the idea of validation has expanded to encompass a variety of tasks, such as the use of analytical techniques for the quality control of therapeutic ingredients and drug products as well as computerized systems for clinical trials, labeling, and process control. Validation is best understood as a fundamental and important part of cGMP, based on regulatory requirements even though it is not authorized by them [2].

Over time, the notion of validation has broadened to encompass an extensive array of endeavors, ranging from computerized systems utilized for clinical trials, labeling, or process control to analytical techniques employed for the quality control of therapeutic ingredients and medical products. Validation is best understood as a significant and essential component of cGMP, but it is not mandated by regulatory standards [2, 3]. All pharmaceutical sectors have the common goal of finding high-quality products at the lowest feasible price. In order to ensure quality and boost efficiency, validation is crucial. Process validation defines the limits and flexibility in the production process controls to achieve the desired characteristics in the pharmaceutical product while avoiding the undesired features [4,5]. FDA regulations 21 CFR sections 210 and 211, which outline current good manufacturing practice (cGMP) for completed pharmaceuticals, serve as the primary basis for validation. According to the cGMP rules, manufacturing processes must be planned and managed to ensure that both the final product and in-process components consistently and reliably meet specified quality requirements. Both generally and specifically, the cGMP requirements in sections 210 and 211 necessitate process validation. Manufacturing processes must be planned and overseen in accordance with cGMP rules to guarantee that raw materials used in production and the finished product consistently fulfill preset quality standards [6, 7].

One of the topics that the pharmaceutical business talks about and is most familiar with these days is validation. Its crucial success factor for continuing commercialization and product support. Any product we consider must always meet the authoritative criteria of quality. As a result, the medications need to be produced with the greatest standards of quality. Completed product testing does not guarantee the product's quality on its own. The present good manufacturing standards regulations for finished pharmaceuticals stipulate the need for a process validation method, which applies to the production of pharmaceuticals [8].

Why it's necessary to validate:

Expensive materials, advanced facilities and equipment, and highly skilled personnel are all used in the pharmaceutical sector. It would not be practical to utilize machinery without knowing if the results would be what we want, to hire workers without knowing if they can perform the job, or to neglect to perform process checks or examinations to ensure that the final product meets specifications. If failure costs are to be decreased and productivity is to be increased, a thorough analysis and management of the manufacturing process batch validation are required. Validation aids in cost savings and quality assurance. Validation contributes to a decrease in product rejections, reworks, recalls, and complaints [9].

for the product's efficacy, quality, and safety. High degree of commitment to uniformity is provided by a proven method. Process validation controls and maintains the measures to consistently meet criteria through sufficient validations, but it does

not enhance anything pertaining to product quality [10].

Benefits of validation:

1. Reduced downtime and requirement for process assistance for reliably controlled processes.
2. Merely fewer batch failures and potentially higher productivity levels.
3. Furthermore, prompt and sufficient validation studies will show a commitment to high-quality products, which may expedite the pre-approval inspection and marketing permission procedure.
4. Validation is a wise business decision.
5. Reworks and rejections are declining.
6. Decreased testing duration and end goods.
7. Quicker and more accurate analysis of process deviations.
8. Reducing the price of excellence.
9. Minimal batch failures, enhanced efficiency and productivity.
10. Rejections have decreased.
11. Steer clear of purchasing new equipment.
12. Reduction in the number of complaints about process errors.
13. Employees have enhanced knowledge of the procedure.
14. Accelerated automation.
15. New equipment has a faster and more reliable startup.
16. Government regulation (meeting validation standards is necessary to get approval to manufacture and market new items).
17. There are less tests conducted on final products and procedures [11–14].

Pharmaceutical Validation: An Essential Part of Quality Assurance:

Validation is methodically evaluating systems, facilities, and processes to determine if they perform their intended functions effectively and consistently. Because it has been shown to provide a high level of assurance that uniform batches will be generated that match the required criteria, a validation technique has been granted official recognition. Validation is not the cause of process improvement; rather, it confirms that a process has been designed appropriately and is being managed. The pharmaceutical sector uses expensive materials, highly skilled labor, technology, and facilities for material removal [15,16].

Scope of Validation:

Since pharmaceutical validation encompasses a wide range of tasks and nearly all aspects of pharmaceutical manufacture, determining the scope of validation becomes an extremely difficult task. However, the following topics for pharmaceutical validation will be at least highlighted by a thorough examination of the pharmaceutical processes [17, 18].

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

Types of Process Validation:

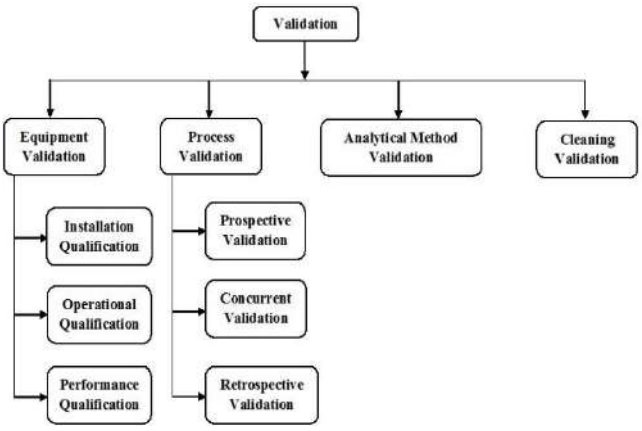

Figure 1: Types of Process Validation

Equipment validation:

Equipment validation is a systematic, documented process that demonstrates that equipment operates as intended and produces reliable, accurate results. The foundation of the equipment validation process is the idea that apparatus needs to be built, maintained, and customized in order to carry out the intended functions [19]. There are three types of equipment validation mentioned as shown in figure 1.

A. Installation Qualification (IQ):

It is a formal confirmation that every feature of a building, service, or piece of equipment that has the potential to compromise the quality of the final result is installed correctly and complies with approved standards. gaining assurance from the food and drug administration (FDA) that ancillary systems and process equipment can reliably operate within predetermined tolerances and restrictions [20].

The following factors are crucial when it comes to IQ:

1. Installation circumstances (utilities, wiring, and functionality);
2. Calibration, preventive maintenance, and cleaning regimens.
3. Features for safety.
4. Supplier manuals, prints, drawings, and paperwork.
5. Software instruction manuals
6. List of spare components [21].

B. Design Qualification (DQ):

"It is an official confirmation that the suggested design is appropriate for the intended use." The main characteristics of the system that are intended to fulfill user needs, comply with regulations, and support the choice of a certain provider are described in the design qualification [22].

Among the crucial DQ factors are:

1. GMPs and legal obligations.
2. Performance standards.
3. Pressure, movement, and air flow regimens inside the facility.
4. Dependability and effectiveness.
5. Commissioning specifications
6. Equipment installation and constructability [23].

C. Operational Qualification (OQ):

It is a formal confirmation that every feature of a building, service, or piece of machinery that has the potential to impact product quality functions as intended over the whole range that is expected. Critical operational parameters for the systems and equipment should be determined during OQ, and studies for critical variables should be conducted. "Worst case" conditions are conditions, or a combination of conditions, that encompass both upper and lower operating limitations [24].

Process control constraints (time, temperature, pressure, line speed, and setup conditions) are one of the OQ factors to be taken into account.

1. Parameters of the software.
2. The specification for raw materials.
3. Operating procedures for the process.
4. The needs for material handling.
5. Process control over changes.
6. Instruction.
7. The process's ability and short-term stability [25].

D. Performance Qualification (PQ):

It is a formal confirmation that every feature of a building, service, or piece of equipment operates as planned and satisfies set acceptance standards. PQ is the process of demonstrating confidence in the process's effectiveness and reproducibility as well as its compliance with the design specifications [26].

The following factors are taken into account in PQ:

1. The actual product and process specifications and procedures that are set in OQ.
2. Acceptability of the merchandise.

3. Confirmation of process capability as specified in the OQ.
4. Repeatability and long-term stability of the procedure [27].

Re-qualification:

The process of confirming that the equipment remains under control following modifications or a predetermined amount of time. It involves frequent evaluations of the equipment within predetermined time frames. This has to be properly reviewed, and documentation needs to be completed. The necessity for re-qualification should be summed up in the review. It is necessary to manage minor changes that have no direct impact on the end or in-process product quality using the Preventive Maintenance Program and Documentation system [28].

Process validation:

USFDA described process validation; Establishing documented evidence which provides high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality characteristics. Process validation offers the manufacturing process controls the flexibility and limitations needed to achieve desired medicinal product quality while preventing undesired features [29, 30].

Types of Process Validation:

A. Prospective process validation:

It is described as the verified, written proof that a system follows through on its prearranged protocol. This validation is typically done on at least three consecutive production batches and is done before a new product or one created using an altered manufacturing process is distributed [31]. Proving or demonstrating that the process will function in line with the validation methodology created for the pilot production trials is the aim of the prospective validation. Usually, prospective validation has to be finished before the pharmaceutical product is sold and distributed. The validation technique is carried out in prospective validation prior to the process being used commercially. The production process should be divided into discrete segments throughout the product development stage. Experience or theoretical considerations should be the basis for evaluating each step-in order to identify the crucial elements that could have an impact on the final product's quality. To ascertain how important these elements are, a number of tests ought to be planned. Every experiment needs to be thoroughly planned and recorded in an approved protocol [32,33]. To create the product for commercial use, prospective process validation is carried out following the conclusion of the R&D trial. This is a critical component of process validation since the majority of validation efforts rely on prospective experimentation to produce evidence supporting the validation. This kind of validation, which entails comprehensive examination of every step in the manufacturing process, is typically associated with the release of a new medication product onto the market [34].

The following should be included in prospective validation:

1. A brief explanation of the procedure
2. an overview of the crucial processing stages that need to be looked into
3. A list of the necessary equipment and the state of its calibration
4. Completed product details for public release
5. An inventory of analytical techniques
6. Suggested in-process controls along with criteria for acceptance
7. Further testing to be conducted 8. Sampling strategy
8. Techniques for documenting and assessing outcomes
9. Responsibilities and functions [35].

B. Concurrent Process Validation:

Concurrent process validation creates recorded proof that, even when the process is being

executed, it is operating under control. Concurrent process validation involves the testing and/or monitoring of important operations during each production batch's manufacture [36]. Processing parameters are monitored using current manufacturing batches in this procedure. It provides information about the current batch under study and provides a limited level of confidence regarding the consistency of quality across batches. Following the taking of the first three commercial batches, the procedure is turned over to the manufacturing facilities, who examine each batch individually to see if any deviations are needed or not. This time, the parameters for in-process quality control are also chosen and tracked, which ultimately results in the IPQC test for routine manufacturing [37]. In some situations, concurrent validation could be the most sensible course of action. These could occur, for instance:

- When a previously approved process is being moved to a different location or a third-party contract manufacturer.
- A high degree of assurance demonstrating that the process is fully under control could not be obtained from the number of lots evaluated under the Retrospective Validation.
- The product is a different strength of a previously validated product with the same ratio of active/inactive ingredients.
- There are only a limited number of batches produced [38].

C. Retrospective Process validation:

After reviewing and analyzing historical data, it is defined as proven, recorded proof that a system performs as intended. This is accomplished by examining previous manufacturing testing data to demonstrate that the process has consistently remained under control [39]. It is done for a product that is already on the market and is predicated on copious amounts of data that have been gathered over time and across multiple batches. Retrospective validation is applicable to older items that need to be validated to meet the standards of division 2, Part C of the Regulation to be Food and Drugs Act, but were not validated by the fabricator when they were first marketed. Only thoroughly defined processes that have undergone recent modifications in product composition, operating procedures, equipment, or facilities are suitable candidates for retrospective validation [40, 41].

The following information should be included in the retrospective process validation:

- Batches manufactured for a specific time
- Number of lots released annually
- Batch size/strength/manufacturer/year/period
- Master production/packaging documents
- Current specifications for active materials and finished products
- A list of process deviations, corrective actions, and modifications to manufacturing documents· · Data for stability testing across multiple batches
- Trend analyses, including those pertaining to quality-related complaints [42].

D. Revalidation:

Necessary in the event that any of the formulation, main packaging components, raw material fabricator, significant equipment, premises, or essential process parameters change. Process re-validation would also be necessary if batches failed to fulfill the product and process specifications. also provide proof that process characteristics and product quality are not negatively impacted by modifications made to a process or its surrounding environment. The standards for documentation will be the same as those for the process's initial validation [43, 44]. There are some circumstances where revalidation is required. The following are a few of the modifications that need to be validated:

- Modifications to the raw materials (physical characteristics that could impact the process or

final product, such as moisture, density, viscosity, and particle size distribution)

- Shifts in the manufacturer of active raw materials supply.
- Modifications to the primary container/closure systems packing material
- Modifications to the procedure (such as batch size, drying temperatures, and mixing times) [45].

Stages of Process Validation:

Process validation is defined as the collection and evaluation of data between commercial production and the process design stage that provides scientific validation that a process is able to consistently produce high-quality goods. Process validation necessitates a series of actions that are taken during the course of the process and product lifetimes. Three phases can be distinguished in the validation study endeavor [45]:

Stage 1: Process Design:

Using the knowledge gathered from development and scale-up operations, this step aims to design a process that can reliably produce a product that satisfies its quality criteria and is appropriate for routine commercial manufacture. This step offers a crucial contribution to the product development studies conducted without the use of good manufacturing practices, which eventually aids in the different design stages such as predicted dosage form and production route [46].

Stage 2: Process Qualification:

In this phase, the process designs suitability for repeatable commercial manufacturing is verified. It attests to the validity of all set Critical Process Parameter limits and the ability to provide acceptable results even in the "worst case" scenarios. There are two stages to process qualification: process performance qualification (PPQ), which requires cGMP-compliant processes to be followed, and design of the facility and qualification of the utilities and equipment [47].

Stage 3: Continued Process Validation:

In this stage, all of the ongoing data that has been gathered to maintain product quality is assessed. The third validation stage aims to provide continuous assurance that the process maintains control throughout standard commercial manufacturing [48].

Phases of Process validation:

Phase 1 (Pre-validation Qualification Phase)

It includes all of the following: creating stability conditions; conducting formulation pilot batch studies; scaling up studies; transferring technology to commercial scale batches; storing and handling finished and in-process dosage forms; equipment qualification; installation qualification; master production document; operational qualification; and process capacity [49].

Phase 2 (Process validation Phase)

Its purpose is to confirm that acceptable products may be generated even in the most adverse circumstances and that all defined limitations of the crucial process parameter are valid [50].

Phase 3 (validation maintenance phase)

To ensure that there haven't been any modifications, deviations, failures, or changes to the production process, as well as that all standard operating procedures (SOPs), including change control procedures, have been followed, it's necessary to regularly review all process-related documents, including validation of audit reports [51].

Analytical Method Validation:

The process of confirming that the analytical testing method employed for a particular test is suitable for its intended use is known as method validation. The analytical methodology is validated in a laboratory setting to determine whether or not its performance characteristics match the requirements for the application under consideration [52].

Validation parameters for the analytical method:

It is important to comprehend the primary objective of the analytical process since it will specify the validation attributes that need to be evaluated. The typical validation attributes that need to be considered are listed below [52]:

- Accuracy
- Precision
- Repeatability
- Intermediate Precision
- Specificity
- Detection Limit
- Quantitation Limit
- Linearity
- Range

Cleaning Validation:

This process verifies that the cleaning method effectively lowers residues from manufacturing facilities to a predetermined level. Cleaning validation is mostly utilized in the pharmaceutical industry for cleaning process equipment. Cleaning cycles or techniques are analyzed through cleaning validation. Additionally, it should describe the development process for acceptability criteria, including chemical and microbiological parameters, detection limits, and sampling protocol selection [53].

Objective of Cleaning Validation:

- Reduction of solvents.
- Increased cleaning equipment and shorter cleaning times.
- Equipment utilization, equipment life extension, and multiproduct.
- Infrastructure, worker safety, and cost-effectiveness [54].

Advantages of Validation Cleaning:

Operator security:

Operator security is improved by validation. Equipment that has been properly calibrated and authorized is utilized to increase safety and decrease accidents.

Improved Customer Quality:

Reducing market recalls through appropriate validation contributes to improved customer service and product quality [55].

Life cycle of validation:

Validation is an ongoing, dynamic process. The validation process involves a methodical and theoretical evaluation of the system and processes performance, ranging from the most basic to the most extensive. Its scope includes training, process and system maintenance, and revision control for documentation. Validation evidence ought to be visible at the corporate level and show up in the management hierarchy. One way to create and preserve quality is through validation as shown in figure 2 [56].

Figure 2: Life cycle of validation

CONCLUSION

An overview of validation in the pharmaceutical sector is provided by this review. GMP requires validation as a necessary component. Validation contributes to the assurance that the product will fulfill GMP standards for quality, safety, efficacy, purity, and effectiveness. Validation is frequently employed in the production of drugs, in manufacturing, and in final product specifications. Batch failure is reduced when products are made with every stage of the manufacturing process optimized, thanks to validation. By lowering the cost of quality, validation contributes to the highest possible product quality. A series of actions that occur during the course of a product's

and process's lifetime are included in validation. Precisely, the pharmaceutical validation contributes to a good guarantee of batch consistency and integrity of the finished product that is produced in compliance with GMP guidelines.

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