

## **202: Buildings and Facilities** **Medical Devices**

(Course length: 2.0 Hours, 37 Graphics, 69 Pages, \$675)

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

### **Objectives:**

1. State the requirements for proper facility design
2. Explain the importance of product, equipment, material and people flow in the facility
3. Describe the requirements for a dedicated space
4. Explain the function and techniques of environmental monitoring
5. Explain the controls and specifications for utilities
6. Explain the value of proper housekeeping



### **Topics and Activities**

#### **1. Introduction**

#### **2. GMP opener activity**

#### **3. Space and Design**

- ◆ Production and process control elements
- ◆ Production and process control buildings
- ◆ Sufficient space defined
- ◆ Design and construction features
- ◆ General areas
- ◆ Appropriate space – safety
- ◆ Separate facilities

#### **4. Product Flow**

- ◆ Product
- ◆ Equipment
- ◆ Material
- ◆ People

#### **5. Designated Spaces**

- ◆ Receiving inspection space
- ◆ Storage environment
- ◆ Laboratory
- ◆ Work in process
- ◆ Reject space
- ◆ Quarantine space
- ◆ Restricted or limited space

#### **6. Environmental Monitoring**

- ◆ Rationale
- ◆ Methods
- ◆ Parameters
- ◆ Demonstrated control

#### **7. Utilities**

- ◆ Overview
- ◆ Lighting
- ◆ HVAC
- ◆ Air system and processes
- ◆ Air pressure differential
- ◆ Air showers
- ◆ Classes of air
- ◆ Laminar flow work spaces
- ◆ Laminar flow hoods
- ◆ Biological safety cabinets
- ◆ HEPA Filters
- ◆ Computerized air control
- ◆ Plumbing
- ◆ Classes of water
- ◆ Water for injection
- ◆ Air breaks
- ◆ Facility system alarms
- ◆ Waste neutralization
- ◆ Refuse and trash
- ◆ Hazardous waste
- ◆ Maintenance

#### **8. Housekeeping**

- ◆ Washing and toileting facilities
- ◆ Work space
- ◆ Levels of cleaning
- ◆ Pest control
- ◆ Pest control suggestions
- ◆ Activity: Facility Design

#### **9. Wrap-Up**