

101: FDA Past, Present, and Future **Pharmaceutical and Biotechnology**

(Course length: 2-4 Hours, 14 Graphics, 72 Pages, \$600)

Purpose: The purpose of this program is to realize the significance of CGMP compliance and how it affects everyone

Objectives:

1. State the critical definitions of the pharmaceutical industry.
2. Describe the law as it applies to various critical functions.
3. State the history of CGMPs.
4. Describe the future goals and initiatives of the FDA.
5. Explain the types of FDA inspections.
6. Explain the legal consequences of CGMP non-compliance.



Topics and Activities:

1. Introduction and GMP opener activity

2. Overview

- ◆ Definition
- ◆ Regulation timeline
- ◆ Agency structure
- ◆ Definitions
- ◆ Drug Development timeline
- ◆ Who regulates clinical research
- ◆ GMP objectives
- ◆ Elements of GMP

3. The growing influence of the FDA

- ◆ Historical dates
- ◆ US prohibition of adulterated drug importation
- ◆ Pure Food and Drug Act
- ◆ Food, Drug, and Cosmetic Act
- ◆ KeFauver-Harris Amendment
- ◆ GMP update 1978
- ◆ The 1980's
- ◆ The 1990's
- ◆ The 2000's
- ◆ A year at a glance
- ◆ Going forward into the new millennium

4. Regulatory inspections

- ◆ Traditional approaches
- ◆ The new approach
- ◆ QSIT - Quality Systems Inspection Technique
- ◆ Sources of information for the FDA

5. Enforcement

- ◆ Legal consequences - Informational
- ◆ Legal consequences - corrective
- ◆ Legal consequences - punitive
- ◆ Actions not requiring a warning letter
- ◆ The two most common mistakes

6. Responsibility and accountability

- ◆ Management responsibility
- ◆ What's it all about
- ◆ Activity: *What's Is All About*

7. Wrap up

- ◆ GMP quiz
- ◆ Company problems
- ◆ GMP closer activity
- ◆ GMP wrap up activity
- ◆ Change history

Glossary