

Course Description

This one-day training event will provide participants with an overview of current industry regulations and industry expectations for working in and monitoring a cleanroom environment. Basic principles surrounding proper aseptic behavior and technique will also be reviewed in class.

Utilizing good aseptic techniques and developing a robust monitoring program are critical to maintaining classified space status. The day will culminate with a presentation on Classified Space Cleaning and Disinfection. We will demonstrate best practices for cleaning order of operations and techniques.

Note: Coffee, water, drinks, snacks, and lunch will be provided for on-site training.

Time	Agenda
9:00 – 9:15 AM	Welcome & Introductions
9:15 – 10:45 AM	The Origin and Importance of cGMP
10:45 – 11:00 AM	Break
11:00 – 12:00 PM	Overview of cGDocP and Data Integrity
12:00 – 1:00 PM	Lunch
1:00 – 1:45 PM	Contamination Control
1:45 – 2:45 PM	Aseptic Behavior and Techniques
2:45 – 3:00 PM	Break
3:00 – 4:30 PM	Classified Space Cleaning and Disinfection
4:30 – 5:00 PM	Questions and Wrap-Up



Module

Learning Objectives

The Origin and Importance of cGMP

- Define GMP and review the historical cases that led to current regulations
- Discuss the Code of Federal Regulations (CFR) and consequences of non-compliance
- Review cGMP violations and US FDA 483's / Warning Letters pertaining to GMP violations
- Discuss Quality Systems and how they align with GMP regulations / requirements

Overview of cGDocP and Data Integrity

- Define GDocP and the importance of compliance
- Discuss and distinguish types of documents found in a GMP environment
- Identify requirements for record keeping, including entering and correcting data
- Review data integrity importance and the data life cycle
- Define ALCOA+ principles and application to both paper and electronic records
- Discuss significant data integrity issues
- Distinguish electronic signature and records as well as and the importance of audit trails
- Review controls to minimize DI issues

Contamination Control

- Define contamination and distinguish the different types (i.e., viable, non-viable, cross contamination)
- Discuss sources of contamination and factors of microbial growth
- Review the history of cleanrooms and classifications
- Describe the methods to minimize contamination through engineering, procedural, and behavioral controls

Aseptic Behavior and Techniques

- Explain the basic differences between aseptic processing and terminal sterilization
- Distinguish between isolation technologies and open vs. closed systems
- Discuss the importance of proper health and hygiene practices for personnel who work in cleanrooms
- Review key cleanroom behaviors utilized to prevent contamination
- Discuss key principles of aseptic technique including critical areas and surfaces, first air rule, aseptic connections, and working with pipettes

Classified Space Cleaning and Disinfection

- Discuss the importance of having an approved, effective cleaning program combined with an environmental monitoring (EM) program
- Describe surfactants, disinfectants, and sporicidal agents and when they should be used
- Describe the proper flow of cleaning
- Discuss the importance of wiping surfaces with unidirectional strokes or other approved techniques
- Review industry standard materials used for cleaning (non-shedding wipes, wall mops, etc.)
- Discuss material transfer in relation to cleaning