

DAY 1 (All times EASTERN) Activity Title and Objectives (with CE information)

10:00–11:00 AM ■ Introduction

11:00 AM–12:30 PM ■ **Critical Elements of Aseptic Technique**

- Recite basic definitions that apply to aseptic processing.
- List elements of proper conduct in controlled environment, staging of supplies, organization of work area, and resanitization of gloves.
- Describe proper use of first air in both vertical and horizontal airflow.
- Explain how to access and manipulate syringes, needles, ampules, vials, bags, and other compounding supplies.
- Discuss the use and integration of emerging technologies into ISO-classified spaces and their impact on first air and aseptic technique work practices.

ACPE UAN: JA0006454-0000-23-3015-L07-P/T; 1.5 credit hours; application-based

12:30–12:45 PM ■ Break

12:45–1:30 PM ■ **Qualification of Vendors and Products**

- Describe the importance of vendor qualification.
- List the elements of an onsite audit or vendor survey.
- Explain how licensees should use the results of the onsite audit or vendor survey to conduct a risk-based assessment.
- Determine when an outsourcing facility can use a vendor certificate of analysis versus conducting its own testing.
- List the critical specifications for component and API testing.
- Identify the requirements for auditing a testing lab as well as the requirements of personnel selected to conduct the audit.

ACPE UAN: JA0006454-0000-22-3122-L07-P/T; 0.75 credit hours; knowledge-based

1:30–2:30 PM ■ **Interactive Exercise: Identifying Insanitary Conditions**

- Identify examples of insanitary conditions.

ACPE UAN: JA0006454-0000-22-3132-L07-P/T; 1 credit hours; application-based

2:30–3:00 PM ■ Break

3:00–4:30 PM ■ **Inspecting 503B Outsourcing Facilities**

- 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: JA0006454-0000-22-3134-L07-P/T; 1.5 credit hours; application-based

4:30–4:45 PM ■ Summary of the day

DAY 2 – All times Eastern

10:00–10:15 AM ■ Questions from the previous day

10:15–11:45 AM ■ **Interactive Group Exercise: Decoding FDA Forms and Warning Letters**

- Decipher a redacted FDA Form 483.
- Identify FDA Form 483 observations that warrant follow-up during an inspection.
- Discuss the significance of a warning letter and the expected remediation efforts.

ACPE UAN: JA0006454-0000-22-3135-L07-P/T; 1.5 credit hours; application-based



11:45 AM –12:30 PM	■ Choosing a Laboratory (USP 797) <ul style="list-style-type: none">• List the characteristics of a laboratory to ensure testing meets USP 797 requirements.• Identify common microbiology terms that will allow you to confidently discuss testing and results with the laboratory.• Recognize the essential components of a testing report. <p><i>ACPE UAN: JA0006454-0000-23-3012-L07-P/T; 0.75 credit hours; knowledge-based</i></p>
12:30–1:30 PM	■ Lab: Review and Analysis of Laboratory Reports (USP 797) <ul style="list-style-type: none">• Evaluate laboratory reports for missing and incorrect information.• Interpret laboratory results to determine if they are acceptable and identify next steps in the event there is an exceeded action level. <p><i>ACPE UAN: JA0006454-0000-23-3013-L07-P/T; 1 credit hours; application-based</i></p>
1:30–2:00 PM	■ Break
2:00–3:15 PM	■ Creating an Effective and Compliant Environmental Monitoring Program (USP 797) <ul style="list-style-type: none">• List the key elements of an environmental monitoring program.• Differentiate between required and best practice components of an EM program.• Identify the standard operating procedures (SOPs) and forms necessary to document the process. <p><i>ACPE UAN: JA0006454-0000-23-3001-L07-P/T; 1.25 credit hours; application-based</i></p>
3:15–4:15 PM	■ Developing a Sampling Plan (USP 797) <ul style="list-style-type: none">• Select sampling locations that will provide valuable data for making decisions that affect compounding operations.• Describe why the ability to explain rationale used for determining sampling locations to surveyors and inspectors is essential to the success of the program.• Discriminate between ad hoc and trended samples. <p><i>ACPE UAN: JA0006454-0000-23-3002-L07-P/T; 1 credit hours; application-based</i></p>
4:15–4:30 PM	■ Summary of the day

DAY 3 – All times Eastern

10:00–10:15 AM	■ Questions from the previous day
10:15–11:15 AM	■ Lab: Preparing for and Performing a Sampling Session (USP 797) <ul style="list-style-type: none">• Discuss how to prepare media, equipment, and other components for entry to the controlled environments.• Describe best practice garbing.• List sampling session workflow for a sterile compounding pharmacy.• Identify where to place the air sampler in relation to the direct compounding area (DCA), pass-throughs, equipment, and people. <p><i>ACPE UAN: JA0006454-0000-23-3008-L07-P/T; 1 credit hours; application-based</i></p>
11:15 AM–12:15 PM	■ Lab: Reading Media (USP 797) <ul style="list-style-type: none">• Describe the steps to inspect and read samples correctly.• Recognize the different colony morphologies of microorganisms commonly found in the sterile compounding environment.• Determine when a sample's count should be verified by another staff member. <p><i>ACPE UAN: JA0006454-0000-23-3011-L07-P/T; 1 credit hours; application-based</i></p>



12:15–12:30 PM	■ Break
12:30–1:45 PM	■ Investigation and Remediation (USP 797) <ul style="list-style-type: none">• Discuss investigation tools and remediation actions that can be applied to the sterile compounding environment.• Determine the significance of the types of organisms recovered.• Evaluate the report results to determine the proper remediation actions. <i>ACPE UAN: JA0006454-0000-23-3014-L07-P/T; 1.25 credit hours; application-based</i>
1:45–2:15 PM	■ Break
2:15–3:30 PM	■ Trending Environmental Monitoring Data <ul style="list-style-type: none">• Define trending as it relates to environmental monitoring in a sterile compounding pharmacy.• Discuss the importance of analyzing microbial trends over time.• Identify a meaningful trending program that incorporates a variety of techniques, including the use of recovery rates. <i>ACPE UAN: JA0006454-0000-23-3009-L07-P/T; 0.75 credit hours; knowledge-based</i>
3:30–3:45 PM	■ Break
3:45–5:00 PM	■ Review of Certification Reports and Smoke Pattern Testing <ul style="list-style-type: none">• Describe the minimum and best practice reporting elements that constitute a comprehensive report.• Determine documentation requirements of applicable certification tests not described in USP <797>.• Summarize testing requirements, methods, and certification equipment used in static and dynamic airflow smoke pattern testing.• Identify appropriate materials for performing airflow smoke pattern testing in the DCA of a PEC used for sterile compounding. <i>ACPE UAN: JA0006454-0000-23-3016-L07-P/T; 1.25 credit hours; application-based</i>
5:00–5:30 PM	■ Summary of the class

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

7 courses/total of 8.5 hours CE

- Aseptic Technique and Conduct
- Overview of Environmental Monitoring
- Viable Air and Surface Sampling
- Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions
- Insanitary Conditions
- What are CGMPs? (21 CFR Part 211)
- Review of FDA 503B Draft and Final Guidance



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Statement of Participation/Course Completion

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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.

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Cost

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

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