Sterile Compounding Boot Camp® Virtual Training Series

Sterile Compounding Inspector Training Live Virtual Course for CISCI Certification (23.5 CE hours)

Inspectors trying for CISCI certification must complete entire Sterile Compounding eCurriclum (see CISCI certification documents)

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, state regulatory authority, 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 related to cleanroom suites and segregated compounding areas (SCAs). • List the three categories of work practices fundamental to contamination control. • List the elements of the 2019 version of USP 797, which may conflict with the currently enforceable 2008 version.
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 sterile-to-sterile nonhazardous 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 day: 2.5 hours

Day 2: 10:00 AM to 3:00 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 design elements to licensees.
11:15-11:30 AM	*Break*	
11:30 AM–1:00 PM	Contamination Control: Hand Hygiene and Garbing and Material Handling	• Differentiate between USP 797 2008, the 2019 revision, and best practice hand hygiene and garbing and material-handling requirements. • Evaluate the sequences and activities of hand hygiene and garbing for sterile, nonhazardous compounding, which may differ depending on the location of the sink. • Discuss the other factors that may influence the garbing order. • Describe desirable but not required operator conduct inside compounding areas.
1:00–1:45 PM	*Lunch*	
1:45–2:15 PM	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 key components of a certificate of analysis. • List the conditions and steps to successful initial GFS. • Recognize the necessary corrective actions and additional training that must occur in the event of initial GFS failures.
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

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

Time	Name of Live Activity	Learning Objectives (for CE Sessions)
10:00–11:00 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 appropriate 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.
11:00–11:45 AM	Aseptic Work Practice Review	• List the "dos and don'ts" of worker conduct inside the perimeter of the SCA and inside of the buffer room. • List the influences on first air and how proper ergonomics, setup of supplies, and aseptic work practices reduce the risk of contamination.
11:45 AM–12:30 PM	*Lunch*	
12:30–1:15 PM	Media-Fill Testing and Subsequent Gloved Fingertip Sampling	• Describe under what conditions surface sampling becomes a personnel metric rather than an environmental metric. • State the minimum requirements 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. • Evaluate if licensees have implemented proper corrective actions in the event of media-fill or GFS failures.
1:15–1:30 PM	*Break*	

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Day 3: 10:00 AM to 3:30 PM Eastern *(continued)*

	Name of Live Activity	Learning Objectives (for CE Sessions)
1:30–2:45 PM	Nonsterile-to-Sterile Compounding	• Contrast the compounding and BUD requirements of the USP 797 2019 and 2008 when licensees perform nonsterile-to-sterile compounding. • Describe methods of sterilization and requirements for each. • 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. • Determine when bacterial endotoxin testing is required, according to USP 797.
2:45-3:30 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: 3.75 hours

Day 4: 10:00 AM to 3:30 PM Eastern

Time	Name of Live Activity	Learning Objectives (for CE Sessions)
10:00–11:00 AM	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. • Discuss certification testing, and confidently communicate with the licensees.
11:00–Noon	Sanitization of Sterile Compounding Primary and Secondary Engineering Controls	• Differentiate between the requirements of USP 797 2008 and USP 797 2019 and best practices for sanitization. • Discuss principles related to the selection and use of cleaning agents and supplies. • Evaluate licensees' activities of daily and monthly cleaning. • List personnel safety, training, and competency considerations. • Describe SOP and documentation requirements.
Noon–12:45 PM	*Lunch*	
12:45–1:45 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.

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Day 4: 10:00 AM to 3:30 PM Eastern *(continued)*

Time	Name of Live Activity	Learning Objectives (for CE Sessions)
1:45–2:45 PM	Quality Systems for Sterile Compounding	• Define quality assurance and quality control, and evaluate USP 797 (2019) elements of a formal QA/QC system. • Summarize how SOPs, documentation, and a change control system are critical to USP 797 compliance.
2:45–3:30 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

Day 5: 10:00 AM to 3:30 PM Eastern

Time	Name of Live Activity	Learning Objectives (for CE Sessions)
10:00–10:45 AM	Pharmacy Inspection Guide	• Organize an inspection visit to ensure the most efficient and effective evaluation of sterile compounding practices. • Evaluate one potential method of structuring an inspection.
10:45–11:30 AM	What's Wrong with this Picture?	• Identify areas of noncompliance in images taken in real-life situations in sterile compounding pharmacies.
11:30 AM –Noon	Summary of the sterile nonhazardous course; final questions and answers	
Noon–12:45 PM	*Lunch*	
12:45–1:45 PM	Overview of USP 800 and HD Handling	• Cite examples of HD-exposure effects on persons who handle HDs. • Describe the location of resources regarding HD practice. • Recall common HD guidelines, standards, and regulatory and best practice events. • List the major elements of USP 800. • Differentiate between the scope of USP Chapters 795, 797, and 800. • Describe current issues related to USP Compounding Chapter enforceability and compendial applicability.
1:45–2:45 PM	Containment Secondary Engineering Controls (C-SECs): Cleanroom Suites and C-SCAs	• Describe the types of compliant C-SECs for nonsterile and sterile HD compounding. • Discuss considerations relevant to the use of pass-throughs in HD applications. • Analyze the allowable but suboptimal design of C-SECs and strategies used to compensate for such. • Describe the tests required for certification of C-SECs.
2:45-3:30 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: 3.5 hours

Day 6: 10:00 AM to 2:15 PM Eastern

Time	Name of Live Activity	Learning Objectives (for CE sessions)
10:00–10:45 AM	Containment Primary Engineering Controls (C-PECs)	• Describe the types of compliant C-PECs for nonsterile and sterile HD compounding. • Describe the tests required for certification of C-PECs.
10:45–11:45 AM	Donning, Doffing, and Types of Personal Protective Equipment (PPE)	• List USP 800 requirements for donning and doffing PPE. • List the best sequence in which to perform donning and doffing of HD PPE resulting in microbial protection of CSPs as well as HD containment and protection of the worker. • Make useful suggestions to licensees about effectively protecting workers and ensuring containment, since USP 800 does not include any "how-to" information.
11:45 AM–12:30 PM	*Lunch*	
12:30–1:30 PM	Work Practice Strategies for Receiving, Storing, Compounding, and Transporting HDs and HD CSPs	• List the practice elements essential to reducing the generation of HD contamination and the risk of exposure throughout the HD-use lifespan. • Correctly state USP 800 requirements for receiving, storing, compounding, and transporting HDs. • Assist licensees in implementing effective handling during compounding to ensure the final HD CSP container and packaging are free from HD contamination. • Evaluate safe transport procedures for HD inventory and final CSPs.
1:30–2:15 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: 2.75 hours

Day 7: 10:00 AM to 3:15 PM Eastern

Time	Name of Live Activity	Learning Objectives (for CE sessions)
10:00–11:00 AM	Elements and Practical Examples of Performing an Assessment of Risk (AoR)	• List which drugs may be exempted from full containment and work practices of USP 800. • Define the components required in an AoR. • Evaluate different approaches to the creation and maintenance of an AoR. • Discuss specific examples of AoR strategies from actual practice.
11:00 AM –Noon	Decontamination, Cleaning and Disinfection, an Residue Removal in HD Compounding Environments	• Define and differentiate the terms deactivation, decontamination, cleaning, disinfection, and sanitization. • Identify agents that may be used for decontamination of hazardous drugs. • Properly sequence decontamination, cleaning and disinfection, and application of sterile IPA in HD environments.
Noon–12:45 PM	*Lunch*	
12:45–1:15 PM	Response to HD Exposure and Spills	• List the required elements of an exposure-control and response plan and evaluate licensees for compliance. • Discuss the requirements for HD spill cleanup. • Describe the logistical and practical hurdles that can be encountered in implementing an effective spill management program. • List potential strategies for effective spill management.
1:15–2:30 PM	Design and Build Evaluation of Facilities Intended for Nonhazardous and Hazardous Compounding	• Evaluate sample layouts, and identify areas of concern relative to USP 797 and 800 compliance, the efficiency of workflow, and best practice considerations. • Revise sample layouts to ensure improved compliance, efficiency, and achievement of best practices.
2:30–3:15 PM	Summary of class; last questions and answers; review of post test requirements for CISCI certification	

CE for the day: 3.75 hours

Inspectors trying for SCIT certification are required to take entire Sterile Compounding Curriculum (34.5 hours) before attending Live Virtual training