

**Sterile Compounding Boot Camp® Virtual Training Series**  
**Best Practices for Nonhazardous Sterile-to-Sterile Compounding Live Virtual Course (18.75 CE hours)**  
**Included and required eLearning precourse curriculum found after the Live Virtual agenda listing**

**Day 1: 10:00 AM to 3:15 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	<ul style="list-style-type: none"> <li>• Define microbial state of control as the overall goal of facility maintenance in sterile compounding practice.</li> <li>• List engineering-related contamination-control principles of cleanroom suites and segregated compounding areas (SCAs).</li> <li>• List the three categories of work practices fundamental to contamination control.</li> </ul>
Noon–12:30 PM	<i>Lunch</i>	
12:30–2:30 PM	Sterile-to-Sterile Compounding	<ul style="list-style-type: none"> <li>• Identify situations that are “not compounding” and the new immediate-use category defined in USP 797 (2019), and contrast them with the 2008 requirements.</li> <li>• Differentiate between Category 1 and 2 BUDs described in USP 797 (2019) from the risk levels in the 2008 USP 797 (currently enforceable).</li> <li>• Compare and contrast the 2008 versus 2019 requirements for the use of commercially available SDCs, MDCs, and pharmacy bulk packages.</li> <li>• Contrast drug-strength testing with stability-indicating methods for drug stability.</li> <li>• Define compounding records versus master formulation records, and describe CriticalPoint best practices for their implementation.</li> <li>• Describe quality release testing for nonhazardous sterile-to-sterile compounding.</li> </ul>
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 hours**

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

Time	Name of Live Activity	Learning Objectives (for CE Sessions)
10:00–10:15 AM	Questions from previous day	
10:15–11:15 AM	Secondary Engineering Controls for Nonhazardous Sterile Compounding	<ul style="list-style-type: none"> <li>• Describe the functions of SECs used for nonhazardous sterile compounding, and list the USP 797 requirements of each.</li> <li>• Explain how proper facility design facilitates the maintenance of a state of control.</li> <li>• Differentiate between ISO 5, 7, and 8 area cleanliness and particulate counts.</li> <li>• Explain the rationale for and describe how to apply best practice design elements to your compounding facility.</li> </ul>
11:15–11:30 AM	<i>Break</i>	
11:30 AM–12:30 PM	Secondary Engineering Controls for Nonhazardous Sterile Compounding ( <i>continued</i> )	<ul style="list-style-type: none"> <li>• Same as above</li> </ul>
12:30–1:00 PM	<i>Lunch</i>	
1:00–2:15 PM	Contamination Control: Hand Hygiene and Garbing	<ul style="list-style-type: none"> <li>• Properly sequence the activities of hand hygiene and garbing for nonhazardous sterile compounding based on the location of the sink.</li> <li>• Differentiate between the garbing requirements of USP 797 2008, USP 797 2019, and best practice recommendations.</li> </ul>
2:15–2:30 AM	<i>Break</i>	
2:30–3:00 PM	Contamination Control: Material Handling	<ul style="list-style-type: none"> <li>• Differentiate between the USP 797 2008, USP 797 2019, and best practice material-handling recommendations.</li> <li>• Identify contamination-control best practices to integrate into your own facility SOPs and work practices.</li> <li>• Describe strategies for staging batches and patient preps not addressed by USP 797.</li> </ul>

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3:00-3:30 PM	Initial Gloved Fingertip Sampling	<ul style="list-style-type: none"> <li>• Describe the difference between solid and liquid media, and identify what each is used for by sterile compounding organizations.</li> <li>• Identify and explain the critical components of a certificate of analysis.</li> <li>• List the conditions and steps to successful initial GFS.</li> <li>• Differentiate between the minimum requirements and best practice recommendations for personnel sampling.</li> <li>• Explain necessary corrective actions and additional training in the event of initial GFS failures.</li> </ul>
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3:30-4:00 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: 4.25 hours**

**Day 3: 10:00 AM to 3:30 PM Eastern**

Time	Name of Live Activity	Learning Objectives (for CE Sessions)
10:00-10:15 AM	Questions from previous day	
10:15-11:30 AM	Primary Engineering Controls for Nonhazardous Sterile Compounding	<ul style="list-style-type: none"> <li>• Differentiate between nonhazardous PECs, and identify airflow characteristics of each.</li> <li>• Differentiate between unidirectional and turbulent airflow, and describe how to determine whether a PEC is appropriate for sterile compounding.</li> <li>• Describe factors important for proper integration of PECs into facilities to ensure optimum workflow and equipment functionality.</li> <li>• Discuss appropriate applications and limitations of the PECs used for sterile compounding.</li> <li>• Explain HEPA filtration and how it applies to the principles of airflow.</li> <li>• Correlate airflow principles to compounding, and describe how proper aseptic technique relates to first air.</li> </ul>
11:30-11:45 AM	<i>Break</i>	
11:45 AM-12:45 PM	Aseptic Work Practices Overview	<ul style="list-style-type: none"> <li>• Define segregation and area clearance and how these concepts improve patient safety and reduce the potential for error.</li> <li>• List the “dos and don’ts” of worker conduct both inside the perimeter of the SCA and inside of the cleanroom suite.</li> <li>• Describe the care/maintenance of the staging cart and the proper way to move items from the staging cart into the PEC.</li> <li>• List the influences on first air and how proper ergonomics, setup of supplies, and aseptic work practices reduce the risk of contamination.</li> <li>• Describe a best practice strategy for removing finished CSPs from the compounding area.</li> </ul>

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12:45–1:15 PM *Lunch*

1:15–2:15 PM PEC, SEC, and Aseptic Work Practices Lab

- Analyze the ideal sterile compounding facility design and workflow to ensure efficiency and compliant material transfer into the SEC.
- Evaluate dynamic airflow smoke-pattern test results and use the results to improve compounding technique and work practices.
- Identify proper hand positioning during compounding for both vertical and horizontal airflow PECs.
- Discuss proper transfer of components and supplies into the PEC.

2:15–3:00 PM 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.
- Explain necessary corrective actions and additional training in the event of media-fill or GFS failures.

3:00–3:30 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: 4 hours**

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**Day 4: 10:00 AM to 4:00 PM Eastern**

Time	Name of Live Activity	Learning Objectives (for CE Sessions)
10:00–10:15 AM	Questions from previous day	
10:15–11:45 AM	Testing and Certification of PECs and SECs	<ul style="list-style-type: none"> <li>• Describe the role certification plays in ensuring patient safety.</li> <li>• Summarize documentation requirements of applicable certification tests.</li> <li>• List required and best practice reporting components to ensure your facility receives a comprehensive certification report.</li> <li>• Discuss certification testing so that you can confidently communicate with the certification technician and facilities personnel.</li> </ul>
11:45 AM–12:15 PM	<i>Lunch</i>	
12:15–1:30 PM	Sterility and Bacterial Endotoxin Testing and Overview of Rapid Microbial Testing	<ul style="list-style-type: none"> <li>• Describe the difference between direct inoculation and membrane filtration USP 71 sterility testing, and list the benefits of using membrane filtration.</li> <li>• Identify the user-requirement specifications of rapid testing and how they relate to taking a risk-based approach to rapid sterility testing.</li> <li>• Explain the need to perform bacterial endotoxin testing on CSPs prepared in your organization.</li> </ul>
1:30–1:45 PM	<i>Break</i>	
1:45–3:15 PM	Sanitization of Sterile Compounding Primary and Secondary Engineering Controls	<ul style="list-style-type: none"> <li>• Differentiate between the requirements of USP 797 2008, USP 797 2019, and best practices for sanitization.</li> <li>• Discuss principles related to the selection and use of cleaning agents and supplies.</li> <li>• Properly sequence critical activities of daily and monthly cleaning.</li> <li>• List personnel safety, training, and competency considerations.</li> <li>• Describe SOP and documentation requirements.</li> </ul>
3:15–4:00 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: 4.25 hours**

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

Time	Name of Live Activity	Learning Objectives (for CE Sessions)
10:00–10:15 AM	Questions from previous day	
10:15–11:30 AM	Environmental Monitoring	<ul style="list-style-type: none"> <li>• Outline a model ongoing-EM program, including the identification of baseline and action levels of microbial growth.</li> <li>• List the conditions and steps to conduct viable air and surface sampling.</li> <li>• Explain the proper use of equipment and supplies for air and surface sampling.</li> <li>• Identify the chapter requirements for investigating an exceeded action level.</li> </ul>
11:30–11:45 AM	<i>Break</i>	
11:45 AM –12:45 PM	Quality Systems for Sterile Compounding	<ul style="list-style-type: none"> <li>• Define quality assurance and quality control, including essential elements of a formal QA/QC system for your organization.</li> <li>• List steps for notification and recall of out-of-specification dispensed CSPs.</li> <li>• Develop a comprehensive, systematic, and written complaint-handling system.</li> <li>• Describe the role of personnel training as it relates to quality assurance.</li> <li>• Summarize how SOPs, documentation, and a change control system are critical to USP 797 compliance.</li> </ul>
12:45–1:15 PM	<i>Lunch</i>	
1:15-2:15 PM	Case Study Lab	<ul style="list-style-type: none"> <li>• Apply USP 797 standards and CriticalPoint best practice recommendations to determine appropriate work practices and facility design.</li> <li>• Identify possible hand hygiene and garbing procedures based on the location of the sink.</li> <li>• Develop a robust material handling and sanitization program to ensure a microbial state of control.</li> <li>• Propose certification testing required for a cleanroom suite and LAFW.</li> </ul>
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: 3.25 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.