



Computerized Systems Validation

Course Objective: This course focuses on developing and implementing regulated computer systems with an appropriate level of documented evidence to satisfy FDA expectations. The course target deliverable document content and how to avoid rework and unnecessary expense through a proactive approach. The core elements of a satisfactory computer validation program will be emphasized.

Course Description: This course is designed to provide an overview of the various aspects of computer systems validation and related validation documents and to provide the basis for compliance and implementation. Also to be addressed are the rules, tools, and techniques to develop and implement a validation program or to validate a specific system. The course provides the principles for computer validation and offers a framework and the methodologies to conduct validation projects.

The emphasis is on the most recent rules and techniques focusing on the relevant regulations, the system life cycle including requirements, design/build, testing, qualifications and maintenance, 21 CFR Part 11 Electronic Records and Electronic Signatures and the journey this regulation has taken. Vendor audits, acquired and developed systems, retrospective validation, validation master plan, the validation project, risk assessment and management, SOPs, requirements documentation, the traceability matrix, and related FDA Guidance documents are discussed.

Course Outline:

- Computerized Systems Validation Overview
- GAMP, The System Life Cycle and Validation Strategies
- 21 CFR Part 11 – Risk based approach
- Validation Plan and Project Management
- Vendor Audit
- Qualifications, IQ/OQ/PQ
- Case Studies - Validation Requirements for :
 - Applicative Software
 - Automated Spreadsheet Calculation Templates
 - MRP and ERP Systems

- Computerized Equipment
- Automated Control and Monitoring Systems
- Computer Network Qualification