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EVENTS LIST

Managing Your FDA Inspection: Before, During and After

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Organizer : GlobalCompliancePanel

Venue :

Location : 2899, Jefferson Davis Hwy
Arlington, VA, USA, ZIP: 22202

FDA's inspection program follows well-established procedures and conducts the inspections with as much consistency as possible. FDA trains its investigators from day one. During the first six months, they attend extensive classroom and hands on training. FDA investigators learn basic skills. As time goes on, special training is given and the field staff use detailed reference materials to guide their thinking, actions, decisions and conclusions. If you understand FDA's management of its investigators and inspectional process, you can keep your establishment ahead of a needless regulatory disaster. FDA conducts inspections with standard operating procedures and detailed information on how to handle almost any situation the FDA investigator may face. The course will let you see inside an FDA investigator's mind set and what the agency will do when it evaluates what the investigator says and documents. What the investigator does and what FDA does are not mysteries, they just seem like it.

Why you should attend:

"Hi, I'm from the FDA and here to conduct an inspection." What is the first thing you do? Ring a fire alarm, close down for the day (some firms have) or do you follow well-planned protocol. You think, "Why is FDA here? Are we in trouble?" Are you prepared to talk about the trouble you know you have with FDA regulations or is your plan of action to cross your fingers.

We all know that a bad FDA inspection has immediate and long-term consequences. The cost of fixing your problems, the bad public relations, upset customers and future business plans can be set into a downward spiral. If you do not understand what FDA is doing or thinking, how can you expect to deal successfully with FDA? If you don't know how to anticipate an investigator's

actions or follow their train of thought, you will not be able to mitigate the effect of inspectional findings.

"Is FDA going to send us a Warning Letter?" You can make a reasonable prediction if you understand your inspectional results and how FDA will "grade" it. The tools are available.

Areas Covered in the Session

- FDA legal authority
- Types of inspections
- FDA investigator training
- FDA's written procedures, policy and operations guide
- Industry inspection protocol
- What to do and not do during an inspection
- Form FDA 483 response
- Warning Letter response
- Enforcement

Who Will Benefit:

- Regulatory Affairs
- Quality Assurance
- Manufacturing

Day 1 Schedule

Lecture 1:

FDA Inspection authority

- FDA Inspection authority
- Inspectional refusal prohibition

Lecture 2:

Types of Inspections: purpose, scope and scrutiny

- Comprehensive GMP
- Abbreviated GMP
- District or Center Directed
- Regulatory Follow-up
- Surveillance
- Limited

- For Cause

Lecture 3:

Impact on you during and after inspection

- How to interact with the FDA investigator
- What not to say and do
- Your protocol
- Mismanagement of the inspection

Lecture 4:

FDA Investigator Training - This is what they are thinking

- On the job training and supervision
- Technical, classroom and mock inspections
- Evidence development to tell the story
- Physical and documentary samples of your violations
- Writing reports, inspectional observations and sample documentation
- Physical threats and assault

Lecture 5:

Investigations Operations Manual

- Procedures and technical guidance. FDA's rules for themselves
- FDA organization chart "in the field." Who is watching you?

Compliance Programs

- Section III - the inspection / specific issues
- Section V - the regulatory response / risk assessment

Lecture 6:

Investigations Operations Manual (continued)

- Writing inspectional observations (Form FDA 483)
- Writing establishment inspection reports
- Evidence documentation and custody

Mock "Limited" inspection

Day 2 Schedule

Lecture 1:

FDA Form 483 - List of objectionable conditions, aka list of observations

- Purpose
- Format / organization
- Managing 483 observations during the inspection
- Responding to 483 observations during "discussion with management"
    - What it means
    - How to manage the discussion
    - How to challenge a 483 observation
    - What to say and not say

Lecture 2:

Your written response to a 483

- Understanding the 483 - using an FDA issued 483
- Time deadlines
- Strategy for corrections and corrective action
- Evidence of corrections and corrective action
- Empty promises

Lecture 3:

FDA Warning Letter - advisory of possible legal action

- FDA Warning Letter procedures
- Responding to a Warning Letter - in 15 working days.

Group Hypothetical Warning Letter Response - in 10 minutes

Lecture 4:

FDA Enforcement Actions

- Judicial
    - Seizure
    - Injunction
    - Prosecution
    - Monetary penalties
- Administrative
    - Import / Export
    - Government contracts
    - Other government agency advisories
    - Fines

- Premarket holds

Casper Uldriks

ex-FDA Expert and former Associate Center Director of CDRH

Casper (Cap) Uldriks owns Encore Insight LLC, which provides consulting services on FDA Law. He 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 as 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. He is recognized as an exceptional and energetic speaker. His comments are candid, straightforward and of practical value. He understands how FDA thinks, operates and where it is headed.

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