Validation: an introduction to IQ, OQ and PQ.

This seminar teaches the basics of validation. The participants will learn how to write practical protocols that are compliant yet flexible enough to allow for real-world conditions. They will receive guidance to help answer the question, 'How much validation is good enough?' 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
- 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 state of validation

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