

**Sterile Compounding Boot Camp®**  
**Best Practices for Nonhazardous Sterile-to-Sterile Compounding**



All times Eastern	Activity Title and Objectives (with CE information)
<b>DAY 1 (November 1) – All times Eastern</b>	
9:00–10:00 AM	■ Introduction
10:00–10:45 AM	<b>■ Sterile Compounding Contamination Control Principles</b> <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> <i>ACPE UAN: JA0006454-0000-22-3026-L07-P/T; 0.75 credit hours; knowledge-based</i>
10:45–11:00 AM	■ Break
11:00 AM–12:15 PM	<b>■ Sterile-to-Sterile Compounding</b> <ul style="list-style-type: none"> <li>• Identify situations that are “not compounding” and the new immediate-use category defined in USP 797 (2021) and contrast them with the 2008 requirements.</li> <li>• Differentiate between Category 1, 2, and 3 BUDs described in USP 797 (2021) from the risk levels in the 2008 USP 797 (currently enforceable).</li> <li>• Compare and contrast the 2008 versus 2021 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>• Describe quality release testing for nonhazardous sterile-to-sterile compounding.</li> </ul> <i>ACPE UAN: JA0006454-0000-22-3030-L07-P/T; 1.25 credit hours; application-based</i>
12:15–1:00 PM	■ Lunch
1:00–1:30 PM	<b>■ Sterile Compounding Documentation</b> <ul style="list-style-type: none"> <li>• Identify the USP 797 requirements for the label of a compounded sterile preparation (CSP).</li> <li>• Define compounding records versus master formulation records and describe CriticalPoint best practices for their implementation.</li> <li>• Compare written and electronic options for compounding documentation.</li> <li>• Describe quality documentation procedures when recording data on forms.</li> </ul> <i>ACPE UAN: JA0006454-0000-22-3021-L07-P/T; 0.50 credit hours; knowledge-based</i>
1:30–3:00 PM	<b>■ Secondary Engineering Controls for Nonhazardous Sterile Compounding</b> <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> <i>ACPE UAN: JA0006454-0000-22-3033-L07-P/T; 1.50 credit hours; application-based</i>
3:00–3:15 PM	■ Break
3:15–4:15 PM	<b>■ Lab: Design Review for USP 797 Compliance</b> <ul style="list-style-type: none"> <li>• Identify facility designs that meet USP 797 requirements.</li> </ul>



- 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 (November 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	<ul style="list-style-type: none"><li>■ <b>Aseptic Work Practices Overview for Sterile Compounding</b><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></li></ul> <p><i>ACPE UAN: JA0006454-0000-22-3024-L07-P/T; 1 credit hours; application-based</i></p>
1:45–2:45 PM	<ul style="list-style-type: none"><li>■ <b>Lab: PEC, SEC, and Aseptic Work Practices</b><ul style="list-style-type: none"><li>• Analyze the ideal sterile compounding facility design and workflow to ensure efficiency and compliant material transfer into the SEC.</li><li>• Evaluate dynamic airflow smoke-pattern test results and use the results to improve compounding technique and work practices.</li><li>• Identify proper hand positioning during compounding for both vertical and horizontal airflow PECs.</li><li>• Discuss proper transfer of components and supplies into the PEC.</li></ul></li></ul> <p><i>ACPE UAN: JA0006454-0000-22-3028-L07-P/T; 1 credit hours; application-based</i></p>
2:45–3:00 PM	■ Break
3:00–4:15 PM	<ul style="list-style-type: none"><li>■ <b>Testing and Certification of PECs and SECs (USP 797)</b><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></li></ul> <p><i>ACPE UAN: JA0006454-0000-22-3022-L07-P/T; 1.25 credit hours; application-based</i></p>
4:15–4:30 PM	■ Summary of the day

---

**DAY 3 (November 3) – All times Eastern**

---

9:00–10:00 AM	<ul style="list-style-type: none"><li>■ <b>Sterility and Bacterial Endotoxin Testing Specific to USP 797</b><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></li></ul> <p><i>ACPE UAN: JA0006454-0000-22-3032-L07-P/T; 1 credit hours; application-based</i></p>
10:00–10:15 AM	■ Break
10:15–11:30 AM	<ul style="list-style-type: none"><li>■ <b>Sanitization of Sterile Compounding PECs and SECs</b><ul style="list-style-type: none"><li>• Differentiate between the requirements of USP 797 2008, USP 797 2021, and best practices for sanitization.</li></ul></li></ul>

---



- 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 CPE 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



In support of improving patient care, TRC Healthcare is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC) to provide continuing education for the healthcare team.

### **Statement of Participation/Course Completion**

Credit will be awarded to participants who attend the course, submit a course evaluation within 20 days of the date of participation, and have provided an accurate NABP e-Profile ID and DOB. Participants who have successfully completed this course AND have provided accurate NABP e-Profile information, including month and day of birth, will have their CE credits submitted to CPE Monitor.

Florida-licensed pharmacists and pharmacy technicians: Course completions will be reported to CE Broker if the participant has successfully fulfilled all course completion requirements AND has provided the name and license number that matches what is on file with the Florida Board of Pharmacy. If this information is not provided within 20 days of the date of the activity, the participant will be responsible for manually uploading their completion to CE Broker.

It is the participant's responsibility to verify credit is accurately posted to CPE Monitor and CE Broker (if applicable). Participants who have questions about their credit or do not see their credit on CPE Monitor (or CE Broker if applicable) 20 days after their participation should [contact TRC](#). Requests received after day 30 may not receive credit. Official statements of credit are only available from [CPE Monitor](#).

Credit for a specific course can only be awarded a single time. If you have previously completed a course as part of another program, you will only receive credit the first time the course is completed.

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

### **Disclosure**

The editors of this activity and its publisher, TRC Healthcare (TRC), have no relevant financial interests related to the products or services covered by this activity. TRC does not receive any commercial support and does not accept any advertising for its educational activities. It is completely independent and is supported entirely by subscriptions. In support of ACCME's Standards for Integrity and Independence, individuals declaring financial relationships with commercial interests (ineligible companies) are detailed below. When no financial relationship is listed, the individual has nothing to disclose. All relevant financial relationships, when present, have been mitigated. TRC focuses on delivering completely objective, unbiased drug information and advice for the benefit of subscribers. Users of this document are cautioned to use their own professional judgment and consult any other necessary or appropriate sources prior to making clinical or legal judgments. Information and Internet links in this activity were current as of the date of release.

### **CriticalPoint/TRC Healthcare Faculty, Editors, & Staff**

**Tammie Armeni, RPh, PharmD**

Vice President, Content Management & Accreditation

**Trish Cipoletti**

Quality Control Manager

**Latousha Jackson, PharmD, BCPS, BCSCP**

Editor



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

**Colene West**  
Continuing Education Content Supervisor

### **Cost**

The fee for this activity is available online. Register at <https://www.criticalpoint.info/activities>

### **Software/Hardware Requirements**

TRC makes every effort to test and support the most recent version. This activity can be viewed on any device with an internet connection using one of the following browsers:

- Google Chrome, most recent stable version. No configuration recommendations.
- Mozilla Firefox, most recent stable version. No configuration recommendations.
- Apple Safari, most recent stable version. No configuration recommendations.

NOTE: For all browsers, you must have JavaScript and cookies enabled. To view PDFs, you will need a PDF-capable browser or standalone PDF viewer.

### **Your Privacy**

In order to provide you with continuing education, Therapeutic Research obtains information such as your name, address, email address, phone number, payment information, etc. We treat this information as confidential and use it to provide you with the best service possible. Therapeutic Research has NEVER released any of this information to any outside organization for such organization's own commercial or marketing use and has a policy against doing so. We do not engage in renting out, selling, or trading names of subscribers or any information about any subscriber.

To provide you with valuable services, we will occasionally employ third parties to meet your needs. In such cases, only the information needed to meet your need will be shared with the outside organization. Therapeutic Research only employs third parties that have similarly protective privacy policies. We do not allow any other organization to send you unsolicited emails about any products or services. We might send you information about your subscription, your continuing education credits, or our own drug information services. We do not gather data or track your web usage of any websites other than our own. For further information see our Privacy Policy or submit a request at <http://info.therapeuticresearch.com/privacyofficer>.