

*Review Article*

**An Overview on Validation Technique.**

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**ABSTRACT**

Quality is the primordial intention to any industry and its products manufactured. Multiple views on obtaining such quality are the current interest in the pharmaceutical industry. Acquainted with a practice that puts us in common and routine convention ensured to deliver a quality that sounds globally in terms of a spoken quality is on the dais of pharmaceutical area Validation is the mean of catering enormous benefits to even more than the acceptable quality level which in the global standard scale. Lending importance to validation is increasingly profound in recent years. Validation is the art of designing and practicing the designed steps alongside with the documentation. Validation and quality assurance will go hand in hand, ensuring the through quality for the products. Hence, an emphasis made on to review that gives a detailed, overview of validation concept.

**KEYWORDS**

Validation, Design Qualification, Installation Qualification.

## **1. INTRODUCTION**

Validation is the process of establishing documentary evidence demonstrating that a procedure, process, or activity carried out in testing and then production maintains the desired level of compliance at all stages. In the pharmaceutical industry, it is very important that in addition to final testing and compliance of products, it is also assured that the process will consistently produce the expected results. <sup>(1)</sup> Or the process of providing, documented evidences that provide high degree of assurance a result with predetermined acceptance criteria. <sup>(2)</sup>

*1.1. Prerequisites for successful validation:*

- a. Experience
- b. Planning
- c. Resources
- d. Understanding and communication
- e. Training
- f. SOP's , Instruments and methodology
- g. Validation master planning(VMP)
- h. Data Analysis
- i. Validation Report

*1.2. Strategies of validation under WHO includes.* <sup>(3)</sup>

1. DQ (Design Qualification)
2. IQ (Installation Qualification)
3. OQ (Operational Qualification)
4. PQ (Performance Qualification)

*1. 3. DQ (Design Qualification)*

Design qualification is defined as a verification process on the design to meet particular requirements related to the quality of pharmaceuticals and manufacturing practices. however, the procedure for design qualification in pharmaceuticals is one reason as to why some products do not make it to the shelves in drug stores.

It is important that these procedures are taken into consideration and followed keenly. the scope of design qualification is intended to include activities that involve the design stage, development and design that includes any activities of procurement of equipment and supplier work to make these process simple. <sup>(4)</sup>

*1.4. IQ (Installation Qualification)*

I.Q is a method of establishing with confidence that all major processing, packaging equipment and ancillary systems are in conformance with installation specifications, equipment manuals, schematics and engineering drawings. This stage of validation includes examination of equipment design, determination of calibration, maintenance and adjustment requirements. Installation qualification (IQ) should be performed on new or modified facilities, systems and equipment. IQ should include, but not be limited to the following: Installation of equipment, piping, services and instrumentation checked to current engineering drawings and specifications.

- A. Collection and collation of supplier operating and working instructions and maintenance requirements
- B. Calibration requirements.
- C. Verification of materials of construction.
- D. Description of equipment.
- E. Piping & Instrument diagrams.
- F. Principle of operation.
- G. Facility functional specifications.
- H. Design requirements.
- I. Equipment utility requirements, equipment specification, equipment features.<sup>(5)</sup>

#### *1.5. (PQ) Performance qualification*

Documented verification that the 235 equipment or system performs consistently and reproducibly within 236 defined specifications and parameters in its normal operating environment 237 (i.e. in the production environment).<sup>(6)</sup>

#### *1.6. Importance of Validation*

1. Process parameters and controls are determined during the validation of any process or system
2. It helps to determine worst case and risk that may arise during the manufacturing of quality products.
3. More rapid and reliable startup of new equipments.
4. Reduction in utility cost
5. More rapid automation.
6. Validation helps to investigate the deviation caused during the process.
7. Deep study and understanding of the system and equipment are made possible due the validation.
8. The risk of the regulatory non-compliance is minimized after the validation.
9. Decrease the chances of the failure of the batches.
10. Reduce the production cost of the product.

#### *1.7. Types of Validation*

- a. Retrospective validation
- b. Prospective validation
- c. Concurrent validation
- d. Revalidation

##### *1.7.1. Retrospective validation*

Establishing documented evidence prior to process implementation that a system does what proposed to do based on preplanned protocols. This approach to validation is normally undertaken whenever the process for a new formula must be validated before routine pharmaceutical production commences. In fact, validation of a process by this approach often leads to 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.

### *1.7.2. Prospective validation*

It is used for facilities, processes, and process controls in operation use that have not undergone a formally documented validation process. Validation conducted prior to distribution either of 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 qualification/validation documents.

### *1.7.3. Concurrent validation*

It is a combination of retrospective and prospective validation. Performed against an approved protocol but 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 & processes do what they purport to do, based on information generated during actual imputation of the process.

### *1.7.4. Revalidation*

It means repeating the original validation effort or any part of it, and includes investigative review of existing performance data. This approach is essential to maintain the validated status of the plant, equipment, manufacturing processes and computer systems. Possible reasons for starting the revalidation process include:

- The transfer of a product from one plant to another.
- The necessity of periodic checking of the validation results.
- Significant increase or decrease in batch size.
- The scope of revalidation procedures depends on the extent of the changes and the effect upon the product

## *1.8. Validation master plan*

### *1.8.1. Principle*

Validation in general requires a meticulous preparation and careful planning of the various steps in the process. In addition, all work involved should be carried out in a structured way according to formally authorized standardized working and administrative procedures.

In addition validation is characterized by:

### *1.8.2. Multidisciplinary approach*

A specific characteristic of validation work is that it requires the collaboration of experts of various disciplines such as pharmacists, technologists, metrologists, chemical analysts, microbiologists, engineers, experts on Q.A. validation etc.

### *1.8.3. Time constraints*

Generally validation work is submitted to rigorous time schedules. These studies are always the last stage prior to taking new processes, facilities into routine operation.

### *1.8.4. Costs*

Validation studies are costly as they require time of highly specialized personnel and expensive technology.

The above factors require a well organised and structured approach that should be adequately described in a Validation Master Plan (VMP)<sup>(11)</sup>.

### *1.8.5. Definition*

Validation master plan is an internally approved document that describes, in clear concise wording, the general expectation, intentions, method and approach to be used during the entire validation efforts.

The following points to be considered in validation master plan

- What are the scope and boundaries of the validation efforts?
- Are the building fed by different utilities?
- What is the scope of activity?
- Who will participate in the development of VMP?
- How long it expect to do?
- When you talk about your process, what species can you identify?
- Who will sign it?

### *1.9. Starting point for validation master plan*

Validation master plan should be started as early as possible, in case of new pharmaceutical plant. For facilities it should be ready even before the building plans are ready in simple word the U.R.S and design qualification (DQ) should be the beginning of the facility validation .Similarly before selecting the equipment the (DQ) of the proposed equipment should be ready and then it should follow the I.Q,O.Q,P.Q,etc.

### *1.10. Some guideline on preparing VMP*

1. Type your VMP on A4 size page with all side borders.
2. File it in a presentable form.
3. Have sufficient explanatory drawings use color drawing if possible.
4. Clearly divide the VMP in different sections like introduction, main body and appendices.
5. it must be dated and signed properly by authorized person
6. If found appropriate you may discuss this with the FDA people in advance.<sup>(6)</sup>

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