Sterile Compounding Boot Camp® Live Training Series

Sterile Compounding Aseptics Class for Noncompounding Personnel (Compounding Quality)

This live training may be taken alone or in conjunction with the "Best Practices for Nonhazardous Sterile to Sterile Compounding" offering for individuals in pursuit of either the QP503A, CO (Compounding Operations) or the QP503A, CQ (Compounding Quality) credentials. The QP503A, CO is for personnel who work to perform or directly manage sterile compounding whereas the QP503A, CQ credential is a new offering in 2020 intended for persons who work in sterile compounding management or quality functions but who do NOT directly perform compounding. Personnel may earn both designations but doing so would require attending Day 2 of the Aseptics Class. The first time to take the compounding operations portion and the next time to take the compounding quality portion, which run concurrently.

Day 1

Time	Description of Session	Learning Objectives (for CE Sessions)
8:00-8:30 pm	*Welcome, Housekeeping, and Program Overview*	
8:30-10:15 am	Critical Elements of Aseptic Technique	• Recite basic definitions that apply to aseptic processing. • List elements of proper conduct in controlled environments, staging of supplies, organization of work area and resanitization of gloves. • Describe proper use of first air in both vertical and horizontal airflow. • Explain how to access and manipulate syringes, needles, ampules, vials, bags and other compounding supplies. • Discuss the use and integration of emerging technologies into ISO classified spaces and their impact on first air and aseptic technique work practices.
10:15-10:30 am	*Break: Students who need to can take time to determine their proper sterile glove size*	
10:30-11:45 am	Review of Best Practices for Hand Hygiene and Garbing for Nonhazardous Sterile Compounding	• Correctly sequence best practice activities associated with hand hygiene and garbing for nonhazardous sterile compounding. • Discuss garbing nuances and rationale.
11:45-12:30 pm	*Lunch*	

Day 1 (continued)

Time	Description of Session	Learning Objectives (for CE Sessions)
12:30-1:00 pm	Considerations and Best Practices for Media-Fill Testing	• Define the requirements for media-fill testing outlined in USP 797 (2019). • Describe best practices and desired nuances related to media-fill testing. • Examine the steps of the media-fill test that will be performed in the lab and for the competency verification later in the class.
1:00-1:15 pm	*Break* (move to conference room for rest of class)	
1:15-3:15 pm	Quality Systems in Sterile Compounding	• Outline the required and desired elements of quality systems. • Describe the role of the quality agent and their relationship to production. • Describe how to best evaluate compounder performance and complete documentation.
3:15-4:30 pm	Observation of Garbing and Aseptic Processing	• Use competency evaluations to perform observation of garbing and aseptic processing.
4:30-5:00 pm	*Summary, Observations and Q/A; Also review of requirements for those trying to earn the QP503A, CO credential; timing on the post test availability, expectations about sampling results; study resources*	

Day 2

8:00-8:15 am	*Welcome and Introduction to the Day*
8:15-11:30 am	***Paired Competency Verification (No CE for Testing Sessions)*** **1.** Paired with faculty, perform hand hygiene and garbing competency verification and obtain 1 initial GFS sample of person being tested and complete competency verification documentation. **2.** Observational Aseptic Technique Competency; Preparation of 3 media-fill units (MFUs); at the conclusion of MFU preparation, 1 instance of subsequent GFS and 1 surface sampling and complete competency verification documentation **3.** Testing Stations: a. Visual Inspection: Identification of Defects in Syringe CSPs b. Visual Inspection: Identification of Defects in Bag CSPs c. Review of Master Formulation Record: Identification of Incorrect or Missing Elements d. Observation of video to identify incorrect or undesirable aseptic technique

As each student finishes the competencies, MFUs, SS and GFS, the faculty will let each student know if they passed their observational competencies. Make certain you take the post test within 30 days of attending the live training class.

Total 6.75 CE hours