

101: FDA Past, Present, and Future **Medical Device**

(Course length: 2-4 Hours, 6 Graphics, 82 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 medical devices industry
2. Describe the objective of the law surrounding the QSR and GMPs as it applies to various critical functions
3. State the history of CGMPs
4. Describe the 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
- ◆ Device Development timeline
- ◆ Clinical research
- ◆ GMP objectives
- ◆ Tools for compliance

3. The growing influence of the FDA

- ◆ History of the FDA
- ◆ The 1980
- ◆ The 1990
- ◆ Domestic issues
- ◆ International issues
- ◆ FDAMA
- ◆ MDUFMA

4. Regulatory inspections

- ◆ The new QSIT - Quality Systems Inspection approach
- ◆ Traditional approaches
- ◆ FDA's sources of information

5. Enforcement

- ◆ Legal consequences
- ◆ Penalties

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