

Itinerary

This five-day event walks participants through the necessary coursework and activities to prepare for working in an aseptic processing environment. Trainers will lead participants through classroom training and hands-on activities to teach critical concepts regarding:

- Contamination Control
- Personnel / Environmental Monitoring
- Laboratory / Cell Process Overview
- Aseptic Operations
- Ancillary Systems

Participants practice the skills and techniques covered throughout the course modules while being guided by training professionals. Students gain a level of comfort and muscle-memory prior to putting these learned skills to use in an aseptic process. The workshop culminates with a demonstration of critical learned skills.

Day 1 – Contamination Control Foundation

Time	Agenda
9:00 – 9:30 AM	Welcome & Introductions
9:30 – 10:00 AM	Introduction to Aseptic Processing
10:00 – 10:15 AM	Break
10:15 – 12:00 PM	Contamination Control – Basics and Methods
12:00 – 1:00 PM	Lunch
1:00 – 2:30 PM	Aseptic Behavior & Techniques
2:30 – 2:45 PM	Break
2:45 – 4:30 PM	Gowning & Gloving Overview / Practice*
4:30 – 5:00 PM	Assessment of Day 1 Material / Q&A

* Denotes hands-on activities

Day 2 – Personnel / Environmental Monitoring Overview

Time	Agenda
9:00 – 9:30 AM	Review of Day 1
9:30 – 10:45 AM	Environmental Monitoring (EM) Overview
10:45 – 11:00 PM	Break
11:00 – 12:30 PM	MOCK Gowning / Gloving Demonstration Activity*
12:30 – 1:30 PM	Lunch
1:30 – 2:30 PM	MOCK Gowning / Gloving Practice Activity (Cont.)*
2:30 – 2:45 PM	Break
2:45 – 4:30 PM	Environmental Monitoring Techniques Activity* Viable and Non-Viable*
4:30 – 5:00 PM	Assessment of Day 2 Material / Q&A

Day 3 – Laboratory / Cell Process Overview

Time	Agenda
9:00 – 9:30 AM	Review of Day 2
9:30 – 10:30 AM	Lab Equipment and Safety Overview
10:30 – 10:45 AM	Break
10:45 – 12:30 PM	Equipment Demonstration and Activity*
12:30 – 1:30 PM	Lunch
1:30 – 2:30 PM	Cellular Process Theory
2:30 – 2:45 PM	Break
2:45 – 4:30 PM	Cell Culture Activity*
4:30 – 5:00 PM	Assessment of Day 3 Material / Q&A

Day 4 - Aseptic Operations

Time	Agenda
9:00 – 9:30 AM	Review of Day 3
9:30 – 10:30 AM	Cleaning, Disinfection, & Line Clearance Activity*
10:30 – 10:45 AM	Break
10:45 – 12:00 PM	Aseptic Techniques Within BSCs/LFHs
12:00 – 1:00 PM	Lunch
1:00 – 2:30 PM	Aseptic Connections
2:30 – 2:45 PM	Break
2:45 – 4:30 PM	Visual Inspection and Sample Handling Activity*
4:30 – 5:00 PM	Assessment of Day 4 Material / Q&A

Day 5 - Critical Ancillary Systems

Time	Agenda
9:00 – 9:30 AM	Review of Day 4
9:30 – 10:30 AM	Equipment Metrology, Maintenance, Validation, & Change Control
10:30 – 10:45 AM	Break
10:45 – 11:45 PM	Deviations & CAPAs Overview
11:45 – 12:45 PM	Lunch
12:45 – 1:45 PM	Media Fill Overview
1:45 – 2:45 PM	Interventions Activity*
2:45 – 4:30 PM	Assessment of Day 5 Material / Exam*
4:30 – 5:00 PM	Final Q&A / Wrap Up

Module

Learning Objectives

Various Activity*

- Practice techniques taught in course presentations.
- Ask questions regarding techniques, as needed.

Intro to Aseptic Processing

- Define aseptic processing and discuss what makes it critical.
- Overview of the history of aseptic processing.
- Review similarities and differences of open vs. closed systems / aseptic processing vs. terminal sterilization.
- Determine acceptable use of aseptic processing.

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 the classification process.
- 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 events.
- Discuss key principles of aseptic technique including critical areas and surfaces, first air rule, specific connections and working with pipettes.

Visual Inspection and Sample Handling

- Identify potential flaws before, during, and after the filling process.
- Discuss the process of taking samples during and after production and the storage needs

Environmental Monitoring (EM) Overview

- Review room classifications and the allowable concentration limits for particulates and microbial contaminants.
- Define regulatory expectations of an EM program.
- Discuss the theory behind developing an EMPQ (Environmental Monitoring Performance Qualification).
- Review considerations for selecting media, defining incubation parameters, and performing growth proficiency testing (GPT).
- Discuss the importance of a robust data set in an EM program and the expectations for data trending.
- Review and demonstrate different methods and best practices for sampling (particulate readers, air samplers, contact/settle plates).

Module

Learning Objectives

Gowning & Gloving Overview / Practice

- Practice aseptic gowning / gloving techniques following the checklist of required steps.
- Review the current methodology to prove successful gowning, utilizing a qualification process.
- Move to the cleanroom to gown / glove aseptically and experience being sampled (not full qualification).

Lab Equipment and Safety Overview

- Review common laboratory equipment used in an aseptic processing environment, including micropipettes, serological pipettes, cell counters, and WAVE bioreactor systems.
- Discuss laboratory and material handling safety with a focus on BSL2 environments.
- Practice using a variety of common laboratory equipment to gain a level of comfort and develop muscle memory.

Cellular Process Theory

- Describe the stages of cellular process including collection, editing, expansion, harvesting, and cryopreservation.
- Discuss common techniques utilized in cell processing.
- Describe various trends in cell and regenerative therapies being developed or already on the market.

Aseptic Techniques within Biological Safety Cabinets (BSCs)/Laminar Flow Hoods (LFHs)

- Describe the different classes of BSCs/LAFs and how they can be utilized.
- Discuss the importance of aseptic technique as it applies to contamination control and maintaining proper airflow.
- Demonstrate several techniques critical to aseptic operation, from material transfer to setting up a workstation within a BSC/LAF.
- Review the significance of a regular cleaning and maintenance schedule.

Equipment Metrology, Maintenance, Validation, & Change Control

- Describe these supporting programs and how they relate to the lab.
- Discuss the importance of keeping lab and manufacturing equipment maintained, calibrated, and qualified.
- Once qualified – how are they kept compliant?
- What is Change Control and how does it apply to lab equipment?

Media Fill Overview

- Describe the objectives of a media fill or aseptic processing simulation (APS).
- Discuss the importance of a media fill for aseptic processing as described in both regulations and industry guidance docs.
- Demonstrate critical parameters and interventions commonly seen in media fills for manual aseptic processing.
- Review the roles involved in a media fill and discuss their responsibilities.

Module

Learning Objectives

Deviations & CAPAs Overview

- Define a deviation and discover what role each division plays in a deviation management system.
- Discover the impact a deviation can have on both the site and the patients.
- Define CAPA and explain how incidents are prioritized based on potential risk and product impact.
- Understand the importance of conducting thorough investigations and closing them in a timely manner.
- Discuss steps that can be taken to reduce the recurrence of deviations

Assessments of Day's Material

- Successfully complete the written assessment provided on the topics from the current day