Sterile Compounding Boot Camp® Virtual Training Series
Best Practices for Nonhazardous Sterile-to-Sterile Compounding Live Virtual Course (14.5 CE hours)
Included and required eLearning precourse curriculum found after the Live Virtual agenda listing

Day 1: 10:00 AM to 3:00 PM Eastern

Time	Name of Live Activity	Learning Objectives (for CE Sessions)
10:00–11:00 AM	Introduction, explanation about course, overview of course goals, introductory activity for group	Each Live vCourse participant will introduce themselves: name, organization, state, specific areas of interest relative to course topics, and one interesting personal fact.
11:00 AM–Noon	Contamination Control: Engineering and Work Practice Principles	• Define microbial state of control as the overall goal of facility maintenance in sterile compounding practice. • List engineering-related contamination-control principles of cleanroom suites and segregated compounding areas (SCAs). • List the three categories of work practices fundamental to contamination control.
Noon–12:45 PM	*Lunch*	
12:45–2:15 PM	Sterile-to-Sterile Compounding	• Identify situations that are "not compounding" and the new immediate-use category defined in USP 797 (2019), and contrast them with the 2008 requirements. • Differentiate between Category 1 and 2 BUDs described in USP 797 (2019) from the risk levels in the 2008 USP 797 (currently enforceable). • Compare and contrast the 2008 versus 2019 requirements for the use of commercially available SDCs, MDCs, and pharmacy bulk packages. • Contrast drug-strength testing with stability-indicating methods for drug stability. • Define compounding records versus master formulation records, and describe CriticalPoint best practices for their implementation. • Describe quality release testing for nonhazardous sterile-to-sterile compounding.
2:15–3:00 PM	Summary of the day; questions and answers as well as discussion about the information covered in this day's session	

CE for the day: 2.5 hours

Day 2: 10:00 AM to 2:30 PM Eastern

Time	Name of Live Activity	Learning Objectives (for CE Sessions)
10:00–11:15 AM	Secondary Engineering Controls for Nonhazardous Sterile Compounding	• Describe the functions of SECs used for nonhazardous sterile compounding, and list the USP 797 requirements of each. • Explain how proper facility design facilitates the maintenance of a state of control. • Differentiate between ISO 5, 7, and 8 area cleanliness and particulate counts. • Explain the rationale for and apply best practice design elements to your compounding facility.
11:15 AM–12:30 PM	Contamination Control: Hand Hygiene and Garbing	• Properly sequence the activities of hand hygiene and garbing for nonhazardous sterile compounding in your facility based on the location of the sink. • Differentiate between the garbing requirements of USP 797 2008, USP 797 2019, and best practice recommendations.
12:30–1:15 PM	*Lunch*	
1:15–1:45 PM	Contamination Control: Material Handling	• Differentiate between the USP 797 2008, USP 797 2019, and best practice material-handling recommendations. • Integrate contamination-control best practices into your own facility SOPs and work practices. • Describe strategies for staging batches and patient preps not addressed by USP 797.
1:45–2:30 PM	Summary of the day; questions and answers, as well as discussion about the information covered in this day's session	

CE for the day: 3 hours

Day 3: 10:00 AM to 1:45 PM Eastern

Time	Name of Live Activity	Learning Objectives (for CE Sessions)
10:00–10:30 AM	Initial Gloved Fingertip Sampling	• Describe the difference between solid and liquid media, and identify what each is used for by sterile compounding organizations. • Identify and explain the critical components of a certificate of analysis. • List the conditions and steps to successful initial GFS. • Differentiate between the minimum requirements and best practice recommendations for personnel sampling. • Implement necessary corrective actions and additional training in the event of initial GFS failures.
10:30–11:30 AM	Primary Engineering Controls for Nonhazardous Sterile Compounding	• Differentiate between nonhazardous PECs, and identify airflow characteristics of each. • Differentiate between unidirectional and turbulent airflow, and describe how to determine whether a PEC is appropriate for sterile compounding. • Describe factors important for proper integration of PECs into facilities to ensure optimum workflow and equipment functionality. • Discuss appropriate applications and limitations of the PECs used for sterile compounding. • Explain HEPA filtration and how it applies to the principles of airflow. • Apply airflow principles to compounding, and describe how proper aseptic technique relates to first air.
11:30 AM–12:15 PM	*Lunch*	
12:15–1:15 PM	Aseptic Work Practice Review	• Define segregation and area clearance and how these concepts improve patient safety and reduce the potential for error. • List the “dos and don’ts” of worker conduct both inside the perimeter of the SCA and inside of the cleanroom suite. • Describe the care/maintenance of the staging cart and the proper way to move items from the staging cart into the PEC. • List the influences on first air and how proper ergonomics, setup of supplies, and aseptic work practices reduce the risk of contamination. • Describe a best practice strategy for removing finished CSPs from the compounding area.
1:15–1:45 PM	Summary of the day; questions and answers as well as discussion about the information covered in this day’s session	

CE for the day: 2.5 hours

Day 4: 10:00 AM to 2:45 PM Eastern

Time	Name of Live Activity	Learning Objectives (for CE Sessions)
10:00–10:45 AM	Media-Fill Testing and Subsequent Gloved Fingertip Sampling	• Describe under what conditions surface sampling becomes a personnel metric rather than an environmental metric. • Differentiate between the minimum requirements and best practice recommendations for personnel sampling. • Summarize the importance of personnel and process media-fill testing as verification of the aseptic-technique skills of staff and the compounding process. • Define the design requirements of a personnel aseptic media-fill and media-process verification. • Describe the best practice integration of media-fill testing, surface sampling, and subsequent GFS. • Implement necessary corrective actions and additional training in the event of media-fill or GFS failures.
10:45–11:00 AM	*Break*	
11:00 AM–12:15 PM	Sterility and Bacterial Endotoxin Testing and Overview of Rapid Microbial Testing	• Describe the difference between direct inoculation and membrane filtration USP 71 sterility testing, and list the benefits of using membrane filtration. • Identify the user-requirement specifications of rapid testing and how they relate to taking a risk-based approach to rapid sterility testing. • Evaluate the need to perform bacterial endotoxin testing on CSPs prepared in your organization.
12:15-1:00 PM	*Lunch*	
1:00–2:00 PM	Testing and Certification of PECs and SECs	• Describe the role certification plays in ensuring patient safety. • Summarize documentation requirements of applicable certification tests. • Navigate and identify the essential details of a certification report. • Request best practice reporting components from your certifier to ensure your facility receives a comprehensive certification report. • Discuss certification testing, and confidently communicate with the certification technician and facilities personnel.
2:00–2:45 PM	Summary of the day; questions and answers, as well as discussion about the information covered in this day's session	

CE for the day: 3 hours

Day 5: 10:00 AM to 3:15 PM Eastern

Time	Name of Live Activity	Learning Objectives (for CE Sessions)
10:00–11:30 AM	Sanitization of Sterile Compounding Primary and Secondary Engineering Controls	• Differentiate between the requirements of USP 797 2008, USP 797 2019, and best practices for sanitization. • Discuss principles related to the selection and use of cleaning agents and supplies. • Properly sequence critical activities of daily and monthly cleaning. • List personnel safety, training, and competency considerations. • Describe SOP and documentation requirements.
11:30–11:45 AM	*Break*	
11:45 AM–12:45 PM	Environmental Monitoring	• Outline a model ongoing-EM program, including the identification of baseline and action levels of microbial growth. • List the conditions and steps to conduct viable air and surface sampling. • Explain the proper use of equipment and supplies for air and surface sampling. • Identify the chapter requirements for investigating an exceeded action level.
12:45–1:30 PM	*Lunch*	
1:30–2:30 PM	Quality Systems for Sterile Compounding	• Define quality assurance and quality control, and develop essential elements of a formal QA/QC system for your organization. • List steps for notification and recall of out-of-specification dispensed CSPs. • Develop a comprehensive, systematic, and written complaint-handling system. • Describe the role of personnel training as it relates to quality assurance. • Summarize how SOPs, documentation, and a change control system are critical to USP 797 compliance.
2:30-3:15 PM	Summary of the day; questions and answers as well as discussion about the information covered in this day's session	

CE for the day: 3.5 hours

eCourse to be Completed Before Attending Live Virtual Training
Fundamentals of Sterile Compounding *(8 lessons/8 hours CE)*

The History of Compounding and USP Sterile Compounding Chapters (1 hour)
- Explain the evolution of pharmacy compounding guidelines up to present-day USP Chapter 797 (2019).
- Describe the roles of the USP and the FDA concerning standards and enforcement.
- Exhibit increased awareness of pharmacy compounding guidelines as they impact your daily decisions while performing sterile compounding activities.
- Describe relevant regulatory requirements associated with compounding.

Determining Beyond-Use Dating (1 hour)
- Describe situations that are not considered compounding.
- Differentiate expiration from beyond-use dates.
- Explain the immediate-use provision in USP 797 (2019).
- Discuss the conditions that influence the beyond-use date (BUD) assignment.
- Define the two categories described in USP 797.
- Describe conditions that differentiate the storage conditions for each category.
- List the use and maximum beyond-use dating for conventionally manufactured products and pharmacy prepared single-dose and multiple-dose containers.

Quality Releases and Final Checks of CSPs (1 hour)
- Identify the purpose of quality release checks.
- List the specific types of quality release checks.
- Explain how to recognize a failed quality release check.
- Describe how the environment and compounders can impact the quality of compounded sterile preparations (CSPs).
- Discuss the release inspections and testing per USP 797 (2019).

Labeling and Packaging (1 hour)
- Identify the required elements of a final compounded sterile preparation (CSP) label.
- Discuss the importance of standardization in labeling.
- Explain considerations for positioning and adhering the label to the final CSP.
- State when to perform final labeling.
- Explain how to properly store and package the final CSP containers.

Master Formulation and Compounding Records (1 hour)

- Identify the key differences between a Master Formulation Record (MFR) and a Compounding Record (CR).
- Describe and explain the purpose of USP 797 (2019) requirements relative to compounding documentation.
- List the circumstances that require the use of an MFR based on USP 797 as well as best practice recommendations about MFRs.
- Develop a plan to implement this compounding documentation at your pharmacy.

Purpose and Effective Use Standard Operating Procedures (1 hour)

- Identify the characteristics of effective standard operating procedures (SOPs).
- List the USP 797 (2019) requirements for SOPs.
- Discuss the content, format, and control of SOPs.

General Elements of Documentation (1 hour)

- Review the required documentation elements of USP 797 (2019).
- List the purposes of documentation.
- Identify elements of good documentation.
- List documentation “Do’s” and “Don’ts.”
- Identify characteristics of effective forms.
- Describe documentation audits.

Use of Automated Compounding Devices (1 hour)

- Contrast the operation of gravimetric and volumetric automated compounding devices (ACDs).
- Describe ACD daily setup, calibration, and cleaning requirements.
- Discuss concerns relative to tubing and source container changes.
- Describe the importance of staff training and competency verification.
- List USP 797 (2019) requirements on the use and proper placement of ACDs.