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World Compliance Seminars

2 DAY IN PERSON SEMINAR

FDA INSPECTION

BOSTON, MASSACHUSETTS

DECEMBER 07-08, 2023, THURSDAY-FRIDAY

Time 09:00 AM - 05:00 PM EST

ENROLL NOW

844-267-7299 support@worldcompliianceseminars.com www.worldcompliianceseminars.com

#02

COURSE DESCRIPTION

Non-compliance is an expense that no healthcare company can afford. Companies must establish proven and sustainable GXP Compliance Strategies and risk mitigation strategies when responding to a crisis so you avoid costly product approval delays, recalls and adverse impacts on shareholder value, including FDA enforcement actions. Companies must adopt a risk-based approach to managing quality and regulatory compliance not only for GCP, GLP and GMP but across the entire platform. Whatever solution you are using it needs to provide a common framework and an integrated approach to meet FDA GxP regulations through effective risk management, document control, compliance training, ongoing auditing, surveillance and monitoring activities and other critical areas that will be addressed during the seminar.

WHAT ARE THE REASONS TO CONSIDER ATTENDING?

- Define and execute proven GxP Compliance Strategies
- Proven Operational Readiness and State of Readiness tactics
- Determine optimal pathway during inspections and post-inspection correspondence and meetings
- Identify the visible signs of GXP compliance that are present as a daily reminder of the importance of GXP compliance with “risk-based” awareness demonstrated by companies
- Improve credibility and trust with FDA and other regulators
- Important training areas in GxP compliance and topical issues
- Gain a better understanding of how to interact and communicate effectively with FDA

WHO SHOULD ATTEND

- Executive Management
- Regulatory Affairs Management
- Regulatory Affairs Specialist
- Auditors
- QC/QC Management
- Compliance Officer
- Compliance Specialist
- Clinical Affairs
- Quality Assurance Management
- Marketing & Sales
- Laboratory Operations
- Legal Counsel
- Engineering/Technical Services

#03

TOPICS FOR DISCUSSION AT THE FDA INSPECTION SEMINAR

Day 1

- Introductions and Background
- FDA's Inspectional Authority and History
- FDA Inspection Program Overview
- Key factors for a successful FDA inspection
- Quality System Readiness
- Organization Readiness
- Manage Inspection Outcomes
- Information and Documentation
- How a firm should prepare for an FDA inspection?
- Ways to train employees in view of the inspection
- How to ensure that required documentation is in place
- How to interact with the investigator-DO's and DON'T's
- What companies should do when the inspection ends
- How to reply to 483's and warning letters
- Legal implications of non-compliance
- Why inspections are conducted and by what statutory authority
- The emphasis on systems-based inspections...and the IOM and other crucial FDA reference documents
- What is subject to FDA purview and what's off-limits
- Understand and apply the do's and don'ts and comprehend that preparation is the key to success
- What are the prohibited "Acts" and the enforcement categories that you need to deal with?
- What you need to know and do to prepare for, during and even after the inspection...and why your inspection response team is key
- The company's Inspection Plan (SOP) can make or break the inspection depending on how to use it and training your personnel.....

Day 2

- Maintain, or return to, regulatory compliance and minimize downtime
- Establish a risk management plan in place to proactively manage compliance, including a crisis-management plan
- Set post-inspection deadlines and working closely with FDA's regulatory partners
- Compliance remediation is the process of recognizing problems, creating a plan to correct and prevent them from occurring in the future, and executing to that plan to helps with your GxP Compliance Strategy.
- Guidance on how to request and conduct PDUFA meetings and expectations for Sponsor-FDA Meetings
- Guidance outlining clear recommendations for sponsors and for FDA staff and managers as well for Pre-Submission meetings as expected timeframes for scheduling meetings
- Mechanics of requesting any FDA meeting and what you need to know to be successful with communication style, approach and tactics
- Prioritize follow-up on warning letters and other enforcement actions
- Develop and implement a formal warning letter "close-out" process
- Untitled Letter and the Warning Letters
- Recent Trends and Enforcement Actions for 2017
- Mock Inspections and Mock Audits and why role playing is important

FDA Inspection Seminar

KNOW YOUR FACULTY

David R. Dills - **Director, Regulatory Services, CROMSOURCE, a ClinChoice Company and Regulatory SME has more than 33 years of leadership experience in the biopharmaceutical and medical device industry** within the regulatory affairs and compliance space. He has held positions of increasing responsibility with sponsors and service providers of various sizes, including large, global OEM's/sponsors, consultancies and a global CRO, as well as virtual, small, mid, and large-sized enterprises.

Early Bird One Attendee - Live

2 Day In Seminar - Boston , MA

$1,895

Live Group Up to 5 Participants

2 Day In Seminar - Boston , MA

$4,995

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