Concept of Validation and Validation Master Plan

B.Pharm.VI Sem (BP 606)

By
Dr. Abhishek Pandey
Assistant Professor

School of Studies in Pharmaceutical Sciences, Jiwaji University, Gwalior

CONTENTS

INTRODUCTION

- **Validation** is defined as “A Documented Programme , which provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality attributes”.

- Validation is the process of evaluating products or analytical methods to ensure compliance with products or cleaning method requirements

TERMS & DEFINITION

➢ As per WHO

Validation means providing documented evidence that any procedure, process, activity or system actually leads to the expected results.

➢ As per ICH

Validation of analytical methodis the process by which it is established by laboratory studies, the performance characteristics of the method meet the requirements for the intended analytical applications.

predetermined standard.

➢ As per FDA

Validation is establishing documented evidence, which provides a high degree of assurance that a specific process will produce a product meeting its pre determined specification & quality attributes.

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.
- It was proposed in direct response to several problems in the sterility of large volume parenteral market.

NEED FOR VALIDATION

1. Basic requirement for the product quality system.

2. Assures that every lot of each product that is released to the market will consistently meet all the quality requirements.

3. Capable of achieving the intended results.

TYPES OF VALIDATION

- **Prospective validation**

Done during the product development stage. during this the input resources are selected and clearly specified.

- **Concurrent validation**

Which is carried out during production. In process quality control parameter are also decided and recorded.

- **Revalidation**

Revalidation is as a rule required under-

Change of formula, equipment, procedure or quality of raw material.

Changes to facilities and installation which influence the process.

On appearance of new finding based on current Knowledge.

➢Retrospective Validation

Based on a review and analysis of historical data. May be allowed when the formulation procedure and equipment have not been altered.

PROCESS VALIDATION

✓**Process Validation** is "Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality attributes".

✓Process validation involves a series of activities taking place over the lifecycle of the product and process.

✓The activities relating to validation studies may be classified into three stages

The activities relating to validation studies may be classified into three stages.

- Process Design
- Process Qualification
- Continued Process Verification

STAGES OF VALIDATION

❖ Conduct Installation qualification:

➢ IQ considerations are:

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

✓ Installation conditions (wiring, utility, functionality, etc.)

✓ Safety features.

✓ Supplier documentation, prints, drawings and manuals.

✓ Software documented.

✓ Environmental conditions (such as clean room requirements, temperature, and humidity)

❖ Conduct Operational qualification:

➢ OQ considerations include:

✓Process control limits (time, temperature, pressure, line speed, setup conditions, etc.)

✓Software parameters.

✓Raw material specifications

❖**Conduct Performance qualification:**

➢PQ considerations include:

✓Acceptability of the product.

✓Assurance of process capability as established in OQ.

✓Process repeatability, long term process stability

❖**Re – Qualification :**

Modification to, or relocation of equipment should follow satisfactory review and authorization of the documented change proposal through the change control procedure.

SCOPE OF VALIDATION

- Analytical
- Instrument Calibration
- Raw materials
- Packaging materials
- Equipment
- Facilities
- Manufacturing operations
- Product Design
- Cleaning

IMPORTANCE OF VALIDATION

- Reduction of quality costs
- Process optimization
- Assurance of quality
- Safety
- Increased output
- More rapid automation

REASONS FOR VALIDATION

- ✓ **Customer satisfaction**: Non-conforming product can lead to lost customers.
- ✓ **Product liability**: Conformance to product specifications must be maintained.
- ✓ **Reduced production costs**: PV leads to reduced inspections, testing, scrap and rework. Shifts costs from production to prevention.
- ✓ **Supports improvements**: Testing data can be used to support improvements in the process or the development of the next generation of the process.
- ✓ **Regulatory requirement**

VALIDATION PROTOCOLS

Validation protocol contain two section:-

1.Procedure

2.Form

Specific protocols (SOP's) that provide detailed information on what is to be validated.

Validation Protocols consist of:

- A description of the process, equipment, or method to be validated.
- A description of the sampling procedure including the kind and number of samples.
- Acceptance criteria for test results.
- Schedule or criteria for revalidation.

VALIDATION MASTER PLAN

- Provides the roadmap for conducting validations.
- Establishes criticality of the process.
- Defines the validation approach.
- Documents rationale for decisions to “not validate”.
- Provides documented evidence of the validation
- Provides an easy to follow trail to locate relevant validation documents and test data.
- Establishes requirements for process changes.

VALIDATION SUMMERY REPORT

- VSR is a controlled document which lists all current validation documentation to demonstrate that processes are validated and specifies any revalidation requirements.
- Each VSR document number is referenced on the Process Validation Master Plan, for ease of document retrieval.
- The VSR contains:
  - Process title.
  - Applicable uncontrolled documentation.
  - List of all validation documentation.
  - Revalidation requirements.
  - Recurring validation requirements.

CONCLUSION

Validation

- A quality tool that makes lot of sense.
- A prevention based activity important part of quality building process.
- Expensive in the beginning later will "save the money back“.
- Risk-based assessment of what needs to be validated or verified.
- The process must be under control validation as such does not improve the process.

REFERENCE

- Robert Nash and Alfred Wachter, Marcel Decker, Pharmaceutical Process Validation, 3rd Ed. Edited by, 2003, pp.507-509.
- Syed Imtiaz Haider, Validation Standard Operating Procedures: A step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, St. Lucie Press, 2002.
- Sidney J. Willig.Marcel Decker, Good Manufacturing Practices for Pharmaceuticals: A Plan for Total Quality Control From Manufacturer to Consumer, 2000.
- M.N.Potdar,Pharmaceutical Qualitry Assurance, Nirali Prakashan,First Edition, pp.8.1-8.42
- Dr. Keyur B. Ahir, Khushboo D. Singh, Sushma P. Yadav, Hetal S. Patel, Chetan B. Poyahari, Overview of Validation and Basic Concepts of Process Validation ,Scholars Academic Journal of Pharmacy (SAJP) Sch. Acad. J. Pharm., 2014; 3(2): 178-190

THANK YOU