

Sterile Compounding Boot Camp®

Best Practices for Environmental Monitoring

DAY 1 (All times EASTERN)	Activity Title and Objectives (with CE information)
10:00-10:30	■ Introduction
10:30-11:45 AM	<p>■ General Concepts of Environmental Monitoring (EM)</p> <ul style="list-style-type: none"> • Summarize the importance of having a robust environmental monitoring program. • Discuss the limitations of EM and how those affect program design. • Identify and source applicable guidance documents. • Select the appropriate sampling media based on pharmacy needs. • Critique media manufacturers to identify those that provide reputable products. • Describe why a pharmacy would need to perform growth promotion testing. <p>ACPE UAN: JA0006454-0000-23-3000-L07-P/T; 1.25 credit hours; application-based</p>
11:45 AM -12:00 PM	■ Break
12:00-1:15 PM	<p>■ Creating an Effective and Compliant Environmental Monitoring Program (USP 797)</p> <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>ACPE UAN: JA0006454-0000-23-3001-L07-P/T; 1.25 credit hours; application-based</p>
1:15-2:00 PM	■ Lunch
2:00-3:00 PM	<p>■ Developing a Sampling Plan (USP 797)</p> <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>ACPE UAN: JA0006454-0000-23-3002-L07-P/T; 1 credit hours; application-based</p>
3:00-4:00 PM	<p>■ Lab: Developing a Sampling Plan for USP 797 Compliance</p> <ul style="list-style-type: none"> • Identify a sampling plan that complies with USP 797 and incorporates best practices. • List the elements of user-friendly documentation used during the sampling session. • Describe why the development of the sampling plan should be a group effort. <p>ACPE UAN: JA0006454-0000-23-3003-L07-P/T; 1 credit hours; application-based</p>
4:00-4:15 PM	■ Summary



DAY 2 – All times Eastern

10:00–10:45 AM	<p>■ Air and Surface Sampling Technique (USP 797)</p> <ul style="list-style-type: none">• Describe how to select the appropriate sampling equipment based on sterile compounding pharmacy's needs.• Identify aseptic techniques related to the handling, packaging, and use of media.• Summarize the steps for using a viable air sampler.• Discuss when and how to reuse opened media. <p><i>ACPE UAN: JA0006454-0000-23-3004-L07-P/T; 0.75 credit hours; knowledge-based</i></p>
10:45–11:45 AM	<p>■ Lab: What's wrong with this picture (USP 797 Sampling Demonstration)</p> <ul style="list-style-type: none">• Analyze all elements of viable air and surface sampling.• Recognize proper sampling technique to avoid inadvertent contamination of the sampling media. <p><i>ACPE UAN: JA0006454-0000-23-3005-L07-P/T; 1 credit hours; application-based</i></p>
11:45 AM –12:00 PM	■ Break
12:00–12:45 PM	<p>■ USP 797 Garbing and Best Practice for Donning Sterile Gloves</p> <ul style="list-style-type: none">• Describe the USP 797 garbing requirements for nonhazardous sterile compounding.• Determine proper glove sizing.• List the requirements for sterile gloves and packaging.• Master the nuances of donning sterile gloves. <p><i>ACPE UAN: JA0006454-0000-23-3006-L07-P/T; 0.75 credit hours; knowledge-based</i></p>
12:45–1:30 PM	■ Lunch
1:30–2:30 PM	<p>■ USP 797 Sampling Session Workflow</p> <ul style="list-style-type: none">• List and prepare all equipment, materials, and documentation needed for the sampling session.• List the steps to execute an EM session in the proper order to reduce the risk of contaminating samples and the compounding environment.• Explain the steps to prepare samples for incubation and laboratory submission. <p><i>ACPE UAN: JA0006454-0000-23-3007-L07-P/T; 1 credit hours; application-based</i></p>
2:30–3:30 PM	<p>■ Lab: Preparing for and Performing a Sampling Session (USP 797)</p> <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>
3:30–4:15 PM	<p>■ Trending Environmental Monitoring Data</p> <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.

ACPE UAN: JA0006454-0000-23-3009-L07-P/T; 0.75 credit hours; knowledge-based

4:15–4:30 PM

■ Summary

Day 3 – All times Eastern

10:00–11:30 AM

■ Incubation and Reading Samples (USP 797)

- List appropriate times and temperatures for sample incubation.
- Identify a sterile compounding pharmacy's ability to incubate and read samples in-house.
- Distinguish between samples that require further evaluation and identification by a laboratory.
- Request the appropriate testing for samples that require identification to the genus level.
- Discuss the process for counting colonies recovered during the viable sampling session.

ACPE UAN: JA0006454-0000-23-3010-L07-P/T; 1.5 credit hours; application-based

11:30–11:45 AM

■ Break

11:45 AM –12:45 PM

■ Lab: Reading Media (USP 797)

- 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.

ACPE UAN: JA0006454-0000-23-3011-L07-P/T; 1 credit hours; application-based

12:45–1:30 PM

■ Choosing a Laboratory (USP 797)

- 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.

ACPE UAN: JA0006454-0000-23-3012-L07-P/T; 0.75 credit hours; knowledge-based

1:30–2:15 PM

■ Lunch

2:15–3:15 PM

■ Lab: Review and Analysis of Laboratory Reports (USP 797)

- 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.

ACPE UAN: JA0006454-0000-23-3013-L07-P/T; 1 credit hours; application-based



3:15-4:30 PM

■ **Investigation and Remediation (USP 797)**

- 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.

ACPE UAN: JA0006454-0000-23-3014-L07-P/T; 1.25 credit hours; application-based

4:30–4:45 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 (5 courses/total of 5.5 hours CE)

- Hand Hygiene and Garbing for Sterile Compounding
- Overview of Environmental Monitoring
- Viable Air and Surface Sampling
- Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions
- Best Practices for USP 797 Material Handling



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



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