COMPLIANCE TRAININGS

2-Day In-Person Seminar

# GMP for Quality Control Laboratories and FDA Audit Preparation

## February 22 - 23, 2018 Hyderabad, India

### LEARNING OBJECTIVES

- ✓ FDA, EU, WHO, PIC/S, India GLP Regulations
- ✓ 21 CFR part 11 and EU Annex 11
- ✓ FDA 483s and Warning Letters Observations
- ✓ Validation Master Plan
- ✓ SOPs and Best Practices
- ✓ Equipment Calibration and Qualification
- ✓ Systems Validation
- ✓ Analytical Method Validation
- ✓ OOS, OOT and OOC
- ✓ Laboratory Data integrity
- ✓ FDA Audit Preparation
- ✓ CASE STUDIES .... and More

### SEMINAR INCLUDES

- ✓ 2-day workshop
- ✓ 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

COMPLIANCE TRAININGS I 861, Peripheral Road, Koramangala, Bangalore - 560095
info@compliancetrainings.com I +91-(0)80-4170-0521

## WHY YOU SHOULD ATTEND

The 2-day workshop on GMP for Quality Control Laboratories and FDA Audit Preparation, is designed to provide an in-depth understanding of the regulatory background and guides attendees through all critical areas of GMP compliance. You will gather a thorough awareness of latest trends and updates with respect to USFDA, EU, WHO and PIC/S (Pharmaceutical Inspection Co-operation Scheme) and Indian GLP Schedule L1 compliance and guideline requirements. This course will also provide examples to develop inspection ready documentation.

Quality control and related contract laboratories are considered high risk because after testing and approval drug products and APIs are released to the market without further check. That's the reason why FDA and other agencies put highest emphasis on inspections of QC laboratories. Even though GMP regulations have been in place since long time, the large number of QC related 483's and warning letters demonstrate that companies have problems with implementation.

On completion of this course, the participants shall be well versed with the global Quality control laboratory compliance requirements, inspection trends as well as strategies and best practices for maintaining regulatory compliant GLP standards to ensure consistent Quality Attributes and bench marking Quality Metrics in the Pharmaceutical Quality Control Laboratories.

Practical examples and interactive exercises will be dispersed into and between the presentations. Here the experts will discuss case studies and create a platform to resolve QC laboratories' day-to-day issues like Documentations, Investigations (OOS, OOT, OOC) and validation compliance checklists to ensure you are well prepared for your next audit.

## WHO MUST ATTEND

A must attend seminar for professionals in Pharmaceuticals, QC Laboratories, Manufacturers of drug substances (APIs), Oral Solid Dosage Form, Clinical Research Organizations, Contract Manufacturing Organizations, Contract Laboratories, and Biopharma companies.

### DEPARTMENTS

- Quality Control
- Quality Assurance & Testing
- Research and Development
- Laboratory
- Manufacturing
- Production
- Regulatory Compliance
- Validation
- Preclinical Development
- Documentation
- Training Departments

### PROFESSIONALS

- Managers & Supervisors
- Department Heads
- Senior Managers
- Team Leaders
- Executives and Senior Executives
- General Managers
- Engineers
- Design Engineers
- Plant Managers
- Laboratory Managers and Supervisors
- Regulatory Affairs Managers
- Documentation Specialists & Analysts

# AGENDA

## DAY 1

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

### Regulatory Requirements and Expectations

- ✓ FDA Regulations and Requirements (FDA 21 CFR Part 211)
- ✓ EU, PIC/S QC Lab Requirements
- ✓ WHO, India GLP Schedule L1
- ✓ 21 CFR part 11 and EU Annex 11
- ✓ Frequently cited FDA 483s and Warning Letters on QC
- ✓ Warning Letter Observations

### Planning for quality and GMP compliance

- ✓ Validation Master Plan
- ✓ Scope, objectives and key elements of the master plan
- ✓ Developing Key SOP's for QC Laboratory
- ✓ Inspection ready documentation
- ✓ Planning for efficiency cost-effectiveness

### Equipment Calibration and Qualification

- ✓ Regulatory Requirements
- ✓ USP for instrument qualification
- ✓ Qualification Steps (DQ, IQ, OQ, PQ)
- ✓ Developing calibration and qualification protocols

### Change Control for QC Adherence

- ✓ Preventive maintenance and documentation
- ✓ Planned and unplanned changes
- ✓ Changing hardware, firmware, documentation
- ✓ Requalification

### Laboratory Computer Systems Validation

- ✓ A Risk based Approach
- ✓ Software and instrument Related Systems validation
- ✓ Integration the GAMP® guide with USP
- ✓ Periodic evaluation to reduce revalidation efforts
- ✓ Revalidation

Q&A Session
Networking and Close: 4.30 PM – 5 PM

## DAY 2

Session Start Time: 9:00 AM

### Analytical Method Validation

- ✓ Key requirements as per USP, ICH and EP/BP/JP/WHO Intl
- ✓ USFDA latest Analytical Method Validation
- ✓ Troubleshooting during AMV
- ✓ AMV a model protocol and report -key requirements
- ✓ AMV method transfer and Method Verification requirements

### Sample Testing - Preparation, Conduct and Documentation

- ✓ Preparing the equipment
- ✓ Setting specifications and acceptance criteria
- ✓ Documentation of test results
- ✓ Review and approval

### OOS, OOT and OOC Test Results

- ✓ Handling Out of Specification (OOS) test results with case studies
- ✓ Handling Out of Trend (OOT) test results with case studies
- ✓ Handling Out of Control (OOC) test results with case studies

### Laboratory Data Integrity

- ✓ FDA Part 11 and EU-PIC/S Annex 11 Requirements
- ✓ Understanding Raw Data
- ✓ Electronic Audit Trail, Archival and Retrieval

### GMP Compliance

- ✓ Regulatory requirements
- ✓ Effective compliance
- ✓ Training Needs and Documentation

### Audits and FDA Inspections

- ✓ Internal Audits and scheduling
- ✓ FDA Inspections as model for laboratory audits
- ✓ Responding to Typical inspectional/audit deviation
- ✓ How to avoid FDA 483s and warning letters

Q&A Session, Certification and Close: 5 PM – 5.30 PM