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EVENTS LIST

Managing Your FDA Inspection: Before, During and After (com) A

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Organizer : NYMT

Venue :

Location : TBASan Francisco, CAUnited States,
San Francisco, CA, US, ZIP: 00001

Managing Your FDA Inspection: Before, During and After

FDA inspects many different kinds of firms. If the FDA regulates your product, they can show up at your lobby and say, “I am here to conduct an inspection.” What do you do? What have you done to prepare for an inspection? How do you deal with the investigator, including their personality? The scary part is having to explain the error of your ways to the FDA and above all, managing an administrative action, e.g., Warning Letter or Import Alert, or a legal action, e.g., civil money penalties, seizure, injunction or prosecution. This course will help you need to know and what you should do to survive an FDA inspection with the least possible pain.

Seminar Instructor Casper Uldriks is an "Ex-FDA Official" who has spent 32 years in FDA. He currently trains FDA personnel and counsels clients on wide range of topics, including: FDA inspections; import operations; advertising and promotion; corrective and preventive actions; medical device reporting and corporate reorganization to improve conformance to the FDA’s requirements.

He understands how FDA thinks, operates and where it is headed.

The course will cover the factors used by the FDA to schedule inspections. You will learn how to predict what an FDA investigator will do and what they will cover in the inspection. There should be no surprises if you have prepared properly. Firms need to understand the details about inspectional techniques to avoid making new problems for yourself during the inspection. You can save yourself a lot of corporate misery if you know what to do before, during and after an

inspection.

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

FDA conducts inspections based on well established procedures. You can lower your anxiety level when you can predict what they will do during an inspection, what products they cover and how they will document your problems. Any type of regulated firm should the ground rules of an inspection to keep it under control. You should be able to see the hand writing on the wall if it looks bad and prepare accordingly. You should understand what is at stake based on the progress of an inspection. How you respond to an investigator, to the inspection in general and to the FDA can seal your fate to an unhappy ending if you don't know what to do, how to do it and how fast you need to do it. Questions are encouraged. What did you want to know about FDA, but were always afraid to ask? What are the big mistakes firms make? Here the firsthand accounts of an ex-FDA investigator.

Learning Objectives:

- FDA legal authority to inspect
    - Over products
    - Over firm's
        - Scientific/clinical studies
        - Premarket requirements
        - Postmarket requirements
- FDA's annual inspection work plan
- Inspection Procedures
    - FDA inspection Manuals
    - FDA Training
    - Documenting violations
    - Refusals
    - Human factors

- Recall procedures (What FDA expects from you.)
    - FDA Field Office Management
    - FDA Center(s) Management
    - The firm's job

- Inspectional observations (Form FDA-483)
- Responding to a 483
- Responding to a Warning Letter
- Recall procedures (What FDA expects from you.)
    - FDA Field Office Management
    - FDA Center(s) Management
    - The firm's job
- FDA enforcement actions
- Follow up inspections
- Foreign Inspections

Who will Benefit:

When you interact with the FDA, you need to look at yourself through FDA's eyes. You can understand the purpose of an inspection, what the investigator will do and what it means for you. Once you learn how to read the signals you are better equipped to mitigate regulatory damage and, best of all, take the drama and mystique out of an inspection. The information in the course gives you rational and comprehensive approach so you do not feel like a deer staring at the headlights. If you know what the investigator is doing and you understand your job, your receptionist will not need a panic button.

- Regulatory Affairs Directors
- Quality Assurance Managers
- Quality Control Managers
- Manufacturing Directors and Managers
- Product Risk Managers
- Venture Capitalists

Topic Background:

FDA inspections can have a big impact on a firm's budget, public image, customers, employees and stockholders. No one wants the bad news that the FDA investigator puts on a written list of observations, aka the "483." Your 483 is like a report card that your teacher shows to everyone else in the class. What an investigator finds pulls together many different legal, administrative and technical factors that end up showing you and the public where you stand with the FDA. Inspections cover a wide range of products and an equally broad range of establishments, so preparing for and understanding an inspection takes work that is specific to your firm.

FDA inspections are assigned for many different reasons. Safety (risk to health) plays a major role in how FDA selects firms for inspections. Firms can estimate their likely risk status in terms of FDA's regulatory interest. Once a firm is selected for inspection, how the inspection is conducted becomes a make-or-break situation. Inspections are designed to find problems. They are

inherently uncomfortable for the people who host the investigator during the inspection. Predicting what an investigator will do during an inspection becomes helpful in how you manage a difficult situation to avoid a potentially disastrous and costly result.

AGENDA

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

- 08.30 AM - 09.00 AM: Registration
- 09.00 AM: Session Start
- 9:00 – 10:30 a.m.
    - FDA Legal Authority
    - FDA inspection plans and risk
    - Preparing for an inspection
- Break 10:30 – 10:45 a.m.
- 10:45 – 12:00 p.m.
    - FDA Inspection Procedures
    - FDA staff guidance
    - FDA staff training
- Lunch 12:00 – 1:00 p.m.
- 1:00 – 2:30 p.m.
    - Inspection strategy and technique (cont.)
- Break 2:30 p.m. – 2:45
- 2:45 – 4:30p.m.
    - Inspection strategy and technique
    - War rooms

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

- 9:00 – 10:30 a.m.
    - Documenting violations
    - Collecting “samples”
    - Responding to inspectional observation (The “483”)
- Break 10:30 – 10:45 a.m.
- 10:45 – 12:00 p.m.
    - Responding to a Warning Letter
    - Legal enforcement actions
- Lunch 12:00 – 1:00 p.m.
- 1:00 – 2:30 p.m.
    - Recall actions and procedures
    - The field District Office
    - The Center(s)

    - The recalling firm
    - Notifying the public
- Break 2:30 – 2:45 p.m.
- 2:45 – 3:00 p.m.
    - Follow up inspections
    - Corrective and Preventive Actions
- 3:00 – 4:30 p.m.
    - Foreign inspections
    - Import Alert

SPEAKER

Casper (Cap) Uldriks,
Former Associate Center Director of FDA's CDRH

Casper (Cap) Uldriks, through his firm “Encore Insight LLC,” brings over 32 years of experience from the FDA. He specialized in the FDA’s medical device program as a field investigator, served as a senior manager in the Office of Compliance and an Associate Center Director for the Center for Devices and Radiological Health. He developed enforcement actions and participated in the implementation of new statutory requirements. His comments are candid, straightforward and of practical value. He understands how FDA thinks, how it operates and where it is headed. Based on his exceptionally broad experience and knowledge, he can synthesize FDA’s domestic and international operational programs, institutional policy and thicket of legal variables into a coherent picture.

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