| Day 1 | Topics |
|---|---|
| | • Introductions |
| | • Course objectives and expectations |
| | • Basic Concepts in CSV |
| | • CSV vs CSA – Is there a difference? |
| | • Guidelines & Regulations background |
| | • Which Regulations and Standards apply to CSV? |
| | • 21 CFR part 11 – high level overview |
| | • EU GMP Annex 11- high level overview |
| | • Data Governance and Data Integrity |
| | • Data Integrity vs Data Quality |
| | • Risk Assessment from a Data standpoint |
| | • What is Critical-Thinking and Risk-Based approaches? |
| | • GAMP5 and System Categorization and the Validation Approach |
| | • Qualification vs Validation |
| | • Data integrity Compliance |
| | • IEC 62304- software requirements overview |
| **Day 1 Wrap-Up** | • Feedback and Session Q&A<br>• Reflection for next session |

| Day 2 | Topics |
| --- | --- |
| | • Reflections from last session |
| | • Computerized Systems Life Cycle and the added value of CSA |
| | • CSV Deliverables per GAMP5 System Categorization |
| | • Risk Assessment from a Data standpoint – The "Save As" option |
| | • Identifying critical systems and the validation approach. |
| | • Validation Documentation/Deliverables explained |
| | • Functional Risk Assessment vs Data Risk Assessment |
| | • Spreadsheet (Excel) Validation- what shall be tested? |
| **Day 2 Wrap-Up** | • Feedback and Session Q&A<br>• Reflection for next session |

| Day 3 | Topics |
|-------|--------|
| | • Reflections from last session |
| | • Emerging Technologies and CSV |
| |     ▪ Cloud-Based Systems |
| |     ▪ SaaS |
| |     ▪ Impact of AI and machine learning on Validation |
| | • Case Studies and Warning Letters |
| **Day 3 Wrap-Up** | • Feedback and Session Q&A |
| | • Reflection for next session |