COMPLIANCE TRAININGS

2 Day In-Person Seminar on

Pharmaceutical Validation - Latest Global Regulations and Trends to Stay Compliant

Hyderabad, India | **December 7th - 8th, 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 Handouts
✓ 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

- ✓ FDA, ICH and EU Regulations
- ✓ Process Validation
- ✓ Validation Master Plan
- ✓ Equipment Qualitfication
- ✓ Risk Management Tools and Techniques
- ✓ Process Design and Development
- ✓ Technology Transfer Methodolgy
- ✓ Continuous Process Verification
- ✓ Analytical Method Validation
- ✓ Cleaning Validation
- ✓ SOPs and Best Practices
- ✓ CASE STUDIES ….*and More*

COURSE DESCRIPTION

This new 2-day Seminar on Pharmaceutical Validation - Latest Global Regulations and Trends to Stay Compliant, is designed to provide an in-depth understanding of the concept of pharmaceutical validations based on the current FDA, EU and ICH guidance documents as well as learnings from the pharmaceutical industry. Special emphasis will be laid on practical approach and simple illustrative examples from the industry for judicious and effective implementation.

A successful validation program depends on proper planning & execution through protocols. Preparation of a 'Validation Master Plan' and 'Validation Protocol' as well as types of records required to demonstrate successful validation will also be presented. This program will cover issues specific to both APIs and Oral Solid Dosage forms and is designed to focus on implementation in work place.

This approach is expected to bring in an element of robustness into the manufacturing process and quality system. Risk management and statistical tools are being used in leading pharmaceutical industry worldwide and is recommended by regulatory agencies in order to gain high level of confidence in the quality of drugs as well as to achieve continuous improvement.

The participants will be exposed to the latest concepts and thinking of international regulatory agencies on validation of manufacturing process, analytical as well as cleaning methods applicable in API & Oral Solid Dosage forms manufacturing. based on assessed risk. The workshop will also include typical examples from the industry and the participants will be able to execute validations in a judicious manner.

WHO WILL BENEFIT

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

DEPARTMENTS:

- ✓ Quality Control & Quality Assurance
- ✓ Research and Development
- ✓ Production & Manufacturing
- ✓ Regulatory Compliance
- ✓ Validation
- ✓ Technology Transfer
- ✓ Laboratory
- ✓ Documentation
- ✓ Training Departments

PROFESSIONALS:

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

www.ComplianceTrainings.in

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AGENDA

DAY 1:

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

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

Regulatory Requirements and Expectations

- ✓ US FDA and the EU Draft Guidance
- ✓ ICH Guidelines
- ✓ Regulatory Expectations

Management of Documents and Qualification

- ✓ Validation Policy
- ✓ Validation Master Plan (VMP)
- ✓ Documents Equipment Qualification
- ✓ Effective SOPs
- ✓ Qualification Phases, IQ, OQ, PQ, DQ
- ✓ Qualification vs. Validation

Process Validation

- ✓ Understanding Process Validation
- ✓ Process Designing
- ✓ Developing a Control Strategy
- ✓ Quality Life Cycles Approach Concept
- ✓ Common Mistakes in Process Validation

Risk Management Tools and Techniques

- ✓ Risk-Based Approach for Pharmaceutical Validation
- ✓ Practical Risk Management Tools and Techniques
- ✓ Critical Issues and How to Overcome Them

Approaches to Process Design

- ✓ Process Development
- ✓ How to use Quality by Design (QbD) strategies to your advantage
- ✓ Technology Transfer Methodology
- ✓ Traditional and Design Space Approaches
- ✓ Regulatory Expectations
- ✓ Facility Qualification - ASTM E 2500

Q&A Session

Networking and Close: 5.30 PM – 6 PM

DAY 2:

Session Start Time: 9:00 AM

Process Qualification & Continuous Process Verification

- ✓ Understanding the Differences
- ✓ Effective Continuous Monitoring
- ✓ Strategies and tools to execute the 2nd and 3rd stages of Process Validation
- ✓ Validation Strategies proposed by European Regulatory Agencies

Analytical Method Validation

- ✓ Scope and Content of the Guidance
- ✓ Validation parameters, tests, and acceptance criteria
- ✓ Lifecycle management of analytical procedures
- ✓ Periodic review and revalidation
- ✓ SOPs and Report Writing
- ✓ Analytical Method Transfer studies
- ✓ Documentation requirements
- ✓ Verification of submitted methods at the FDA
- ✓ Chromatographic method

Cleaning Validation

- ✓ Development of cleaning procedures
- ✓ Preventing Product Contamination
- ✓ Critical Cleaning Procedures based on risk levels
- ✓ Types of cleaning options
- ✓ A risk based approach to Cleaning Validation
- ✓ Strategy for the validation of cleaning methods
- ✓ Calculation of Cleaning Limits
- ✓ Sampling and detection methods
- ✓ Effective Execution of cleaning validation
- ✓ Development of cleaning protocols

CASE STUDIES

- ✓ Review of FDA warning letters
- ✓ Learning from Various Industry Examples

Final Q&A Session

Certification

Networking and Close: 6 PM – 6.30 PM

CONTACT DETAILS

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