Validation

Dr. Anupriya Kapoor
Assistant Professor
School of Pharmaceutical Sciences,
CSJMU, Kanpur

What is Validation in Pharmaceutical Industry?

- Validation is a term that comes from the word “valid” which means “can be justified or defended”
- Validation is demonstrating and documenting that something does (or is) what it is supposed to do(or be)

- Validation is an activity that involve establishing documented evidence that the systems, equipments, instruments facilities and processes do what they purport to do based on a plan, on other ways stating that validation is systematic approach to gathering and analyzing sufficient data that will give reasonable assurance (documented evidence), based on scientific judgment, that a process, when operating within specified parameters, will consistently & continuously produce results within predetermined specifications

Definition of validation as per FDA

- “Establishing the documented evidence which provides a high degree of assurance that a specific process will consistently produce a product of predetermined specifications and quality attributes.”

Situations that need pharmaceutical validation

A validated process, formally approved is the one that demonstrates a high degree of assurance and also ensures manufacturing of a uniform batch that meets the required specifications. An adequate validation is beneficial to the manufacturer in many ways, and is important in following situations

- New process
- New equipment
- Change of process or equipment for any reason
- Process where the end product test is not satisfactory and fails to indicate the complete product quality

Situations that do not require revalidation

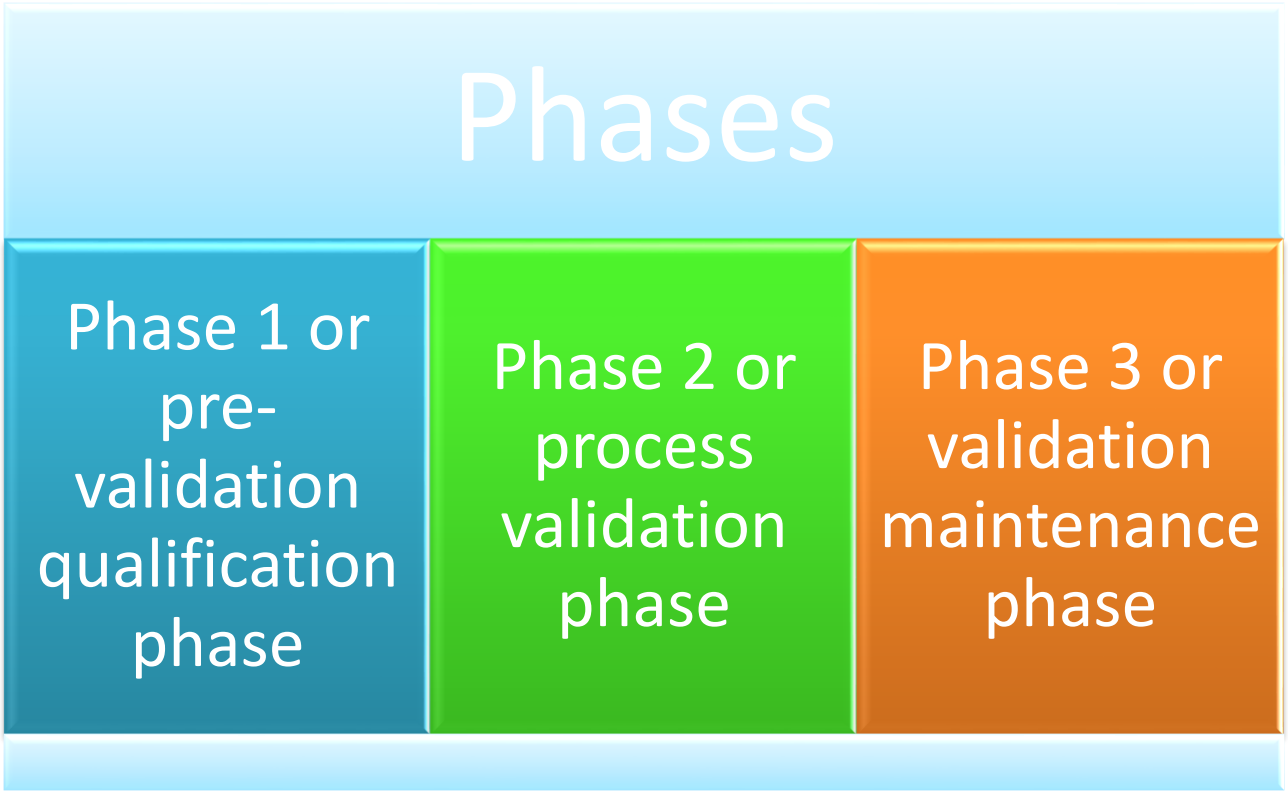
- Similar equipments are used
- Similar products have been produced
- The final product conforms to the in-process controls and final product specification

Advantages of validation

- Process understanding becomes simpler
- Prevention of problem becomes easier
- Risk of defect cost is decreased
- Risk of regulatory noncompliance is reduced
- Exhaustive in-process control is minimized
- Assures smooth running of process
- Decreases the risk of defects
- Decreases the risk of regulatory non-compliance

- Gives assurance of quality and safety
- The product meets the quality attributes and specifications

Phases of validation



Protocols of validation

- The purpose and scope of study
- The process equipment system should be clearly defined
- Installation and qualification requirements for new equipments
- Where existing equipments require up gradation proper justification should be given
- Stepwise detail statement of actions to be performed

- Statement on all test methodology to be employed
- Calibration of test is required
- References to any relevant SOP
- Acceptance criteria
- The personnel responsible for evaluating and certifying the acceptability of each stage in study and for final evaluation and certification