FDA Inspections: How to be Prepared

The best way to pass an FDA inspect is, of course, to be in compliance. But there are many actions you can take in advance to make the inspection easier for both you and the inspectors. This seminar takes the participant step by step through the entire inspection process and describes various types of inspections, i.e. pre-approval inspections (PAI), routine GMP inspections, bioresearch monitoring inspections, quality systems inspections techniques (QSIT) applied to device companies and system-based inspections program applied to drug companies. It teaches the employees how to answer the inspectors' questions in a professional and concise manner.

Who Should Attend: Individuals in the Medical Device, Pharmaceutical, Food, or Bio industry who manage auditors. Anyone who expects to be audited in the near future.

Class Length: Four hours

Maximum Class Size: 25

Course Prerequisites: Participants must have a working knowledge of cGMP's.

Course Objectives: At the conclusion of the class a participant will have an understanding of the following:

- The Regulatory Requirements and Guidelines
- FDA's Forms of communication
- Types of inspection
- What samples can FDA take?
- What kinds of questions can FDA ask?
- What pictures can FDA take?
- What can FDA look at?
- How to interact with the inspector, DO's and DON"Ts
- Terminology
- How to organize personnel for the inspection, the contact team and the "Go For" team
- Define who will conduct tours and identify tour route
- Identify conference room where interviews will be conducted
- Identify bathrooms and routes to them
- Sampling of documentation to make sure that it's in order
- What should be in an inspection SOP
- Make sure the plant is clean
- "And keep it that way"
- Refresher training for employees that the inspectors may encounter
- How to handle opening and closing meetings
- How to reply to 483's and warning letters

VALIDATION & COMPLIANCE INSTITUTE
537 Fort Dearborn St.
Dearborn, MI 48124
734-274-4680