

309: FDA Inspections

Pharmaceutical and Biotechnology

(Course length: 2.0 Hours, 9 Graphics, 52 Pages, \$675)

Purpose: The purpose of this program is to understand the importance of an FDA inspection, how it is conducted, how we are to respond, and our individual role in the process.

Objectives

1. State the types of FDA inspections
2. Explain the guidelines for FDA inspection involvement
3. Explain why FDA inspections are necessary
4. Describe the FDA inspection process
5. State personal roles and responsibilities
6. Describe legal consequences

Topics and Activities

1. Introduction and GMP opener activity

2. Quality systems inspection technique

- ◆ Quality systems
- ◆ Why have quality systems
- ◆ Benefits
- ◆ Structure
- ◆ The inspection
- ◆ Abbreviated inspections
- ◆ Full inspections
- ◆ Compliance inspections
- ◆ Critical deficiencies

3. Checklist Preparation

- ◆ First reception of FDA
- ◆ Official greeting plan
- ◆ Documentation control
- ◆ Inspection history
- ◆ Training

4. The inspection process

- ◆ Flow chart
- ◆ Receiving investigators
- ◆ Developing an agenda
- ◆ Company introductions
- ◆ Facility tour
- ◆ Interacting with the FDA
- ◆ Unacceptable behaviors
- ◆ Data gathering
- ◆ Daily briefing



5. Behaviors

- ◆ Interacting with the FDA
- ◆ Unacceptable behaviors

6. Roles and responsibilities

- ◆ Escort qualifications
- ◆ Escort team
- ◆ Supervisors
- ◆ Plant personnel
- ◆ What the FDA is looking for

7. Legal consequences

- ◆ Warning letters
- ◆ Recalls
- ◆ Seizure; voluntary hold or embargo
- ◆ Injunction
- ◆ Consent decree
- ◆ Debarment
- ◆ Disgorgement
- ◆ Fines
- ◆ Prison
- ◆ Activity: Case studies
- ◆ Optional Activity: FDA Inspection Interviews

8. Wrap up

- ◆ GMP quiz
- ◆ Company problems
- ◆ GMP closer and wrap up activities
- ◆ GMP activity