Global CompliancePanel

NetZealous

2-day In-person Seminar:

Understanding FDA and Avoiding Inspections Leading to Warning Letters, Seizures, Injunctions and Prosecutions

By **David R. Dills,** Regulatory Affairs & Compliance Consultant,

Location: Minneapolis | June 5th & 6th 2014 **Location: Boston | July 10th & 11th 2014**

About GlobalCompliancePanel:

GlobalCompliancePanel is a training source that delivers diverse, high quality regulatory & compliance trainings. These trainings are simple while being relevant and cost-effective while being convenient. GlobalCompliancePanel imparts knowledge of best practices across a broad range of user-friendly mediums such as webinars, seminars, conferences and tailored, individualized consulting. These help organizations and professionals implement compliance programs that meet regulatory demands and put business processes in place. Through our trainings, we bring together the regulators or experts on regulation on the one hand, with the community that needs to learn or be aware of those regulations, on the other.

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2-day In-person Seminar 2014

David R. Dills

Regulatory Affairs & Compliance Consultant,

David R. Dills, Regulatory & Compliance Consultant with more than 24 years of hands-on experience and a proven track record within the FDA regulated industry, has an extensive regulatory and compliance background with Class I/II/III and IVD devices, pharmaceutical operations, and manages activities within the global regulatory and compliance space. He has been involved in many FDA and other regulatory inspections as well as part of multiple FDA remediation activities involving CIA's Consent Decrees, Seizures and other enforcement actions, including responding to Warning Letters.

Course Outline:

Day One (9 AM to 6 PM)

Lecture 1: **FDA History, Inspection Preparation, Handling and Closure**

- 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
- Post inspection actions
- 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
- How to respond to findings and facilitating the documentation and remediation process...and reaching final closure
- Define clear responsibilities, roles and goals for personnel involved in SOP development
- Classroom exercise-Mock FDA Inspection/Role Playing

Lecture 2: **Warning Letters**

- Considered an Advisory Action
- A communication to the firm that has been reviewed within several levels of the FDA, including the district office and the Center at FDA's headquarters
- The Warning Letter generally states that the firm has made products that are adulterated, violating the Food, Drug, and Cosmetic Act and that the firm has a very limited amount of time to address the problem(s) before the FDA takes further regulatory action against the firm, the adulterated product, and responsible individuals
- Intent to elicit voluntary correction
- Established background of prior warning
- Published under FOI
- Should only be issued for violations of regulatory significance
- Responding to a WL/483 and group discussion with written responses to FDA
- Types of Warning Letters on the FDA Website
- Review of recent WL's and trends
- Group discussion with Response Letters

Lecture 3: **Recap of Day 1**

Day Two (9 AM to 6 PM)

Lecture 4: **Seizures**

- Seizures are made if there is an imminent public health threat that the drug or device manufacturer is not correcting on its own or if the FDA is trying to get the attention of the firm's senior management that, up to this point, has not satisfactorily complied with the FDA's requirements
- Seizures are approved by a U.S. Federal Court judge; U.S. Marshals accompany the FDA during a seizure
- After seizure, no one may tamper with the goods except by permission of the court
- The court usually gives the owner or claimant of the seized merchandise approximately 30 days to decide a course of action
- General Guidelines for Seizures
- Types of Seizures
- Direct Reference Seizure Authority
- Approval Process for Seizure and Injunction Cases
- Responsibilities for Seizure Actions

Lecture 5: **Injunctions**

- Adequate Notice Preceding Injunction Actions
- Prerequisites for a TRO or Preliminary Injunction
- Refreshing Evidence - Updating Inspections
- Approval Process for Seizure and Injunction Cases
- Responsibilities for Injunction Actions
- Cover Letter to DOJ
- Complaint for Injunction
- Declarations
- Consent Decree
- Costs of Supervision
- Compliance Follow-Up
- Vacating Injunctions
- Injunction/Consent Decree: If a firm has repeatedly violated cGMP requirements, the FDA may make a legal agreement with the firm to force them to make specific changes; the agreement, the consent decree, is enforced by the federal courts.
- Consent decrees include fines ("disgorgements"), reimbursements to the government for inspection costs, due dates for specific actions, and penalties for noncompliance.
- Consent decrees usually are permanent, but at times specified in the agreement when the firm has achieved compliance, it can petition the court to remove the decree.
- Injunction is a civil judicial process initiated to stop or prevent violation of the law, such as to halt the flow of violative products in interstate commerce, and to correct the conditions that caused the violation to occur.

Lecture 6: **Prosecution**

- Criminal Prosecution: In some cases, usually involving fraud, FDA and federal prosecutors will file criminal charges against an individual. If found guilty, the person is subject to fines and prison time.
- Punishment in a prosecution and sentencing guidelines and recent examples
- In furtherance of Commissioner Hamburg's call-to-action, FDA has issued special procedures and considerations for "Park" prosecution recommendations now...industry is on notice.
- Communication Between OCI and Other FDA Components
- Processing A Summary And Recommendation
- Criminal Prosecution after Section 305 Notice
- Criminal Prosecution Without Section 305 Notice
- The FDA Regulatory Procedures Manual (RPM) provides agency personnel - primarily inspectors, investigators and compliance officers - with information on internal procedures used in processing regulatory and enforcement matters.
- Office of Criminal Investigations (OCI) is responsible for reviewing all matters in FDA for which a criminal investigation is recommended, and is the focal point for all criminal matters.
- FDA personnel must refer all criminal matters, regardless of their complexity or breadth, to OCI and this includes criminal search warrants, misdemeanor prosecutions, felony prosecutions, referrals for criminal investigation, and Section 305 meetings.

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Pricing List:

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Look forward to meeting you at the seminar
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