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# FDA Inspection Training

## ***Purpose***

To prepare a plant site for an FDA Inspection.

## ***Objectives***

At the completion of the class, students will be able to:

1. State acceptable behaviors during an FDA inspection.
2. State unacceptable behaviors during an FDA inspection.
3. Practice responding to FDA questions.
4. Develop a plan for hosting the FDA for an inspection; job responsibilities, presenting a site overview, conducting tours with the FDA, planning for the proper space for hosting the FDA, and site rules for photocopies and photographs,

## ***Prerequisite***

Attendees in this class should have a solid understanding of the GMP regulations.

## ***Who should attend this class?***

Anyone who is responsible for interacting with the FDA during an inspection should attend this class.

## ***About the class***

1. This class uses current lecture and skill practice to learn to interact with the FDA.
2. This class uses small break out groups to decide how to address many of the planning steps of the inspection.
3. The optional final exam is approximately 25 questions.
4. Each student receives a student guide containing a representation of the program's slides and graphics with space provided for note taking.
5. This class can accommodate up to 20 people.
6. Duration: 7 hours.

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## **Topics Covered**

### **Introduction**

1. The authority to inspect

### **Inspection approaches**

1. Full and abbreviated
2. Quality Systems
3. Inspection and risk assessment

### **Notification**

1. Announced
2. Unannounced
3. Court ordered

### **The inspection team**

1. Roles and responsibilities of team members

### **Inspection documents**

2. Documents to help the inspection

### **FDA Arrival**

1. Greeting
2. Credentials
3. Meeting room selection

### **Site rules**

4. Arrival
5. Safety and security
6. Photographs
7. Photocopies

### **The inspection**

1. The agenda
2. Tours
3. Handling product
4. Walk through audit
5. Documentation review
6. Close out meeting

### **Interacting with the FDA**

1. Seeking to understand
2. Responding and procedures
3. Disagreeing
4. Supervisory intervention
5. Leading responses
6. Acceptable interventions
7. "Off-the-record"
8. Listen, understand, speak
9. Hypothetical questions
10. Requests for opinions
11. Approximations

### **Documentation control**

1. Shared
2. Freedom of Information
3. Confidential documents
4. Forms and affidavits
5. Document handling
6. Photocopies
7. Inspection history

### **Samples**

1. Close out meeting
2. Establish Inspection Report
3. 483's

### **Inspection training**

1. Planning
2. Preparation
3. Communication

### **The right to disagree**

**This class is always customized to reflect your company's terminology around deviation investigations. Call us to discuss your needs.**