2 Days Workshop:FDA Penalties for Regulatory Non-Compliance in the Pharmaceuticals Industry - 2017 in Review

Date : Jan 30, 2018 - 09:00 AM

Event URL : http://www.BostonEventsList.com/events/-worldcomplianceseminars-com-seminardetails-30

Organizer : Conference Mnanager

Venue :

Location : WCS Consulting Inc.3190 Stirling Rd, Unit K4, Hollywood, FL 33021,
Hollywood, Florida, United States, ZIP: 33021
Phone: 347 282-5400

Ticket Price: Seminar One Registration $ 1295 |Special Group Discount Register for Four attendees $ 3885

Course “FDA Penalties for Regulatory Non-Compliance in the Pharmaceuticals Industry - 2017 in Review“ has been Pre-approved by RAPS as eligible for up to 12 credits towards a participant's RAC recertification upon full completion.

This hands-on seminar provides a comprehensive approach to learning how to proactively prevent non-compliance. There will be intensive reviews on the negative consequences of receiving regulatory enforcement actions. FDA Warning Letters are posted publicly on the CDER web site. Your competitors, shareholders, the public and your patients now become aware of your shortfalls. Many Warning Letters today mandate the hiring of third party consultants, which can be quite expensive. An Injunction will require pharmaceutical companies to spend millions of dollars and require years until you “bounce back.” Multimillion disgorgement penalties are being levied along with Injunctions.

The FDA is increasing its enforcement actions both for domestic and foreign inspections. Enforcement statistics have not been summarized yet because 2017 has not ended yet. We are certainly seeing more Warning Letters and Import Alerts based on Data Integrity (21 CFR Part 11: Electronic Records; Electronic Signatures. In the past FDA used to issue several Warning Letters

to the same firms upon consecutive inspections. Today, after receiving one Warning Letter the next regulatory action is elevated to Import Alert, Consent Decree, and Injunctions for domestic manufacturers.

Senior Management must take the initiative in setting the tone of full compliance:

• Taking “regulatory risks” may no longer be worth the price of getting caught

• Planned deviations cannot be used as an excuse for not following your written procedures

• Retesting into compliance has been unacceptable for many years and will no longer be tolerated

• Senior officials are being held responsible. Today, these “Captains” may go down with the ship – sent to prison and fined millions of dollars

FDA’s Office of Manufacturing Quality (OMQ) at the Center for Drug Evaluation and Research (CDER) evaluates compliance with current Good Manufacturing Practice (cGMP) for drugs based on inspection reports and evidence gathered by FDA investigators. The office also develops and implements compliance policy and takes advisory actions to protect the public from adulterated drugs in the U.S. market. This year we have seen:

• Increased use of Contract Manufacturing Organizations (CMO) has increased the regulatory focus on CMO and requirements for Quality Agreements are being enforced

• There has been an increase in Warning Letters in 2017

• An increase in Import Alerts enforcement actions

• Data Integrity issues are being found more frequently

Areas Covered

- Introduction and Background
- Summary and Highlights of 2017 Enforcement Actions
- Penalties and Negative Financial results of Enforcement Actions
- ICH Guidelines on Quality Risk Management
- Adequate Responses to FDA
- Change in Attitude and Culture
- Metrics on Improvements

Who will Benefit

- Drugmakers
- Devicemakers
- Biologics firms
- Diagnostics firms

- Executive suite
- Manufacturing/GMP
- QA/QC
- Regulatory affairs
- Strategic planners
- Legal counsel
- Consultants

Learning Objectives

This 2 Days Workshop is intended for professionals in the

- Pharmaceuticals
- Biotech
- Medical Device

Although not presently stated in the draft , the same guide could be used by FDA Regulated Industries personnel.

Event Categories :