

Seminar Computerized Systems Validation (CSV)

Learning content

- Definitions of terms
- Regulatory requirements
- CSV procedure
- CSV validation evaluation
- CSV and risk management
- Validation plan
- Test specification
- Validation implementation and documentation
- Best practices

Schedule

Time	Content
09:00 am - 09:15 am	Welcome and question about expectations
09:15 am - 10:00 am	Introduction, definitions of terms (incl. IQ, OQ, PQ), examples of systems, overview of process
10:00 am - 10:30 am	Regulatory requirements for the CSV
15 min break	
10:45 am - 11:15 am	Determine intended use, process and software requirements
11:15 am - 12:00 pm	Analyze risks, classify systems, determine scope of validation
12:00 pm - 12:15 pm	Summary, recap, Q&A
60 min lunch break	
01:15 pm - 02:00 pm	Select test methods and tools
02:00 pm - 02:45 pm	Create validation plan and test specification
15 min break	
03:00 pm - 03:30 pm	Perform and document validation, Good Documentation Practice (GDP)
03:30 pm - 03:45 pm	Change systems, decide on re-validation

Time	Content
03:45 pm - 04:15 pm	Roles and responsibilities, standard operating procedure for the CSV
04:15 pm - 05:00 pm	Overview of best practice guides e.g., IEC 80002-2, GAMP
05:00 pm - 05:15 pm	Summary, recap, Q&A