COMPLIANCE TRAININGS

2-Day In-Person Seminar

Computer System Validation (CSV), Data Integrity and 21 CFR Part 11 Compliance

FDA

April 19 - 20, 2018 Mumbai, India

LEARNING OBJECTIVES

- ✓ Role of FDA
- ✓ CSV Points
- ✓ Why Validation? Its Benefits
- ✓ GAMP 5
- ✓ 21 CFR Part 11 Compliance
- ✓ Annex 11
- ✓ Data Integrity
- ✓ Risk Assessment
- ✓ Recent Learnings & Avoiding Warning Letters
- ✓ CSV Deliverables
- ✓ SOPs and Best Practices
- ✓ CASE STUDIES ….and More

SEMINAR INCLUDES

- ✓ 2-day workshop & discussions
- ✓ Case Studies
- ✓ Lunch and High Tea

Bonus:

- ✓ Presentation Handouts
- ✓ Brochure & Trainings Catalog
- ✓ Participation Certificates

Special price on:

- ✓ Future purchase of our online training courses
- ✓ Our future seminars & workshops
- ✓ Networking with industry's top notch professionals

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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. The FDA performs GxP & Part 11 inspections, with an updated Annex 11 regulation, & companies must update their systems and processes to maintain compliance.

There is no doubt that data integrity is the current and future inspection focus of all regulatory health care agencies. More than 60% inspection reports such as 483's and Warning Letters quote data integrity as deviations from GxP regulations. Only way to control and avoid warning letters is by receiving effective Training. Mr. Kalpesh Vaghela's extensive years of experience in Data Integrity can help your team to better understand & could help reduce your vulnerability of getting 483's and warning letters.

Our instructor will use examples and real life case studies to better illustrate the application of the techniques for any validation project. Using recent warning letters as examples, this seminar will demonstrate how current Part 11 requirements will be met. With effective implementation of learnings from this seminar, you can avoid warning letters, reduce costs, improve quality, increase compliance with less documentation. The course not only ensures a full understanding of the regulations and guidelines for raw data and other records but also develop inspection ready documentation. Interactive exercises will be dispersed into and between the presentations.

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, and Suppliers of Computer Systems.

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

AGENDA

DAY 1

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

Validation

- ✓ Understanding Validation
- ✓ V Module
- ✓ GAMP 4 vs GAMP 5
- ✓ Validation Master Plan (VMP)
- ✓ Supplier Agreement and Vendor Agreement Report
- ✓ Understanding GAMP 5

21 CFR Part 11

- ✓ Important Observations
- ✓ Annex 11
- ✓ Legacy System, Open and Close System
- ✓ Electronic Records & Hybrid Systems
- ✓ Electronic Signatures, Digital & Biometric Signatures
- ✓ Black Box and White Box
- ✓ Learning from Recent Warning Letters related to Part 11
- ✓ 21 CFR Part 11 compliance of a computer system

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
- ✓ Computerized Systems for Data Integrity

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

DAY 2

Session Start Time: 9:00 AM

Computer System Validation

- ✓ Understanding CSV & CSV as per GAMP 5: It's Easy!! Really!!
- ✓ CSV Components and Deliverables
- ✓ User Requirement Specification (URS), Functional Specifications (FS) & Design Specification (DS)
- ✓ TRM, SR, IRA and FRA
- ✓ Risk Based Approach for CSV

Risk Assessment

- ✓ Understanding Risk Assessment
- ✓ Risk-Based Validation approach to lower costs
- ✓ Regulatory Expectations
- ✓ Examples and Good Practices
- ✓ Benefits of larger project

CSV - Step-by-Step

- ✓ Formation of Validation Team
- ✓ Writing Effective URS
- ✓ Deliverable SRS and GxP Assessment
- ✓ Qualification (IQ, OQ, PQ and DQ) and Traceability Matrix
- ✓ Effective Installation and Testing
- ✓ Risk Based Approach for CSV per GAMP Category
- ✓ Effective SOPs, Verification and Testing
- ✓ Validation & Revalidation
- ✓ Qualification vs Validation

CASE STUDIES

- ✓ Avoiding Warning Letters and Reduce Cost

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

CONTACT DETAILS

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