FDA Penalties for Non-Compliance in Pharma - 2017 case studies and Readiness for 2018

Date : Apr 19, 2018 - 08:30 AM - Apr 20, 04:00 PM

Event URL : http://www.nyeventslist.com/events/fda-penalties-for-non-compliance-in-pharma---2017-case-studies-and-readiness

Organizer : MetricStream, Inc

Venue : To Be Announced

Location : 1, Main St
Orlando, FL, USA, ZIP: 00000

FDA Penalties for Non-Compliance in Pharma - 2017 case studies and Readiness for 2018

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.

Who will Benefit:

- Compliance Officers
- Complainant Managers
- Managers (RA, QA/QC, CA)
- Consultants
- Contractors and Subcontractors
- Manufacturing Personnel & Management

- Regulatory Affairs Personnel & Management
- Quality Assurance Personnel & Management
- Supplier Quality Personnel & Management
- Senior Management, CEOs, VPs, Project Managers
- Attorneys and Counsel
- Senior management for companies developing new products for US market
- People investing in FDA-regulated products intended for the US market
- Operations, Plant and Facility Managers
- Anyone interested in the topic

Seminar Fee Includes:
Lunch
AM-PM Tea/Coffee
Seminar Material
USB with seminar presentation
Hard copy of presentation
Attendance Certificate
$100 Gift Cert for next seminar
DOWNLOAD BROCHURE

Topic Background:

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

AGENDA

DAY 01(8:30 AM - 4:00 PM)

- 08.30 AM - 09.00 AM: Registration
- 09.00 AM: Session Start
- Lecture 1: Introduction and Background
    - Introductions / Participants' Understanding / Participants' Objectives for the Course (Please come prepared to discuss)
    - Background
    - Industry Context
    - Key Concepts
- Lecture 2: Summary and Highlights of 2017 Enforcement Actions
    - Warning Letters
    - Import Alerts
    - Consent Decrees
    - Injunctions
- Lecture 3: Penalties and Negative Financial results of Enforcement Actions
    - Detailed Costs and Expenditures for Remediation
    - Loss of Sales and Customers
    - Decreases in Patients Access
    - Loss of Good Reputation
    - Loss of Jobs
- Lecture 4: ICH Guidelines on Quality Risk Management
    - Science Based Quality Risk Management
    - Quality Risk Management Process
    - Initial Risk Assessment
    - Implement & Verify Appropriate Controls
    - Review Risks & Monitor Controls

DAY 02(8:30 AM - 4:00 PM)

- Lecture 5: Adequate Responses to FDA
    - Comprehensive Corrective and Preventative Action (CAPA) Plans
    - Sincere and Specific timelines

    - Quarterly Follow-ups
    - Adequate but not overwhelming documentation
    - Training
- Lecture 6: Change in Attitude and Culture
    - Full Support and Commitment of Senior Management
    - Responsibilities to Customers
    - Proactive Not Reactive
- Lecture 7: Metrics on Improvements
    - Management Involvement
    - Personnel Involvement
    - Positive Increases in Metrics Lead to Positive Attitudes
    - Incentives and Acknowledgements
- Interactive Session: Group Activities Writing FDA-483 Responses
    - Instructors Evaluation and Recommendations

SPEAKER

Brian G. Nadel
President, Brian G. Nadel, GMP Consulting, LLC

Brian G. Nadel is the President/Sole Proprietor of Brian G. Nadel, GMP Consulting, LLC. He has over twenty-five years of diverse experience in: Pharmaceutical Quality Assurance and Quality Systems; FDA Pre-Approval and Inspection Readiness Inspections; International CGMP Auditing for finished drug products, Active Pharmaceutical Ingredients, Fermentation, Process Validation and botanical extraction.

Mr. Nadel utilizes his broad background to assess compliance issues and develop effective, efficient comprehensive systems to ensure CGMP Compliance. He assists pharmaceutical firms in maintaining and developing quality manufacturing operations. He has worked with NDA, ANDA, DMF, BLA and OTC product manufacturers. He has also conducted CGMP training for FDA, Industry and at industry conferences. He has worked to assist clients to comply with the requirements of Consent Decrees. He has used his experience in the pharmaceutical and government regulatory industries to author SOPs in quality and compliance areas.

Mr. Nadel holds a BA in Microbiology and Parasitology from the State University of New York at Albany, NY and is a certified Regulatory Affairs Professional. He is a member of the Parenteral Drug Association and the Regulatory Affairs Professional Society. Mr. Nadel has spoken at many industry conferences, including three conferences in India in 2017.

Mr. Nadel has just completed his third trip to India in 2017. During these visits, he has been working with Indian Pharma to train them to proactively prevent problems and respond to “issues” with the US FDA.

Please contact the event manager Marilyn (marilyn.b.turner(at)nyeventslist.com) below for:
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