

## **203: Equipment and Calibration** **Medical Devices**

(Course length: 2.0 Hours, 32 Graphics, 55 Pages, \$1050)

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

### **Objectives**

- Explain the rationale for equipment design and selection
- Explain the requirements for appropriateness of equipment use
- State the requirements for equipment cleaning
- State the requirements for equipment maintenance
- State the requirements for equipment documentation
- Explain what is meant by control and test equipment
- Describe the requirements and process of calibration
- List the requirements for calibration documentation



### **Topics and Activities**

#### **1. Introduction**

- ◆ CGMP opener activity

#### **2. Regulations**

- ◆ Subpart G

#### **3. Design**

- ◆ Specified requirements
- ◆ Equipment selection
- ◆ Blueprints of process
- ◆ Control devices
- ◆ Validation and qualification

#### **4. Filters**

- ◆ HEPA Filters

#### **5. Use**

- ◆ Procedures
- ◆ Training

#### **6. Cleaning**

- ◆ Procedures
- ◆ Sources of contamination
- ◆ Levels of cleaning
- ◆ Equipment cleaning log
- ◆ Work orders and repair orders

#### **7. Maintenance**

- ◆ Work orders and repair orders on finished devices
- ◆ Logs
- ◆ Identification requirement and exceptions

#### **8. Calibration**

- ◆ Purpose
- ◆ Key elements
- ◆ Measurement frequency
- ◆ Timing
- ◆ Standards
- ◆ Procedures
- ◆ Logs
- ◆ Consultants and outside firms

#### **9. Items to be calibrated**

- ◆ Production equipment
- ◆ Laboratory equipment
- ◆ Test equipment
- ◆ Process instrumentation
- ◆ Other items

#### **10. Calibration actions**

- ◆ Out of calibration actions
- ◆ Out of calibration investigations
- ◆ Out of service

#### **11. Documentation**

- ◆ Calibration master log
- ◆ Stickers
- ◆ Certificate of calibration
- ◆ Retention times
- ◆ Activity: Design a cleaning checklist

#### **12. Wrap-Up**