COMPLIANCE TRAININGS

2-Day In-Person Seminar

CSV, Part 11 Compliance for Software Validation and SaaS/Cloud

FDA

May 10 - 11, 2018

Bangalore, India

WHY YOU SHOULD ATTEND

This latest 2-day Seminar on **Computer Systems Validation** will explore proven techniques for reducing costs associated with implementing, using, & maintaining computer systems in regulated environments. Many companies are outsourcing IT resources and getting involved with Software as a Service (SaaS) and cloud computing. These vendors are not regulated and therefore regulated companies must ensure compliance for both infrastructure qualification and computer system validation. It is the regulated company that wants to avoid FDA form 483s and warning letters. The seminar is intended for regulated companies, software vendors, and SaaS/Cloud providers. The instructor will address the latest computer system industry standards for data security, data transfer, audit trails, electronic records and signatures, software validation, and computer system validation.

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WORKSHOP OBJECTIVE

✓Understand what is expected in Part 11 and Annex 11 inspections	✓ "Right size" change control methods that allows quick and safe system evolution
✓Avoid 483 and Warning Letters	✓ Minimize the validation documentation
✓Learn how to buy COTS software and qualify vendors.	✓ Reduce costs without increasing regulatory or business risk
✓Implement a computer system using risk-based validation	✓ Avoid Data Integrity Issues
✓Gain maximum productivity and reduce cost	✓ Write test cases that trace to elements of risk management
✓Requirements for local, SaaS, and cloud hosting	✓ Protect intellectual property and keep electronic reco safe
✓How to select resources and manage validation projects	

WHO MUST ATTEND

A must attend seminar for professionals in Pharmaceuticals, QC Laboratories, Manufacturers of drug substances (APIs), Finished Products, Contract Laboratories, CROs, Medical Device & Biotech companies, IT professionals working in the health care, clinical trial, biopharmaceutical, and medical device sectors and Suppliers of Computer Systems. It is essential for software vendors, auditors, and quality staff involved in GxP applications.

DEPARTMENTS

- Quality Control & Quality Assurance
- Research and Development
- Laboratory
- Regulatory Compliance
- IT/IS & Software Departments
- Validation
- Production & Manufacturing
- Documentation
- Training Departments

PROFESSIONALS

- Managers and Supervisors
- Senior Managers and Team Leaders
- Directors, VP's, CxO's, General Managers
- Analytical Chemists
- Validation Specialists
- Laboratory Managers and Supervisors
- Regulatory Affairs Managers
- Documentation Specialists & Analysts
- Consultants and Systems Administrators

THIS WORKSHOP INCLUDES

2-DAY PROGRAM	BONUS	SUBSCRIPTION PLANS ON
✓ Training & Discussions	✓ Presentation Handouts	✓ Our vast library of online training courses
✓ Case Studies	✓ Brochure & Trainings Catalog	✓ Our future seminars & workshops
✓ Lunch and High Tea	✓ Participation Certificates	✓ On-Site Training

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AGENDA

DAY 1

Registration Process: 8:30 AM – 9:00 AM
Session Start Time: 9:00 AM

Regulatory Requirements and Expectations

- ✓ US FDA and other Regulatory Guidance
- ✓ How the regulations help your company to be successful?
- ✓ Which data and systems are subject to Part 11

21 CFR Part 11

- ✓ What Part 11 means to you, not just what it says in the regulations
- ✓ Annex 11 Latest Updates
- ✓ Avoid 483's and Warning Letters
- ✓ SOPs, software product features, and validation documentation
- ✓ How SaaS/cloud computing changes qualification and validation
- ✓ Electronic signatures, digital pens, and biometric signatures
- ✓ Using validation documents

Data Integrity

- ✓ Understanding Data Integrity and Security
- ✓ Most frequent data integrity issues & their impact
- ✓ Knowing the occurrence of data integrity failures
- ✓ Data Backup, Restoration, Archival & Retrieval, Retention
- ✓ ALCOA
- ✓ Maintenance Qualification
- ✓ Data integrity Inspections – How FDA & other Regulatory Authorities Inspect

Computer Systems Validation

- ✓ Understanding CSV & Validation Team
- ✓ Risk-Based System Validation per GAMP5
- ✓ Laboratory Instrument Validation
- ✓ GxP Assessment
- ✓ Patch Management
- ✓ Validation & Revalidation
- ✓ Qualification vs Validation

Q&A Session
Networking and Close: 5 PM – 5.30 PM

DAY 2

Session Start Time: 9:00 AM

Commercial Off-the-Shelf CSV

- ✓ Documents the FDA expects to audit
- ✓ How to use the risk-based validation approach to lower costs
- ✓ How to link requirements, specifications, risk management, and testing
- ✓ SOPs required for the IT infrastructure
- ✓ How to Write Requirements
- ✓ How to Write Specifications
- ✓ How to Write Protocols

Hazard Analysis / Risk Assessment - Exercise

- ✓ Understanding Risk Assessment
- ✓ Regulatory Expectations
- ✓ Step-by-step instructions for performing and documenting a risk assessment
- ✓ How to use the results to reduce validation documentation
- ✓ Regulatory Expectations

Software Testing

- ✓ Reduce testing by writing test cases
- ✓ How to write efficient test cases

System Change Control

- ✓ How to manage a validated system with minimal documentation

Purchasing COTS Software

- ✓ How to purchase COTS software and evaluate software vendors

Cost Reduction Without Increasing Regulatory or Business Risk

- ✓ How to save money
- ✓ How to increase quality
- ✓ How to increase compliance with less documentation

Q&A Session, Certification and Close: 5.30 PM – 6 PM

CONTACT DETAILS

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