

## Surviving and FDA Inspection

- 1. FDA Authority**
  - a. Congressional enactment
  - b. Enter and inspect
  - c. FDA Mission
  - d. Current information
  - e. Definitions
  - f. Reasons for inspections
  - g. Inspection goals
  - h. Regulatory matrix
  - i. Inter-agency cooperation
- 2. Inspection Approaches**
  - a. Comprehensive v directed inspections
  - b. Full v abbreviated inspections
  - c. Common elements of inspections
  - d. Quality systems inspections
  - e. Risk based approached to inspections
- 3. Notification of Inspection**
  - a. Unannounced
  - b. Pre-announced
  - c. Court ordered
- 4. The Inspection Team**
  - a. Leadership
  - b. Documentation control specialist
  - c. Facilitators
  - d. Scribe
  - e. SME's
  - f. Escorts
- 5. Inspection Documentation**
  - a. Key persons
  - b. Supervisors
  - c. Job descriptions
  - d. Call list
  - e. Other documents
  - f. 482 Notice of Inspection
- 6. Reception of Inspectors**
  - a. Security
  - b. Visitors area
  - c. Official reception
  - d. Credentials
  - e. Meeting room selection
- 7. Site Rules and Policies**
  - a. Safety and security
  - b. Photography
  - c. Recording
- 8. The inspection**
  - a. The agenda
  - b. Facility tour
  - c. Product requests
  - d. Walk through audit
  - e. Documentation review
  - f. Close out meeting
- 9. Interacting with Inspectors**
  - a. Employee behavior general
  - b. Professional responses
  - c. Seek to understand
  - d. Refer to procedures
  - e. Disagreements
  - f. Supervisory intervention
  - g. Leading responses
  - h. Acceptable interventions
  - i. Off-the record questions
  - j. Listen, understand, respond
  - k. Hypothetical questions
  - l. Opinion questions
  - m. Approximations
  - n. Responding for others
  - o. Deferring
  - p. Demonstrate justification
  - q. What to do when unsure
  - r. Clarify roles
- 10. Documentation Control**
  - a. Document handling plan
  - b. U.S. Freedom of Information Act
  - c. Shared documents
  - d. Confidential documents
  - e. Document review
  - f. Signing forms and affidavits
  - g. Photocopies
  - h. Inspection history
- 11. Samples**
  - a. Investigational samples
  - b. Official samples
  - c. Sample documentation
- 12. Inspection Debrief and Response**
  - a. Close out meeting FDA
  - b. Close out meeting management
  - c. Form 483
  - d. 483 Distribution
  - e. Establishment Inspection Report
  - f. Non-reportable observations

- g. Potential significance
  - h. Regulatory action
- 13. Preparation**
- a. Procedures
  - b. Training

**Course Length:** 160 Minutes includes time to take the final exam.

Times are estimates and vary depending on the speed of taking the course assessments. Quiz questions are presented twice, once for the practice quiz and once for the final exam. Quiz times are estimated at 0.75 minutes for each question. Individual student response times may vary.

**Who should take this class?** Those who must prepare a company for an upcoming inspection, those who are to participate in an inspection for the first time and those who need to review what to expect during an inspection.

**To learn more about this program call:** (415) 487-3500 to speak to a training consultant.