

## **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**

##### **1. Introduction and GMP opener activity**

##### **2. Introduction**

- ◆ Purpose
- ◆ Validation life cycle
- ◆ The business case for validation
- ◆ Significant dates
- ◆ Assessing validation need
- ◆ Deciding what get validated

##### **3. Qualification**

- ◆ Qualification versus validation
- ◆ Flow chart
- ◆ Design qualification
- ◆ Installation qualification
- ◆ Operation qualification
- ◆ Performance qualification

##### **4. Qualification documentation**

- ◆ Design qualification protocol
- ◆ Installation qualification protocol
- ◆ Operation qualification protocol

- ◆ Performance qualification protocol
- ◆ Protocol supplement
- ◆ Protocol deviations

##### **5. Validation**

- ◆ Definitions
- ◆ Process validation
- ◆ State of control
- ◆ Batch control
- ◆ Worst case
- ◆ Edge of failure
- ◆ Proven acceptable range

##### **6. Validation timing**

- ◆ Prospective validation
- ◆ Concurrent validation
- ◆ Retrospective validation
- ◆ Re-validation
- ◆ Re-validation triggers

##### **7. Cleaning validation**

- ◆ Purpose
- ◆ Cleaning validation scope
- ◆ Objectives
- ◆ Acceptable levels of contamination
- ◆ Impurity accept limit

- ◆ Evaluation of cleaning validation
- ◆ Case example
- ◆ Activity: Validation

##### **8. Validation documentation**

Master plan  
Validation protocol  
Basic protocol  
Final report  
Report format  
Protocol supplement  
Summary and evaluation  
Protocol certification  
Documentation retention

##### **9. Wrap up**

Common problems  
GMP quiz  
Company problems  
GMP closer activity  
GMP wrap up activity