

## **206: Packaging and Labeling**

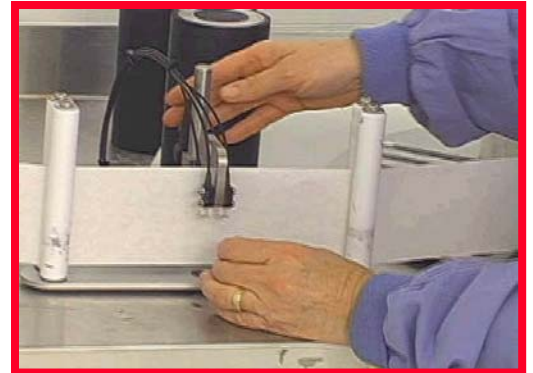
### **Pharmaceutical and Biotechnology**

(Course length: 1.75 Hours, 22 Graphics, 48 Pages, \$600)

**Purpose:** The purpose of this module is to learn how the regulations impact the receipt of packaging and labeling supplies.

#### **Objectives**

1. Describe the requirements for sourcing raw materials
2. Describe the value and uses of specifications
3. Describe the requirements for receiving materials
4. Describe the requirements for sampling materials
5. Describe the requirements for testing and examining materials
6. Describe the requirements for secondary containers
7. State the requirements for packaging and labeling documentation



#### **Topics and Activities**

1. **Introduction and GMP opener activity**
2. **Regulations**
3. **Materials examination and usage**
  - ◆ Procedures
  - ◆ Examination
  - ◆ Acceptance or rejection
  - ◆ Documentation
  - ◆ Stored separately
  - ◆ Restricted or limited access
  - ◆ Destruction of obsolete labeling
  - ◆ Gang printing
  - ◆ Cut labeling
  - ◆ Imprinting devices
4. **Sampling**
  - ◆ Statistical, random, representative
  - ◆ Taking a sample
  - ◆ Sample container labeling
  - ◆ Labels and labeling
5. **Label issuance**
  - ◆ Label reconciliation
  - ◆ Strict controls
  - ◆ Destruction of unused imprinted labeling
6. **Packaging and labeling operations**
  - ◆ Lot numbers and expiration dates
  - ◆ Physical or spatial separation
  - ◆ Work in process
  - ◆ Inspection
7. **Expiration dating**
  - ◆ Regulatory requirements
  - ◆ Exemptions
8. **Specifications and supply source**
  - ◆ Where specifications come from
  - ◆ Packaging and labeling suppliers
9. **Tamper-evident packaging**
  - ◆ Regulatory requirements
  - ◆ Defined
  - ◆ Packaging requirements
  - ◆ Tamper-resistant packaging
  - ◆ Durability of packaging
  - ◆ Labeling
  - ◆ Requests for exemptions
10. **Packaging and labeling documentation**
11. **Wrap up**
  - ◆ *Activity: Inspection*
  - ◆ GMP quiz
  - ◆ Company problems
  - ◆ GMP closer activity
  - ◆ GMP wrap up activity