Validation: The Three Stage Lifecycle

This seminar teaches the Three Stage Lifecycle for Process Validation. Students will learn how the three stages interact with each other. They will learn how planning and risk management during each stage can reduce costs and timelines in the other stages. It emphasizes the need for a clear understanding of the technology to provide inputs to validation protocols. The participants then learn how to write practical protocols. The class ends with a discussion of systems necessary to maintain the process in a validated state.

Who Should Attend: Medical Device, Pharmaceutical and Bio industry: Project managers, engineers, quality & production team members and business managers who need a basic introduction to validation concepts and design.

Class Length: 1½ day

Maximum Class Size: 20

Course Prerequisites: Participants must have a working knowledge of cGMP's.

Course Objectives: At the conclusion of the class a participant will have an understanding of the following:

- The Regulatory Requirements and draft guidelines that apply to validation
- The business case for validation
- Definition of critical process parameters / Acceptance Criteria
- How to tell when Stage 1 begins
- The User Requirements Specification
- How Process Design interacts with Process Qualification
- Process Characterization
- Definition & Assembly of a Validation Master Plan (VMP)
- Installation Qualification (IQ)
    - How to execute the IQ
    - IQ Acceptance Criteria
- Operational Qualification (OQ)
    - How to execute the Operational Qualification (OQ)
    - Operational Qualification (OQ) Acceptance Criteria
    - Operational Qualification (OQ) report
- Performance Qualification (PQ)
    - How to execute the Performance Qualification (PQ)
    - Performance Qualification (PQ) Acceptance Criteria
    - Performance Qualification (PQ) report
- What must be included in a Validation Final Report (VFR)
- Guidelines on sampling plans. How many samples are enough?
- Training requirements
- Parameter checks and balances to use after validation
    - Standards or knowns
    - Statistical Process Control (SPC)
    - Calibration and Preventive Maintenance
- Maintaining the process in a validated state

VALIDATION & COMPLIANCE INSTITUTE
537 Fort Dearborn St.
Dearborn, MI 48124
734-274-4680