

301: Validation

Pharmaceutical and Biotechnology

(Course length: 2.0 Hours, 19 Graphics, 57 Pages, \$1050)

Purpose: To learn the terminology, types and stages of equipment, process and cleaning validation.

Objectives

1. Describe the purpose of validating equipment and processes
2. Explain the different steps of validation; IQ, OQ, PQ, and PV
3. Explain the goals of validation documentation
4. Describe a validation protocol
5. Describe the different types of validation
6. State the requirements for cleaning validation
7. List the documentation requirements for validation



Topics and Activities

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| <ol style="list-style-type: none"> 1. Introduction and GMP opener activity 2. Introduction <ul style="list-style-type: none"> ◆ Purpose ◆ Validation life cycle ◆ The business case for validation ◆ Significant dates ◆ Assessing validation need ◆ Deciding what get validated 3. Qualification <ul style="list-style-type: none"> ◆ Qualification versus validation ◆ Flow chart ◆ Design qualification ◆ Installation qualification ◆ Operation qualification ◆ Performance qualification 4. Qualification documentation <ul style="list-style-type: none"> ◆ Design qualification protocol ◆ Installation qualification protocol ◆ Operation qualification protocol | <ul style="list-style-type: none"> ◆ Performance qualification protocol ◆ Protocol supplement ◆ Protocol deviations <ol style="list-style-type: none"> 5. Validation <ul style="list-style-type: none"> ◆ Definitions ◆ Process validation ◆ State of control ◆ Batch control ◆ Worst case ◆ Edge of failure ◆ Proven acceptable range 6. Validation timing <ul style="list-style-type: none"> ◆ Prospective validation ◆ Concurrent validation ◆ Retrospective validation ◆ Re-validation ◆ Re-validation triggers 7. Cleaning validation <ul style="list-style-type: none"> ◆ Purpose ◆ Cleaning validation scope ◆ Objectives ◆ Acceptable levels of contamination ◆ Impurity accept limit | <ul style="list-style-type: none"> ◆ Evaluation of cleaning validation ◆ Case example ◆ <u>Activity: Validation</u> <ol style="list-style-type: none"> 8. Validation documentation <ul style="list-style-type: none"> Master plan Validation protocol Basic protocol Final report Report format Protocol supplement Summary and evaluation Protocol certification Documentation retention 9. Wrap up <ul style="list-style-type: none"> Common problems GMP quiz Company problems GMP closer activity GMP wrap up activity |
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