Sterile Compounding Boot Camp®
Sterile Compounding Inspector Training for CISCI Certification

All Times Eastern	Activity Title and Objectives *(with CE information)*

Day 1 – All times Eastern

Introduction

8:00–9:00 AM — *Housekeeping and welcome exercise*

Contamination Control: Engineering and Work Practice Principles

9:00–10:00 AM

- 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: JA0006454-0000-22-3082-L07-P/T; 1 credit hour; application-based

10:00–10:15 AM — *Break*

Sterile-to-Sterile Compounding

10:15–11:45 AM

- Identify situations that are "not compounding" and the new immediate-use category defined in USP 797 (2022) and contrast them with the 2008 requirements.
- Differentiate between Category 1, 2, and 3 BUDs described in USP 797 (2022) from the risk levels in the 2008 USP 797.
- Compare and contrast the 2008 versus 2022 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.

ACPE UAN: JA0006454-0000-22-3083-L07-P/T; 1.5 credit hours; application-based

11:45 AM–12:30 PM — *Lunch*

Secondary Engineering Controls for Nonhazardous Sterile Compounding

12:30–1:45 PM

- 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: JA0006454-0000-22-3084-L07-P/T; 1.25 credit hours; application-based

Interactive Group Exercise

1:45–2:45 PM

- Determine the appropriate beyond-use dates a sterile compounding pharmacy can assign based on its facility design.
- Discuss the design features that a sterile compounding pharmacy should consider when designing a facility for current and future needs.

ACPE UAN: JA0006454-0000-22-3085-L07-P/T; 1 credit hour; application-based

2:45–3:00 PM	*Break*
Contamination Control: Hand Hygiene and Garbing and Material Handling	
3:00–4:30 PM	■ 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 2022, and best practice recommendations. *ACPE UAN: JA0006454-0000-22-3086-L07-P/T; 1.5 credit hours; application-based*
4:30–4:45 PM	*Summary*

Day 2 – All times Eastern

8:00–8:15 AM	*Welcome and introduction to the day*
Interactive Exercise: Hand Hygiene and Garbing and Material Handling	
8:15–9:15 AM	■ Describe best practice material staging using pass-throughs or cart exchange. ■ Practice the steps to successfully don sterile gloves. ■ Summarize the proper sequence for performing hand hygiene and garbing for nonhazardous sterile-to-sterile compounding when the sink is on the clean side of the line of demarcation. ■ Explain how to perform initial gloved fingertip sampling according to USP 797 requirements. *ACPE UAN: JA0006454-0000-22-3087-L07-P/T; 1 credit hour; application-based*
Initial Gloved Fingertip Sampling (GFS)	
9:15–9:45 AM	■ 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. ■ Explain necessary corrective actions and additional training in the event of initial GFS failures. *ACPE UAN: JA0006454-0000-22-3088-L07-P/T; 0.5 credit hours; knowledge-based*
9:45–10:00 AM	*Break*

Primary Engineering Controls for Nonhazardous Sterile Compounding

10:00–11:00 AM

- 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: JA0006454-0000-22-3089-L07-P/T; 1 credit hour; application-based

Aseptic Work Practices Overview

11:00–11:30 AM

- 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: JA0006454-0000-22-3090-L07-P/T; 0.5 credit hours; knowledge-based

11:30 AM–12:15 PM *Lunch*

Interactive Exercise: Aseptic Technique Demonstration and Video Evaluation

12:15–12:45 PM

- Differentiate between horizontal and vertical primary engineering controls.
- Predict how first air can be affected by the placement of materials in the direct compounding area (DCA).
- Explain the conditions needed to properly establish a DCA.
- Summarize the particle generation that can occur during sterile compounding and which material-handling strategies can minimize the impact of particles on CSPs.
- Discuss how transferring materials into and out of PECs impacts particle counts.

ACPE UAN: JA0006454-0000-22-3091-L07-P/T; 0.5 credit hours; knowledge-based

Interactive Exercises

12:45–2:15 PM **Interactive Exercise: Sterility Testing** *(45 minutes)*

- Describe when sterility testing is required and how licensees must determine the number of final CSPs and volume from each final CSP to send for sterility testing.
- Contrast sterility testing by membrane filtration following the requirements of USP 797 (per USP 71) with other methods that are often incorrectly employed in pharmacies.

ACPE UAN: JA0006454-0000-22-3092-L07-P/T; 0.75 credit hours; knowledge-based

Interactive Exercise: Bubble Point (Filter Integrity) Testing *(45 minutes)*

- Describe the conditions that require bubble point testing.
- List the required elements of documentation.
- Evaluate licensees for compliance with bubble point testing requirements

ACPE UAN: JA0006454-0000-22-3093-L07-P/T; 0.75 credit hours; knowledge-based

2:15–2:30 PM *Break*

Testing and Certification of PECs and SECs

2:30–3:30 PM

- 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: JA0006454-0000-22-3094-L07-P/T; 1 credit hour; application-based

Interactive Exercise: Certification Report Lab

3:30–4:30 PM

- Identify missing elements in a certification report.
- Describe the desired information in a certification report.

ACPE UAN: JA0006454-0000-22-3095-L07-P/T; 1 credit hour; application-based

4:30–4:45 PM *Summary*

Day 3 – All times Eastern

8:00–8:15 AM *Welcome and introduction to the day*

Overview of USP 800 and HD Handling

8:15–9:15 AM

- Cite examples of HD exposure effects on persons who handle HDs.
- Describe the location of resources regarding HD practice.
- Recall common HD guidelines, standards, 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.

ACPE UAN: JA0006454-0000-22-3096-L07-P/T; 1 credit hour; application-based

Elements and Practical Examples of Performing an Assessment of Risk (AoR)

9:15–10:00 AM

- List which drugs may be exempted from full containment and work practices of 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.

ACPE UAN: JA0006454-0000-22-3097-L07-P/T; 0.75 credit hours; knowledge-based

10:00–10:15 AM *Break*

Work Practice Strategies for Receiving, Storing, Compounding, and Transporting HDs and HD CSPs

10:15–11:15 AM

- 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 that the final HD CSP container and packaging is free from HD contamination.
- Evaluate safe transport procedures for HD inventory and final CSPs.

ACPE UAN: JA0006454-0000-22-3098-L07-P/T; 1 credit hour; application-based

Response to HD Exposure and Spills

11:15–11:45 AM

- 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.

ACPE UAN: JA0006454-0000-22-3099-L07-P/T; 0.5 credit hours; knowledge-based

11:45 AM–12:15 PM *Lunch*

Wipe Sampling and CSTDs for Sterile and Nonsterile Hazardous Drug Compounding

12:15–12:45 PM

- Differentiate USP 800 wipe sampling recommendations from CriticalPoint best practice recommendations.
- List the wipe sampling methods available on the market.
- Identify potential wipe sampling locations and the frequency of sampling.
- Discuss the types of CSTDs available for use in compounding and administration.
- Evaluate the efficacy of CSTDs using appropriate references.

ACPE UAN: JA0006454-0000-22-3100-L07-P/T; 0.5 credit hours; knowledge-based

Donning, Doffing, and Types of Personal Protective Equipment (PPE)

12:45–1:45 PM

- 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.

ACPE UAN: JA0006454-0000-22-3101-L07-P/T; 1 credit hour; application-based

1:45–2:00 PM *Break*

Interactive Exercise: Doffing of HD Garb

2:00–3:00 PM

- Perform best practice doffing of HD PPE with visual feedback.
- Explain how licensees could use fluorescent tracer mist and dust to evaluate their practice.

ACPE UAN: JA0006454-0000-22-3102-L07-P/T; 1 credit hour; application-based

Interactive Exercise: Negative-Pressure Compounding Versus the Use of a CSTD

3:00–4:00 PM

- Perform simple syringe manipulations using simulated drug and compounding using positive, negative, and CSTD strategies contrasting the difficulty of each of the compounding strategies.
- Discuss the time necessary to correctly perform negative-pressure compounding versus the use of CSTDs with licensees.
- Observe HD administration with a model CSTD as required by USP 800.

ACPE UAN: JA0006454-0000-22-3103-L07-P/T; 1 credit hour; application-based

4:00–4:15 PM *Break*

Decontamination, Cleaning and Disinfection, and Residue Removal in HD Compounding Environments

4:15–5:15 PM

- 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.

ACPE UAN: JA0006454-0000-22-3104-L07-P/T; 1 credit hour; application-based

5:15–5:30 PM *Summary*

Day 4 – All times Eastern

8:00–8:15 AM *Welcome and introduction to the day*

Containment Secondary Engineering Controls (C-SECs): Cleanroom Suites and C-SCAs

8:15–9:15 AM

- 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.

ACPE UAN: JA0006454-0000-22-3105-L07-P/T; 1 credit hour; application-based

Containment Primary Engineering Controls (C-PECs)

9:15–10:30 AM

- Describe the types compliant of C-PECs for nonsterile and sterile HD compounding.
- Describe the tests required for certification of C-PECs.

ACPE UAN: JA0006454-0000-22-3106-L07-P/T; 1.25 credit hours; application-based

10:30–10:45 AM *Break*

Sanitization of Sterile Compounding Primary and Secondary Engineering Controls

10:45–11:45 AM

- Differentiate between the requirements of USP 797 2008, USP 797 2022, 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: JA0006454-0000-22-3107-L07-P/T; 1 credit hour; application-based

11:45 AM–12:30 PM *Lunch*

Environmental Monitoring

12:30–1:30 PM

- 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: JA0006454-0000-22-3108-L07-P/T; 1 credit hour; application-based

Interactive Exercise: Developing an Environmental Sampling Plan

1:30–2:30 PM

- Explain which air and surface sampling locations should be considered as part of a routine sampling plan.
- Describe how to use air and surface sampling equipment.
- Discuss the required elements of environmental and personnel sampling documentation.

ACPE UAN: JA0006454-0000-22-3109-L07-P/T; 1 credit hour; application-based

2:30–2:45 PM *Break*

Quality Systems for Sterile Compounding

2:45–3:45 PM

- 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: JA0006454-0000-22-3110-L07-P/T; 1 credit hour; application-based

Nonsterile-to-Sterile Compounding

3:45–5:00 PM

- Contrast the compounding and BUD requirements of the USP 797 2022 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.

ACPE UAN: JA0006454-0000-22-3111-L07-P/T; 1.25 credit hours; application-based

5:00–5:15 PM	*Summary*

Day 5 – All times Eastern

8:00–8:15 AM	*Welcome and introduction to the day*

Media-Fill Testing and Subsequent Gloved Fingertip Sampling (GFS)

8:15–9:00 AM

- 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.

ACPE UAN: JA0006454-0000-22-3112-L07-P/T; 0.75 credit hours; knowledge-based

Pharmacy Inspection Guide

9:00–10:15 AM

- Organize an inspection visit to ensure the most efficient and effective evaluation of sterile compounding practices.
- Evaluate one potential method of structuring an inspection.

ACPE UAN: JA0006454-0000-22-3113-L07-P/T; 1.25 credit hours; application-based

10:15–10:30 AM	*Break*

Interactive Exercise: What's wrong with this picture?

10:30–11:30 AM

- Identify areas of noncompliance in images taken in real-life situations in sterile compounding pharmacies.

ACPE UAN: JA0006454-0000-22-3114-L07-P/T; 1 credit hour; application-based

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Interactive Exercise: Design and Build Evaluation of Facilities Intended for Non-HD and HD Compounding

11:30 AM–12:30 PM

- Evaluate sample layouts and identify areas of concern relative to USP 797 and 800 compliance, efficiency of workflow and best practice considerations.
- Revise sample layouts to ensure improved compliance, efficiency, and achievement of best practices.

ACPE UAN: JA0006454-0000-22-3115-L07-P/T; 1 credit hour; application-based

12:30–12:45 PM	*Summary*

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CriticalPoint/TRC Healthcare Faculty, Editors, & Staff

Tammie Armeni, RPh, PharmD
Vice President, Content Management & Accreditation

Trish Cipoletti
Quality Control Manager

Latousha Jackson, PharmD, BCPS
Editor

Adam West, RCCP-SCF, NSF-49 accreditation
Environmental Monitoring and Training Specialist

Colene West
Continuing Education Content Supervisor

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