

202: Buildings and Facilities Pharmaceutical and Biotechnology

(Course length: 1.5 Hours, 32 Graphics, 62 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 and GMP opener activity

2. Space and Design

- ◆ Design and constructions features
- ◆ Sufficient space defined
- ◆ Defined areas
- ◆ General areas
- ◆ Appropriate space
- ◆ Separate penicillin facilities

3. Product Flow

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

4. Designated Spaces

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

5. Environmental Monitoring

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

6. Utilities

- ◆ Lighting
- ◆ HVAC
- ◆ Air systems and processes
- ◆ Air pressure differential
- ◆ Air pressure differential and personnel
- ◆ Air classification
- ◆ Laminar flow
- ◆ HEPA filters
- ◆ Computerized air systems
- ◆ Plumbing
- ◆ Classes of water
- ◆ Air breaks
- ◆ Facility alarms
- ◆ Refuse and trash
- ◆ Hazardous waste
- ◆ Maintenance

7. Housekeeping

- ◆ Washing and Toilet facilities
- ◆ Work space and levels of cleaning
- ◆ Pest control and suggestions

8. Wrap up

- ◆ GMP quiz
- ◆ Company problems
- ◆ GMP closer and wrap up activities