COMPLIANCE TRAININGS

2 Day In-Person Seminar on

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

New Delhi, India | **November 16th - 17th, 2017**

SEMINAR INCLUDES

- ✓ 2-day workshop and training
- ✓ Learning Objectives
- ✓ Interactive sessions with the expert
- ✓ Case Studies
- ✓ Chalk and Talk Training
- ✓ Lunch and High Tea

Seminar Materials:

- ✓ Presentation Handout, ID Tag, Brochure, Trainings Catalog, notepad and pen
- ✓ Brochure & Trainings Catalog
- ✓ Participation Certificates
- ✓ ID Tag, notepad and pen
- ✓ Post event email assistance to your queries

Special price on:

- ✓ Future purchase of our online training courses
- ✓ Consulting or On-site expert services
- ✓ Our future seminars & workshops
- ✓ Networking with industry's top notch professionals

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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*

COURSE DESCRIPTION

This new 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.

Majority of inspection reports such as 483's and Warning Letters quote issues with 21 CFR Part 11 and data integrity as deviations from GxP regulations. Only way to control and avoid warning letters is by receiving effective Training. Our presenter's extensive years of experience in the field of third party audit can help your team to better understand & could help reduce your vulnerability of getting 483's and warning letters, by great amount.

You will get a full understanding of how to perform Risk Assessment as part of the step-by-step risk-based approach to computer system validation. This distinct approach will help minimize project time. You can ensure compliance with QA, FDA, and clients. A central element of this course will be an explanation of the GAMP approach to 21 CFR Part 11 compliance, as well as compliance with other international regulations covering ERES. The GAMP Guide provides timely and much needed direction on meeting current regulatory expectations for compliant ERES. You will learn how to use risk management to ensure compliance of regulated ERES.

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 WILL BENEFIT

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



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AGENDA

DAY 1:

Registration Process: 8:30 AM – 9:00 AM

Session Start Time: 9:00 AM (Welcome and Introduction)

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
- ✓ Electronic signatures, digital pens, and biometric signatures
- ✓ 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
- ✓ Data Backup, Restoration, Archival & Retrieval, Retention
- ✓ ALCOA
- ✓ Data integrity Inspections – How FDA & other Regulatory Authorities Inspect
- ✓ Computerized Systems for Data Integrity

Q&A Session

Networking and Close: 5.30 PM – 6 PM

DAY 2:

Session Start Time: 9:00 AM

Computer System Validation

- ✓ Understanding CSV: It's Easy!! Really!!
- ✓ CSV Components and Deliverables
- ✓ User Requirement Specification (URS), Functional Specifications (FS) & Design Specification (DS)
- ✓ TRM, SR, IRA and FRA

Risk Assessment

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

CSV - Detailed Study

- ✓ Qualification (IQ, OQ, PQ and DQ) and Traceability Matrix
- ✓ Deliverable SRS and GxP Assessment
- ✓ Risk Based Approach for CSV & GAMP Category
- ✓ Effective SOPs, Verification and Testing
- ✓ Qualification vs Validation

CASE STUDIES

- ✓ Avoiding Warning Letters and Reduce Cost

Final Q&A Session

Certification

Networking and Close: 6 PM – 6.30 PM

CONTACT US FOR MORE INFO ON THIS SEMINAR

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