

305: Electronic Records

Pharmaceutical and Biotechnology

(Course length: 1.75 Hours, 26 Graphics, 64 Pages, \$675)

Purpose: The purpose of this program is to identify the action steps necessary to implement an electronic signature program in compliance with GMP guidelines.

Objectives

1. State the requirements of Part 11, Electronic Records and Signatures.
2. Describe the difference between open and closed systems.
3. State examples of bio-metric access systems.

Topics and Activities

1. Introduction and GMP opener activity

- ◆ History of Part 11 regulation
- ◆ What the FDA looks for
- ◆ Program goals

2. Definitions

3. Requirements for Open and Closed Systems

- ◆ Part 11 components
- ◆ Common requirements in perspective
- ◆ Records and documents
- ◆ Record protection
- ◆ Documentation controls
- ◆ Archiving and retrieving records
- ◆ What to archive
- ◆ Accurate copies
- ◆ File format
- ◆ Access control
- ◆ Limited system access
- ◆ Authority checks
- ◆ ID and password loss management
- ◆ Breach practices
- ◆ Audit trails
- ◆ Requirements
- ◆ Time and date stamp
- ◆ Training
- ◆ Management role and responsibility
- ◆ Policy statements

- ◆ Agency certification
- ◆ Confidential records
- ◆ Legacy systems
- ◆ Common requirements

4. Open system requirements

- ◆ Goals
- ◆ Access control
- ◆ Period of access control

5. Computer validation

- ◆ Introduction
- ◆ Design qualification
- ◆ Installation qualification
- ◆ Operation qualification
- ◆ Performance qualification
- ◆ Validation
- ◆ Performance
- ◆ Alarms
- ◆ Shutdown and recovery
- ◆ Worst case
- ◆ Change control

6. Wrap up

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

