Computerized Software Validation (CSV) Course Syllabus Rev.2

Day 1

Module	Topics
Session Kick-Off	• Introductions • Course objectives and expectations
Session 1	• Examples from Warning Letters Regarding CSV • Detailed review of the 21 CFR part 11 requirements: • Access management • Password management • Electronic Records and Signature (ERES) requirements • Audit trail • Session Q&A
Session 2	• IEC 62304- software requirements overview • Software Design Specification (SDS) and FDA General practice software validation (GPSV) guidance emphasis on what should be tested • EU GMP Annex 11- requirements detailed overview • Emphasis on Audit trail tests+ examples • Audit trail Review
Session Wrap-Up	• Feedback and Session Q&A • Reflection for next session

Day 2

Module	Topics
Session Kick-Off	• Reflections from last session
Session 3	• Data integrity: ALCOA + definitions and requirements overview • Software Risk Assessment and traceability to software requirements - types of risks related to software that shall be mitigated by software validation • Software Vs Hardware emphasizes • FDA Guidance-Computer-Software-Assurance (CSA) • Critical Thinking & Software Assurance • FDA Validation Paradigm
Session 4	• Software Requirement structure • Commercial Off the Shelf Software (COTS) and Black Box testing • White Box -code test types overview • Session Q&A
Session Wrap-Up	• Feedback and Session Q&A

Day 3	
Module	Topics
Session Kick-Off	• Reflections from last session

Session 5	• Detailed GAMP5 Software Categories and V shape models
	• Examples from CSV IQ, OQ and PQ protocols
	• Software Test Types overview
	  • Load test
	  • Backup and restore
	  • Regression Analysis & Testing
	  • Negative VS Positive tests
	• Deviation Handling and examples
	• Spreadsheet (Excel) Validation- what shall be tested?
	• Session Q&A

Session 6	• IEC 62304- software requirements overview • Software Design Specification (SDS) and FDA General practice software validation (GPSV) guidance emphasis on what should be tested • EU GMP Annex 11- requirements detailed overview • Emphasis on Audit trail tests+ examples • Audit trail Review
Session Wrap-Up	• Feedback and Session Q&A