

## 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. Describe examples of bio-metric access.

#### 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

