**Sterile Compounding Boot Camp® Virtual Training Series**

**Sterile Compounding Inspector Training Live Virtual Course for CISCI Certification** (25 CE hours)

**Inspectors attempting CISCI certification must complete entire Sterile Compounding eCurriculum (see CISCI certification documents)**

**Day 1: 10:00 AM to 5:15 PM Eastern**

| Time | Name of Live Activity | Learning Objectives (for CE Sessions) |
|---|---|---|
| 10:00–11:00 AM | Introduction, explanation of the course, overview of course goals | Live vCourse participants 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.<br>• List engineering-related contamination-control principles related to cleanroom suites and segregated compounding areas (SCAs).<br>• List the three categories of work practices fundamental to contamination control. |
| Noon–12:30 PM | *Lunch* | |
| 12:30–2:00 PM | Sterile-to-Sterile Compounding Basics | • Identify situations that are "not compounding," and discuss the new immediate-use category defined in USP 797 (2019).<br>• Explain the differences between Category 1 and 2 BUDs described in USP 797 (2019), and discuss how the categories are different from the risk levels in the 2008 USP 797 (currently enforceable).<br>• List the requirements for the use of commercially available SDCs, MDCs, and pharmacy bulk packages.<br>• Describe how a potency study is different from a stability-indicating assay.<br>• Discuss the differences between compounding records versus master formulation records, and describe CriticalPoint best practices for their implementation.<br>• Describe quality release testing required by USP 797 for sterile-to-sterile nonhazardous compounding. |
| 2:00–2:15 PM | *Break* | |
| 2:15–3:30 PM | Secondary Engineering Controls | • List the different types of SECs, and describe their function as related to nonhazardous sterile compounding.<br>• Discuss how proper facility design facilitates the maintenance of a state of control.<br>• Differentiate between ISO 5, 7, and 8 area cleanliness and particulate counts, and identify how each applies to a sterile compounding facility.<br>• Summarize the rationale and describe how to apply best practice design elements to licensee compounding facilities. |

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| 3:30–3:45 PM | *Break* | |
| 3:45–4:45 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.<br>• Properly sequence the activities of hand hygiene and garbing for nonhazardous sterile compounding based on the location of the sink.<br>• Identify contamination-control best practices to suggest to licensees for integration into their facility SOPs and work practices.<br>• Describe strategies for staging batches and patient preps not addressed by USP 797. |
| 4:45–5:15 PM | Summary of the day; questions and answers as well as discussion about the information covered in this day's session | |

**CE for day: 4.75 hours**

**Day 2: 10:00 AM to 5:00 PM Eastern**

| Time | Name of Live Activity | Learning Objectives (for CE Sessions) |
|---|---|---|
| 10:00–10:15 AM | *Questions from previous day* | |
| 10:15–10:45 AM | Initial Gloved Fingertip Sampling | • Describe the difference between solid and liquid media, and identify what each is used for by sterile compounding organizations.<br>• Identify and explain the key components of a certificate of analysis.<br>• List the conditions and steps to successful initial GFS.<br>• Differentiate between the minimum requirements and best practice recommendations for personnel sampling.<br>• Explain necessary corrective actions and additional training that must occur in the event of initial GFS failures. |
| 10:45–11:45 AM | Primary Engineering Controls | • Describe the differences between nonhazardous PECs, and identify airflow characteristics of each.<br>• Identify unidirectional and turbulent airflow, and describe how to determine whether a PEC is appropriate for sterile compounding.<br>• List factors important for proper integration of PECs into facilities to ensure efficient workflow and equipment functionality.<br>• Explain appropriate applications and limitations of the PECs.<br>• Describe HEPA filtration and how it applies to the principles of airflow used in sterile compounding environments.<br>• Correlate airflow principles to compounding, and describe how proper aseptic technique affects first air. |

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| 11:45 AM–12:15 PM | *Lunch* | |
| 12:15–1:15 PM | Aseptic Work Practice | • Identify proper worker conduct inside the perimeter of the SCA and the cleanroom suite.<br>• List the influences on first air; and describe how proper ergonomics, setup of supplies, and aseptic work practices reduce the risk of contamination. |
| 1:15–2:15 PM | Interactive Exercise: 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.<br>• Evaluate dynamic airflow smoke-pattern test results, and use the results to improve compounding technique and work practices.<br>• Identify proper hand positioning during compounding for both vertical and horizontal airflow PECs.<br>• Discuss proper transfer of components and supplies into the PEC. |
| 2:15–2:30 PM | *Break* | |
| 2:30–3:15 PM | Personnel Sampling | • Explain how surface sampling can be utilized as a personnel metric rather than an environmental metric.<br>• List the minimum requirements for media-fill and subsequent gloved fingertip sampling.<br>• Describe the value of personnel and process media-fill testing as verification of the aseptic-technique skills of staff and the compounding process.<br>• List the design requirements of a media-fill and media-process verification.<br>• Give examples of how licensees can implement proper corrective actions in the event of media-fill or GFS failures. |
| 3:15–4:30 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.<br>• Describe methods of sterilization and requirements for each.<br>• Describe the difference between direct inoculation and membrane filtration USP 71 sterility testing, and list the benefits of using membrane filtration.<br>• Identify the user requirement specifications of rapid testing and how they relate to taking a risk-based approach to rapid sterility testing.<br>• Determine when bacterial endotoxin testing is required according to USP 797. |
| 4:30–5:00 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: 5.5 hours**

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

| Time | Name of Live Activity | Learning Objectives (for CE Sessions) |
|---|---|---|
| 10:00–10:15 AM | *Questions from previous day* | |
| 10:15–11:15 AM | Engineering Control Testing and Certification | • Summarize the role engineering control certification plays in ensuring patient safety.<br>• List documentation requirements of applicable certification tests.<br>• Identify the essential details of a certification report as required by CAG-003.<br>• Discuss the required certification testing so that you can confidently communicate with licensees. |
| 11:15 AM–12:15 PM | Sanitization of Primary and Secondary Engineering Controls | • List the requirements of USP 797 2008 and USP 797 2019 and best practices for sanitization.<br>• Summarize the principles related to the selection and use of cleaning agents and supplies.<br>• Identify gaps in licensee SCA and cleanroom suite daily and monthly cleaning activities.<br>• List personnel safety, training, and competency considerations related to cleaning and sanitization.<br>• Discuss SOP and documentation requirements specified by USP 797. |
| 12:15–12:45 PM | *Lunch* | |
| 12:45–1:45 PM | Environmental Monitoring Basics | • Outline a model, ongoing EM program.<br>• Describe the chapter requirements for viable air and surface sampling.<br>• Identify the proper use of equipment and supplies for air and surface sampling.<br>• List the chapter requirements and best practices for investigating an exceeded action level. |
| 1:45–2:00 PM | *Break* | |
| 2:00–3:00 PM | Quality System Considerations | • Define quality assurance and quality control, and identify essential USP 797 (2019) elements of a formal quality system.<br>• Explain how SOPs, documentation, and a method for change control system are critical to USP 797 compliance and a well-functioning pharmacy. |
| 3:00–4:00 PM | Pharmacy Inspection Guide | • Prioritize an inspection visit to ensure the most efficient and effective evaluation of sterile compounding practices.<br>• Evaluate one potential method of structuring an inspection. |
| 4:00–4:30 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: 5 hours**

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

| Time | Name of Live Activity | Learning Objectives (for CE Sessions) |
|---|---|---|
| 10:00–10:15 AM | *Questions from previous day* | |
| 10:15–11:15 AM | Interactive Exercise: What's Wrong with this Picture | • Identify areas of noncompliance in images taken in real-life situations in sterile compounding pharmacies. |
| 11:15–11:45 AM | Summary of the sterile nonhazardous course; final questions and answers | |
| 11:45 AM–12:15 PM | *Lunch* | |
| 12:15–1:15 PM | Overview of USP 800 and HD Handling | • Cite examples of HD-exposure effects on persons who handle HDs.<br>• Describe the location of resources regarding HD practice.<br>• Recall common HD guidelines, standards, and regulatory and best practice events.<br>• List the major elements of USP 800.<br>• Differentiate between the scope of USP Chapters 795, 797, and 800.<br>• Describe current issues related to USP Compounding Chapter enforceability and compendial applicability. |
| 1:15–2:15 PM | 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.<br>• Define the components required in an AoR.<br>• Evaluate different approaches to the creation and maintenance of an AoR.<br>• Discuss specific examples of AoR strategies from actual practice. |
| 2:15–2:30 PM | *Break* | |
| 2:30–3:00 PM | Response to HD Exposure and Spills | • List the required elements of an exposure-control and response plan.<br>• Discuss the requirements for HD spill cleanup.<br>• Describe the logistical and practical hurdles that can be encountered in implementing an effective spill management program.<br>• List potential strategies for effective spill management. |
| 3:00–4:00 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.<br>• Discuss considerations relevant to the use of pass-throughs in HD applications.<br>• Analyze the allowable but suboptimal design of C-SECs and strategies used to compensate for such.<br>• Describe the tests required for certification of C-SECs. |
| 4:00–4:30 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: 4.5 hours**

**Day 5: 10:00 AM to 4:45 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 | Containment Primary Engineering Controls (C-PECs) | • Describe the types of compliant C-PECs for nonsterile and sterile HD compounding.<br>• Describe the tests required for certification of C-PECs. |
| 11:15 AM–12:15 PM | HD Garb and Personal Protective Equipment (PPE) | • Explain USP 800 requirements and best practice suggestions for donning and doffing PPE.<br>• Sequence donning and doffing of HD PPE.<br>• Evaluate PPE used for sterile HD compounding. |
| 12:15–12:45 PM | *Lunch* | |
| 12:45–1:45 PM | Cleaning-Related Activities for HD Compounding Environments | • Summarize how the terms deactivation, decontamination, cleaning, disinfection, and sanitization apply to HD compounding environments.<br>• List the types of agents that may be used for decontamination of hazardous drugs.<br>• Properly sequence the cleaning-related activities performed in HD environments. |
| 1:45–2:00 PM | *Break* | |
| 2:00–3:00 PM | HD Work Practice Strategies | • Summarize the work-practice elements essential to reducing the generation of HD contamination and the risk of exposure.<br>• List the USP 800 requirements for receiving, storing, compounding, and transporting HDs.<br>• Describe safe transport procedures for HD inventory and final CSPs. |
| 3:00–4:15 PM | Interactive Exercise: 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.<br>• Revise sample layouts to ensure improved compliance, efficiency, and achievement of best practices. |
| 4:15–4:45 PM | Summary of class; answer questions; review of post test requirements for CISCI certification | |

**CE for the day: 5.25 hours**

**Inspectors attempting the SCIT certification are required to take entire Sterile Compounding Curriculum (34.5 hours) before attending Live Virtual training.**