

Validation

Validation – General Concepts

What is Validation?

- Validation is a documented proof that a process, method, equipment, or system consistently produces results that meet predetermined specifications and quality standards.



- In **Scale-Up and Technology Transfer**, validation ensures that:
 - What worked on the lab scale also works in pilot and commercial scale
 - The product quality remains the same even after transferring to another site

Why Validation is Important

- Ensures product safety, quality, and efficacy
- Reduces batch failures during scale-up
- Required by regulatory authorities (FDA, WHO, GMP)
- Build confidence in manufacturing process
- Help in smooth technology transfer between sites

Key Principles of Validation

- Consistency** – Process should give same results every time
- Reproducibility** – Same results in different locations (important in tech transfer)
- Documentation** – Everything must be written and recorded
- Scientific Approach** – Based on data, not assumptions

Validation Lifecycle (Simple View)

1. **Design Stage** – Develop process at lab scale
2. **Qualification Stage** – Test equipment and systems
3. **Verification Stage** – Confirm process works in real production

Important Terms:

- **Process Validation:** Ensures manufacturing process works consistently
- **Qualification:** Ensures equipment/utilities are working properly
- **Revalidation:** Repeating validation after changes
- **Critical Quality Attributes (CQA):** Properties that affect product quality
- **Critical Process Parameters (CPP):** Process variables affecting CQAs

Stages of Validation Lifecycle:

1. Process Design (Development Stage)

- Define how product should be made
- Identify risks and critical parameters

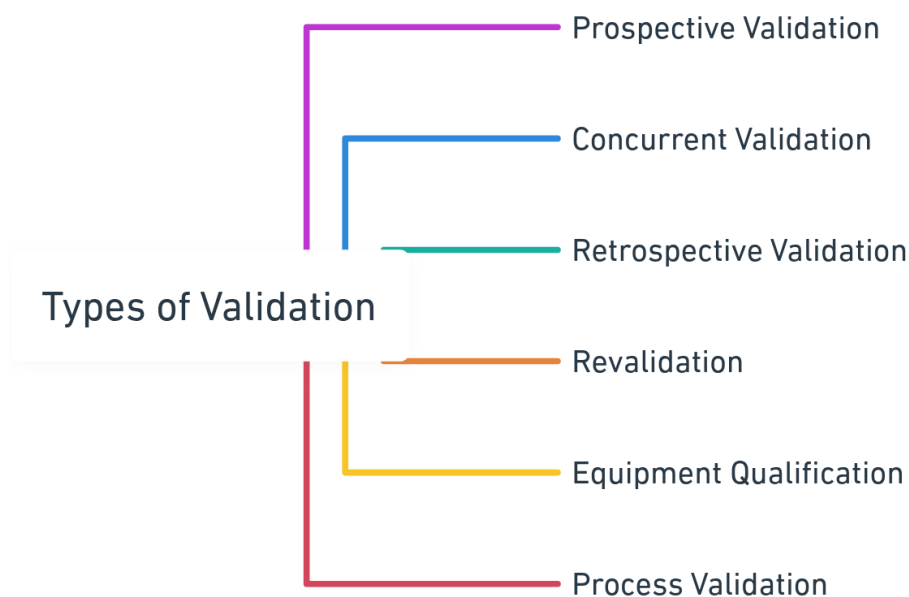
2. Process Qualification

- Demonstrate process works at commercial scale

3. Continued Process Verification

- Ongoing monitoring during routine production

Types of Validation



1. Prospective Validation

- Performed before commercial production begins
- Based on pilot batches or trial runs
- Most preferred during scale-up and new product development
- **Example:** Before launching a new tablet, 3 validation batches are manufactured and evaluated.

2. Concurrent Validation

- Performed during actual commercial production
- Data is collected from batches being manufactured and sold
- **Used when:**
 - There is urgent market demand
 - Limited batch production is possible
- **Example:** Monitoring quality parameters while producing batches for sale.

3. Retrospective Validation

- Based on historical data of previously produced batches
- Uses past batch records and results
- Not commonly used today due to lower reliability
- **Example:** Analyzing data from the last 20 batches to confirm consistency.

4. Revalidation

- Performed when significant changes occur in the process
- **Triggers include:**
 - Change in equipment
 - Change in raw materials or formulation
 - Change in process parameters
 - Site transfer (technology transfer)

5. Equipment Qualification (Part of Validation)

- Ensure that equipment is **suitable and performs correctly**.
- **Stages:**
 - **DQ (Design Qualification):** Equipment design is appropriate
 - **IQ (Installation Qualification):** Equipment is installed correctly
 - **OQ (Operational Qualification):** Equipment operates as intended
 - **PQ (Performance Qualification):** Equipment performs consistently under real conditions

6. Process Validation (Core in Scale-Up & Tech Transfer)

- Ensures that the manufacturing process consistently produces quality products.
- **Includes:**
 - **Process Design** – Define process and identify risks
 - **Process Qualification** – Verify performance at commercial scale
 - **Continued Process Verification** – Ongoing monitoring during production

Validation Procedures & Protocols

- A protocol is a **written plan** that explains **how validation will be performed**.

Contents of a Validation Protocol:

A. Title & Objective

- What is being validated and why

B. Scope

- Which product, process, or equipment

C. Responsibilities

- Who will perform, review, approve

D. Equipment & Materials

- List of machines, raw materials

E. Process Description

- Step-by-step manufacturing process

F. Critical Parameters

- Temperature, pressure, mixing time, etc.

G. Sampling Plan

- Where and how samples will be taken

H. Acceptance Criteria

- Limits for quality (e.g., assay 95–105%)

I. Testing Methods

- Analytical methods used

J. Number of Batches

- Usually 3 consecutive successful batches

K. Data Recording Method

- How results will be documented

L. Deviation Handling

- What to do if results fail

Validation Procedure (Step-by-Step)

1. Preparation

- Define process and parameters

2. Protocol Approval

- Approved by QA (Quality Assurance)

3. Execution

- Perform validation runs (usually 3 batches)

4. Data Collection

- Record all observations

5. Analysis

- Compare results with acceptance criteria

6. Report Preparation

- Final validation report

In Scale-Up & Tech Transfer:

- Protocol ensures same process is followed at new scale/site
- Helps in identifying process variability
- Ensures smooth transfer without quality loss

Validation Documentation

- Documentation is the **backbone of validation**.
- "If it is not documented, it is not done."

Types of Validation Documents



FREE PREVIEW

[Click here to visit our website](#)

PHARMACY PREMIUM NOTES

Complete subject and semesters are available on FirstHope app only.



[Scan or click here](#)

Click here to get the app



Available on Google Play

JOIN THE FIRSTHOPE COMMUNITY

Join our Telegram channel

Click here to join Telegram



[Scan or click here](#)

@FirstHopeNotes

Instagram

@firsthope.official

[Click here to follow >](#)

YouTube channel

FirstHope-Pharmacy / Live streams

[Click here to watch >](#)

WhatsApp channel

Follow FirstHope on WhatsApp

[Click here to join >](#)

FirstHope website

firsthopenotes.com

[Click here to visit >](#)

B.Pharm / D.Pharm / M.Pharm / Pharm.D

Preview notes. Complete subjects and semesters in the FirstHope app.