

105: Materials
Medical Devices

(Course length: 2.5 Hours, 38 Graphics, 69 Pages, \$900)

Purpose: The purpose of this module is to learn how the cGMP regulations impact the receipt, handling and use of materials.

Objectives

1. Explain the importance of raw materials sources
2. Explain the major components of supplier qualification
3. Describe the function and importance of specifications
4. Describe the function and methods of material control
5. Demonstrate the application of random, representative sampling
6. Describe the value of online testing
7. Describe the requirements for the control of labeling
8. List the methods for proper handling of non-conforming materials



Topics and Activities

1. Introduction and GMP opener activity

2. Regulations

3. Purchasing controls

- ◆ Approving material suppliers
- ◆ Evaluation of suppliers
- ◆ Purchasing data
- ◆ Regular review

4. Specifications

- ◆ Sources of specifications
- ◆ Acceptable limits or ranges
- ◆ Labels and labeling

5. Quarantine system

- ◆ Definitions
- ◆ Purpose of the system
- ◆ Quarantine components
- ◆ Approved components
- ◆ Rejected components
- ◆ Experimental status
- ◆ Dedicated areas

6. Sampling

- ◆ Timing
- ◆ Procedure practices - general
- ◆ Procedure practices - specific
- ◆ Container identification
- ◆ *Activity: Bead Sort*

7. Receipt of materials

- ◆ Inspection by warehouse
- ◆ Receiving and storing
- ◆ Receiving inspection
- ◆ Testing
- ◆ Material examination
- ◆ Certificate of analysis

8. Identification of materials

- ◆ Serial numbers
- ◆ Expiration dates
- ◆ Containerization labeling
- ◆ Re-containerization

9. Contamination

- ◆ Types of material damage
- ◆ Types of component failures
- ◆ Chemical and physical contaminants
- ◆ Material storage space

10. Material controls

- ◆ FIFO
- ◆ Addition of active ingredients for combination devices
- ◆ Amount of active ingredients for combination devices
- ◆ In line testing
- ◆ Calculation of yield for combination devices
- ◆ Double checking for combination devices

11. Labels and labeling

- ◆ Packaging and labeling supplies
- ◆ Labels and labeling examination
- ◆ *Activity: Product Labeling*
- ◆ Strict control over labeling supplies
- ◆ Label accountability
- ◆ Returned labeling stock
- ◆ Destruction of labeling

12. Non-conforming materials

- ◆ Purpose
- ◆ Investigations

13. Wrap up

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

14. Glossary