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# Buildings and Facilities

## ***Purpose***

The purpose of this module is to raise relevant GMP issues as they relate to the design, construction, cleaning and maintenance of buildings and facilities for pharmaceutical manufacturing.

## **Objectives**

At the completion of the class, managers and executives will be able to:

1. Identify design and function requirements.
2. Explain workflow and traffic.
3. Describe environmental monitoring considerations.
4. Explain housekeeping requirements.
5. Describe common pest control practices.
6. Explain the requirements for cleaning.
7. Explain the requirements for building and facility maintenance.
8. Describe the critical tools for conducting a root cause analysis.
9. Define the essential components and options of a deviation investigation report.
10. Explain the new approach to validation in light of risk assessment.
11. Explain the new direction of change control and regulatory filings.

## ***Prerequisite***

None

## ***Who should attend this course?***

This class is targeted to maintenance and engineering groups, quality assurance, and supervisors and managers who have responsibility for the design, use, cleaning, and maintenance of buildings and facilities.

## ***Intent of the class***

This course is intended for training purposes only and is not a substitute for technical recommendations, regulatory or legal advice. These materials are intended to raise compliance issues for further discussion at your company. It is recommended that you consult appropriate authorities for specific recommendations and advice.

***Class Length:*** This time does not include testing time.

*75 Minutes in 9 segments*

## ***On-site Options***

This class can be taught with a live instructor at your company. Call for details.

## Topics Covered

### Introduction

1. Regulatory observations relating to building and facilities

### Space and Design

1. Facility location
2. Suitable space
3. Physical separation
4. Layout
5. Placement of equipment
6. Location of equipment
7. Work flow
8. Product flow
9. One and two-way flow
10. Security
11. Access and control
12. Penicillin facilities

### Suitable Construction

1. Walls
2. Floors
3. Windows
4. Doors
5. Piping

### Defined Spaces

1. Separate or defined
2. Shipping and receiving
3. Storage
4. Warehousing
5. Weighing and dispensing
6. Staging area
7. Manufacturing
8. On-line testing
9. Packaging
10. Label control
11. Locker rooms
12. Rest rooms
13. Quarantine
14. Work in progress
15. Reject area
16. Laboratories
17. Hazardous materials holding

### Utilities: Electricity and Air

1. HVAC Equipment locations
2. Lighting and electricity
3. HVAC
4. Design documentation
5. Procedures and training
6. Qualification
7. Air intake and exhaust
8. Dust collection
9. Vapor and fume handling
10. USP Storage
11. Temperature and humidity
12. Air pressure differentials
13. Negative pressure uses
14. Classes of air: US, EU, ISO
15. Air showers
16. Laminar flow
17. HEPA Filters

### Utilities: Water

1. Requirements
2. Water systems
3. Classes of water
4. Water pre-treatment
5. Water storage and distribution construction
6. Water storage and distribution methods
7. Water storage and distribution systems
8. Water storage and distribution specifications
9. Water distribution piping
10. Steam
11. Chilled water
12. Drainage systems
13. Air breaks and check valves

### Other Utilities

1. Gas systems
2. Automation systems
3. Fire protection
4. Pest control goals and objectives
5. Pest control suggestions

### Cleaning and Maintenance

1. Cleaning and maintenance
2. Refuse removal
3. Levels of cleaning
4. Work area cleaning
5. Clean in Place, Sterilize in Place, Steam in Place
6. Computer system and software
7. Computer system and software procedures

### Environmental Monitoring

1. Rationale
2. Basic principles
3. Methods
4. Parameters
5. Demonstrated control