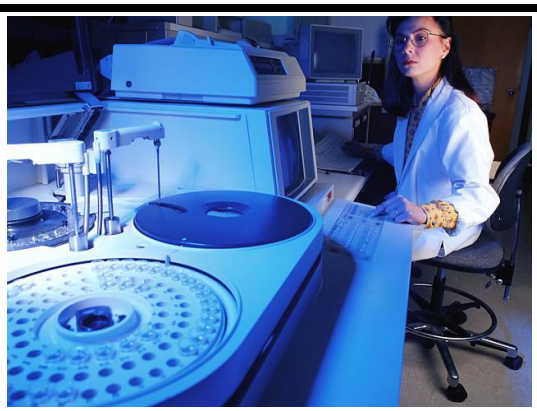
Validation: Analytical Methods



This seminar teaches the basics of analytical method 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 enough?' Participants will learn the procedures necessary for validation and how to execute protocols. The class ends with a discussion of systems necessary to maintain the process in a validated state.

Who Should Attend: 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 and Quality Control experience.

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 laboratory validation, ICH, USP, FDA
- How to write and execute Installation Qualifications
- How to write and execute Operational Qualifications
- How to write and execute Performance Qualifications: Specificity, Linearity, Accuracy, Precision, Robustness, Range, Detection Limit (LOD), Quantitation Limit (LOQ), Ruggedness, Selectivity, System Suitability
- How documents should written and retained
- How to use and store reference standards and laboratory control
- How statistics are used in validation design
- The SOP's that must be written and followed during a validation process, Discrepancies, Deviation Control, Change Control, Out of Specification Results, Failure Investigation, and the analytical method itself
- What must be included in a Validation Final Report (VFR)
- Training requirements
- Calibration and Preventive Maintenance
- Maintaining the process in a validated state

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