COMPLIANCE TRAININGS

2-Day In-Person Seminar

Good Laboratory Practices (GLP)
– Current Global Trends and Strategies for Implementation

FDA

June 14 - 15, 2018 Hyderabad, India

LEARNING OBJECTIVES

- GLP Regulations
- 21 CFR part 58
- ISO 17025:2017
- SOPs and Best Practices
- Instrument Calibration & Qualification
- Control of Standards
- OOS, OOT and LIRs
- Impurity Profiling of Drugs
- Analytical Method Validation
- GLP Inspection Observations
- Data Integrity
- Quality Metrics .... 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

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

WHY YOU SHOULD ATTEND

This two-day workshop on '**Good Laboratory Practices**' is an important element of GMP in pharmaceutical manufacturing and a regulatory compliance requirement. Accurate, consistent and reliable analytical results are crucial for assessing the quality of drug substances, drug products and other pharmaceutical materials. Very high level of knowledge & discipline is required in the QC laboratory to achieve this objective. During the past several years Integrity of laboratory data in Indian pharmaceutical companies, specifically electronic records and data are in the focus by international regulatory agencies. The work shop has been designed to cover various aspects of laboratory activities and disciplines in line with the expectations of international regulatory agencies and ICH guidance documents to ensure data reliability and compliance to regulations.

The workshop will provide an in-depth understanding of various elements of GLP as applied to chemical analysis in a typical pharmaceutical QC / AR&D laboratory. The discussion will focus on validation of key analytical methods like chromatographic method, impurity profiling of actives, stability study program as well as means of achieving adequate control of electronic data along with other laboratory issues. The discussion will also cover current concerns of FDA with regard to integrity of electronic data in the laboratory and strategies to address these regulatory concerns.

KEY TAKEWAY:

The participants will learn latest concepts of GLP and expectations of international regulatory agencies/ ICH guidance documents as well as current regulatory concerns on data integrity issues. The workshop will enable the participants to frame a strategy to address these regulatory concerns while establishing a laboratory system to provide assurance on the accuracy and reliability of analytical data.

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 Pharma-Chem companies.

DEPARTMENTS

- Quality Control
- Quality Assurance & Testing
- Research and Development
- Laboratory
- Manufacturing
- Production
- Regulatory Compliance
- Validation
- Preclinical Development
- Documentation
- Technology Transfer
- 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
- ✓ Evolution of pharmaceutical laboratory regulations
- ✓ 21 CFR part 58 & OECD guideline on GLP
- ✓ ISO 17025:2017 & accreditation

General Laboratory Controls
- ✓ Organisation & Management
- ✓ Specifications & Certificate of analysis
- ✓ Laboratory environment
- ✓ Documents, records & SOPs
- ✓ Traceability
- ✓ Sampling & Testing program

Instrument Calibration and Qualification
- ✓ Performance verification
- ✓ Traceability to national & international standards
- ✓ Frequency of calibration & monitoring
- ✓ Levels of Instruments qualification
- ✓ Analyst qualification

Control of standards, reagents & solutions
- ✓ Primary and secondary standards
- ✓ Reference & Working standards
- ✓ Shelf life, re-standardisation/requalification periods

Handling of OOS investigations/OOTs/LIRs
- ✓ Diagnostic testing
- ✓ Hypothesis testing
- ✓ Manufacturing investigations
- ✓ Tools for root cause identification
- ✓ Current regulatory concerns
- ✓ Cause of human errors
- ✓ Incidence handling and reporting

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

DAY 2

Session Start Time: 9:00 AM

Impurity Profiling of Drug Substances and Drug Products
- ✓ Process related impurities
- ✓ Residual solvents
- ✓ Genotoxic impurities
- ✓ Degradation impurities
- ✓ Defining limits

Analytical Method Validation
- ✓ Selection of validation parameters
- ✓ Validation of Chromatographic methods
- ✓ Protocols and reports
- ✓ Impact of method changes

GLP Inspection Observations
- ✓ Best Practices Before, During & After FDA GLP Inspection
- ✓ Most Common Deficiencies - Case Studies

Overcoming Data Integrity Issues
- ✓ Regulatory observations
- ✓ ALCOA evaluation of data
- ✓ Control of electronic records
- ✓ FDA /MHRA guidance on data integrity & concerns
- ✓ Industry case study: Investigation of electronic records
- ✓ Remedial actions & quality culture

Prevention of Human Errors
- ✓ Identifying Human Errors
- ✓ What conditions provoke human error
- ✓ Human Error Prevention Techniques

Quality Metrics
- ✓ Current FDA thinking on quality Metrics data
- ✓ How these observations may impact your organisation

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

CONTACT DETAILS

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