

# Surviving an FDA Inspection

## ***Purpose***

This program examines the critical components of planning for a successful inspection.

## ***Objectives***

At the completion of the class, employees will be able to describe what to expect from an FDA inspection and how to interact with inspectors.

## ***Prerequisite***

None

## ***Who should attend this course?***

This class is appropriate for all employees of drug, biologic, or medical device manufacturing who might interact with the FDA inspector at some level.

## ***Intent of the class***

This course is intended for training purposes only and is not a substitute for technical recommendations, regulatory or legal advice. These materials are intended to raise compliance issues for further discussion at your company. It is recommended that you consult appropriate authorities for specific recommendations and advice.

## ***Class Length: This time includes testing time.***

*3 Hours in 13 segments*

## ***On-site Options***

This class can be taught with a live instructor at your company. Call for details.

## Topics Covered

### Introduction

1. FDA authority
2. Congressional enactment and FDA mission
3. Pure Food and Drug Act - 1906
4. The Food Drug and Cosmetic Act - 1938  
FD&C Act
5. Access
6. Inspection versus investigation
7. Inspection goals
8. Regulatory matrix

### Inspection approaches

1. Comprehensive versus directed
2. Full versus abbreviated
3. Common elements
4. Quality Systems Inspection approach
5. Risk based inspections
6. Depth of inspections

### Notifications

1. Unannounced
2. Pre announced

### Inspection team

1. Host
2. Facilitators
3. Scribe
4. Subject matter experts
5. Escort

### Inspection documentation

1. Corporate personnel
2. Key persons
3. Key managerial personnel
4. Supervisors
5. Job descriptions
6. Call list
7. 482 Notice of Inspection

### Reception

1. Security and visitors
2. Official reception
3. Credentials
4. Meeting room selection

### Site rules

1. Safety
2. Security
3. Photographs
4. Recordings

### The inspection

1. Agenda
2. Tour
3. Product requests
4. Walk through audit
5. Documentation review
6. Close out meeting

### Interacting with the FDA

1. What to do
2. What to avoid
3. This segment shows simulated FDA interactions

### Documentation control

1. Document handling plan
2. Freedom of information
3. Shared documents
4. Marking documents confidential
5. Document review
6. Signing affidavits
7. Photocopies
8. Inspection history

### Samples

#### Daily debrief

#### Close out meeting

1. Close out meeting
2. 483 Notification of Observations
3. 483 Distribution
4. Non reportable observations
5. Potential significance observations
6. Regulatory actions

#### Preparation