

203: Equipment and Calibration

Pharmaceutical and Biotechnology

(Course length: 2.0 Hours, 32 Graphics, 49 Pages, \$1050)

Purpose: To learn how the cGMP regulations guide the design, use, cleaning, and maintenance of equipment.

Objectives

3. Explain the rationale for equipment design and selection
4. Explain the requirements for appropriateness of equipment use
5. State the requirements for equipment cleaning
6. State the requirements for equipment maintenance
7. State the requirements for equipment documentation
8. Explain the need for equipment identification
9. Describe the requirements and process of calibration
10. List the requirements for calibration documentation



Topics and Activities

1. **Introduction and GMP opener activity**
2. **Regulations**
3. **Design**
 - ◆ Appropriate and suitable
 - ◆ Equipment selection
 - ◆ Blue prints of process
 - ◆ Control devices
4. **Construction**
 - ◆ Equipment materials of construction
 - ◆ Lubricants
5. **Filters**
 - ◆ Design and specifications
 - ◆ Fiber releasing
 - ◆ High Efficiency Particular Air Filters (HEP)
6. **Use**
 - ◆ Procedures
 - ◆ Training requirements
 - ◆ Training program structure
7. **Cleaning**
 - ◆ Levels of cleaning
 - ◆ Procedures
 - ◆ Equipment cleaning logs
8. **Maintenance**
 - ◆ Work orders and repair orders
 - ◆ Logs
9. **Identification**
 - ◆ Requirements and exceptions
10. **Calibration**
 - ◆ Purpose
 - ◆ Key elements
 - ◆ Measurement frequency
 - ◆ Timing
 - ◆ Standards
 - ◆ Procedure
 - ◆ Logs for due dates
 - ◆ Consultants and outside firms
11. **Items to be calibrated**
 - ◆ Production and laboratory equipment
 - ◆ Process instrumentation and other items
12. **Calibration actions**
 - ◆ Out of calibration
 - ◆ Out of calibration investigation
 - ◆ Out of service
13. **Documentation**
 - ◆ Calibration master log
 - ◆ Stickers
 - ◆ Certificate of Calibration
 - ◆ Retention times
14. **Wrap up activities**
 - ◆ Activity: *Equipment cleaning*
 - ◆ GMP quiz
 - ◆ Company problems