



# Validation: The Three Stage Lifecycle

---

This seminar teaches the basics of validation. It focuses primarily on the large group of team members whose work is essential to a validated process, but who do not spend the majority of their time on validation. 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:** One 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
- Definitions of Protocols & SOP's
- Definition of critical validation parameters / Acceptance Criteria
- 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
- The SOP's which must be written and followed during a validation process
- What must be included in a Validation Final Report (VFR)
- Guidelines on sampling plans. How many samples are enough?
- How to track action items and establish accountability
- 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