All times Eastern	Activity Title and Objectives *(with CE information)*
DAY 1 – All times Eastern	
9:00–10:00 AM	Introduction
10:00–10:45 AM	**Sterile Compounding Contamination Control 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. *ACPE UAN: JA0006454-0000-22-3026-L07-P/T; 0.75 credit hours; knowledge-based*
10:45–11:00 AM	Break
11:00 AM–12:15 PM	**Sterile-to-Sterile Compounding** • Identify situations that are "not compounding" and the new immediate-use category defined in USP 797 (2021) and contrast them with the 2008 requirements. • Differentiate between Category 1, 2, and 3 BUDs described in USP 797 (2021) from the risk levels in the 2008 USP 797 (currently enforceable). • Compare and contrast the 2008 versus 2021 requirements for the use of commercially available SDCs, MDCs, and pharmacy bulk packages. • Contrast drug-strength testing with stability-indicating methods for drug stability. • Describe quality release testing for nonhazardous sterile-to-sterile compounding. *ACPE UAN: JA0006454-0000-22-3030-L07-P/T; 1.25 credit hours; application-based*
12:15–1:00 PM	Lunch
1:00–1:30 PM	**Sterile Compounding Documentation** • Identify the USP 797 requirements for the label of a compounded sterile preparation (CSP). • Define compounding records versus master formulation records and describe CriticalPoint best practices for their implementation. • Compare written and electronic options for compounding documentation. • Describe quality documentation procedures when recording data on forms. *ACPE UAN: JA0006454-0000-22-3021-L07-P/T; 0.50 credit hours; knowledge-based*
1:30–3:00 PM	**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 describe how to apply best practice design elements to your compounding facility. *ACPE UAN: JA0006454-0000-22-3033-L07-P/T; 1.50 credit hours; application-based*
3:00–3:15 PM	Break
3:15–4:15 PM	**Lab: Design Review for USP 797 Compliance** • Identify facility designs that meet USP 797 requirements.

	• Discuss the design features that a sterile compounding pharmacy should consider when designing a facility for current and future needs. *ACPE UAN: JA0006454-0000-22-3023-L07-P/T; 1 credit hours; application-based*
4:15–5:15 PM	**Hand Hygiene and Garbing for Sterile Compounding** • Properly sequence the activities of hand hygiene and garbing for nonhazardous sterile compounding based on the location of the sink. • Differentiate between the garbing requirements of USP 797 2008, USP 797 2021, and best practice recommendations. *ACPE UAN: JA0006454-0000-22-3027-L07-P/T; 1 credit hours; application-based*
5:15–5:30 PM	Summary of the day

DAY 2 – All times Eastern

9:00–9:30 AM	**USP 797 Material Handling** • Differentiate between the USP 797 2008, USP 797 2021, and best practice material-handling recommendations. • Identify contamination-control best practices to integrate into your own facility SOPs and work practices. • Describe strategies for staging batches and patient preps not addressed by USP 797. *ACPE UAN: JA0006454-0000-22-3031-L07-P/T; 0.50 credit hours; knowledge-based*
9:30–10:30 AM	**USP 797 Personnel 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 and subsequent GFS and media-fill testing. • Differentiate between the minimum requirements and best practice recommendations for personnel sampling. • Explain necessary corrective actions and additional training in the event of GFS and media-fill test failures. *ACPE UAN: JA0006454-0000-22-3020-L07-P/T; 1 credit hours; application-based*
10:30–10:45 AM	Break
10:45–Noon	**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. • Correlate airflow principles to compounding and describe how proper aseptic technique relates to first air. *ACPE UAN: JA0006454-0000-22-3035-L07-P/T; 1.25 credit hours; application-based*
Noon–12:45 PM	Lunch

12:45–1:45 PM	**Aseptic Work Practices Overview for Sterile Compounding** • 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. *ACPE UAN: JA0006454-0000-22-3024-L07-P/T; 1 credit hours; application-based*
1:45–2:45 PM	**Lab: PEC, SEC, and Aseptic Work Practices** • 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. *ACPE UAN: JA0006454-0000-22-3028-L07-P/T; 1 credit hours; application-based*
2:45–3:00 PM	Break
3:00–4:15 PM	**Testing and Certification of PECs and SECs (USP 797)** • Describe the role certification plays in ensuring patient safety. • Summarize documentation requirements of applicable certification tests. • List required and best practice reporting components to ensure your facility receives a comprehensive certification report. • Discuss certification testing so that you can confidently communicate with the certification technician and facilities personnel. *ACPE UAN: JA0006454-0000-22-3022-L07-P/T; 1.25 credit hours; application-based*
4:15–4:30 PM	Summary of the day

DAY 3 – All times Eastern

9:00–10:00 AM	**Sterility and Bacterial Endotoxin Testing Specific to USP 797** • 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. • Explain the need to perform bacterial endotoxin testing on CSPs prepared in your organization. *ACPE UAN: JA0006454-0000-22-3032-L07-P/T; 1 credit hours; application-based*
10:00–10:15 AM	Break
10:15–11:30 AM	**Sanitization of Sterile Compounding PECs and SECs** • Differentiate between the requirements of USP 797 2008, USP 797 2021, 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. *ACPE UAN: JA0006454-0000-22-3025-L07-P/T; 1.25 credit hours; application-based*
11:30 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. *ACPE UAN: JA0006454-0000-22-3029-L07-P/T; 1.25 credit hours; application-based*
12:45–1:30 PM	Lunch
1:30–2:30 PM	**Quality Systems for Sterile Compounding** • Define quality assurance and quality control, including 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. *ACPE UAN: JA0006454-0000-22-3019-L07-P/T; 1 credit hour; application-based*
2:30–3:30 PM	**Lab: USP 797 Facility Design and Work Practices Case Study** • Apply USP 797 standards and CriticalPoint best practice recommendations to determine appropriate work practices and facility design. • Identify possible hand hygiene and garbing procedures based on the location of the sink. • Develop a robust material handling and sanitization program to ensure a microbial state of control. • Propose certification testing required for a cleanroom suite and LAFW. *ACPE UAN: JA0006454-0000-22-3034-L07-P/T; 1 credit hours; application-based*
3:30–3:45 PM	Summary

This program also requires the following self-study courses as pre-course work (will be added to your CriticalPoint LMS account after registration):

Fundamentals of Sterile Compounding (8 courses/each with 1 hour CE)

- History of Sterile Compounding
- Determining USP 797 Beyond-Use Dating
- Quality Releases and Final Checks for Sterile Compounding
- USP 797 CSP Handling: Staging through Transport
- Master Formulation and Compounding Records for Sterile Compounding
- Standard Operating Procedures for Sterile Compounding
- General Elements of Documentation for Sterile Compounding
- Use of Equipment and Integrating Technology for Sterile Compounding

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Target Learners: This activity is intended for pharmacists and pharmacy technicians in any practice setting.

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