COMPLIANCE TRAININGS

2-Day In-Person Seminar

cGMP Audits and Inspections

– Preparation and Readiness

FDA

June 14 - 15, 2018 **Hyderabad, India**

SEMINAR INCLUDES

- 2-day workshop & discussions
- Case Studies
- Lunch
- 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 two-day workshop on '**cGMP Audits and Inspections**' is a knowledge-packed training program for regulated industry professionals, to have an excellent understanding of nitty-gritties of cGMP regulations, to understand the key steps for being inspection ready for FDA audits, which can make or break your company.

Have you done everything you can to prepare for your next FDA Inspection? Do you have the perfect SOP for Regulatory Inspections? Do your employees know what to do when they get that phone call from security or a receptionist? Who should security/receptionist call when FDA arrives unannounced at your firm? That's right, FDA and other regulatory bodies do not schedule an inspection - they just show up, present their credentials and state "*we're here for an inspection*".

Your organization's non-conformances need to be addressed quickly and systematically. That is why you need to ensure your management systems are equipped to document non-conformities efficiently, enabling you to tackle the issue as effectively as possible. Our CAPA process training will provide you with the knowledge you need to ensure that your organization conducts proper containment, correction and preventive actions. Preparation and planning that is indispensable to make an audit painless and that is expected of you to avoid being handed out a non-conformance as a 483.

Don't panic! Be prepared! The earlier you learn the FDA rules and expectations; the better off you will be in setting up and maintaining a bullet proof quality system.

- Ensure that your company successfully pass these inspections there is a need to create a culture of compliance throughout the firm that incorporates on-going preparations and frequent inspection readiness practice.
- Determine non-conformances more effectively
- Understand how to complete a containment and correction plan
- Identify and differentiate the root cause of any non- conformity
- Ensure immediate, preventive response and verification-in line with all requirements
- Verify the completion of any action taken
- Carry out a follow-up to show the effectiveness of corrective and preventive action plans
- Get complete CAPA requirements for all GMP international/ National regulatory/ Client/ other regulatory

WHO MUST ATTEND

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

DEPARTMENTS

- Quality Control
- Quality Assurance
- Regulatory Compliance
- Research and Development
- Manufacturing
- Production
- CQA - Corporate Quality Assurance
- Documentation
- Laboratory
- Audits and Compliance Departments
- Training Departments

PROFESSIONALS

- Managers & Supervisors
- Department Heads
- Senior Managers
- Team Leaders
- Executives and Senior Executives
- GMs/AGMs/DGMs
- Engineers
- Plant Managers
- Chemists
- Internal Auditors
- Document Specialists

AGENDA

DAY 1

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

Global cGMP Requirements
- ✓ cGMP Key requirements in USFDA and EU
- ✓ Inspections Requirements in USFDA / EU / TGA / MCC / Health Canada / WHO Geneva / PIC(s) and ROW
- ✓ For API Manufacturing
- ✓ For Formulation GMP Compliance
- ✓ For Laboratory Quality Systems
- ✓ For Sterile Manufacturing

Data Integrity
- ✓ Laws of Data Integrity
- ✓ What is Human Error? What is an Ethical Error?
- ✓ Detecting Data Integrity Issues
- ✓ How to report and communicate
- ✓ How to Fix Data Integrity issues

Behavioral GMPs (bGxP®)
- ✓ The New Paradigm in Compliance Management
- ✓ How to bring Compliance-cGMP environment
- ✓ Human behavior issues and salvation techniques
- ✓ How to bring ethical cGMP compliance

CAPA Audit Observations
- ✓ How Audit observations to be recorded
- ✓ How to document CAPA on audit observations
- ✓ CAPA format

Effective CAPA Management
- ✓ How to implement effective CAPA
- ✓ Effectiveness Verification of CAPA
- ✓ How to assess and to document Effectiveness verification
- ✓ What questions to be evaluated during effectiveness verification of CAPA

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

DAY 2

Session Start Time: 9:00 AM

Spotting Overall Weak GMP Compliance Systems
- ✓ Discussion on Current weakness in industry & How to avoid them

Laboratory Compliance
- ✓ Recent Critical USFDA/EU Laboratory QMS/Audit observations
- ✓ How to rectify and effective CAPA on these observations

Failure Investigation and Root Cause Analysis
- ✓ How to conduct Failure Investigation on OOS, Deviations, Market complaint, Laboratory incident, Event failures and its Root cause analysis
- ✓ CAPA on failure investigations
- ✓ How to close Audit-related CAPA

Facing Regulatory Audits and Inspections
- ✓ Writing welcome letter with supporting documents
- ✓ KEY Documents requirements
- ✓ National and International Regulatory Audits
- ✓ How to behave and what to answer
- ✓ What you should be ready for when the FDA knocks at the door for an Unannounced Inspection
- ✓ Inspector's expectations
- ✓ Do's and Don'ts during an inspection
- ✓ Future inspection expectation trends
- ✓ Avoiding FDA Enforcement Actions
- ✓ How to implement robust Quality system to achieve
- ✓ Optimal and Sustainable Compliance Program

Practical Workshop
- ✓ How to address CAPA for Recent USFDA warning letters
- ✓ EU Non-compliance observations
- ✓ Regulatory Audits
- ✓ Quality issues through Case Studies

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

CONTACT DETAILS

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