

## **Viable Air and Surface Sampling for USP <797> Compliance Live Training**

Viable Air and Surface Sampling for USP <797> Compliance Live Training is a two and a half-day training held onsite at the learner's location, utilizing both lecture and hands-on activities. It is designed to provide the necessary training to implement a viable sampling program and perform sample collection, as the expected changes to USP <797> will necessitate internal sampling. It is appropriate for those who are responsible for the viable sampling program and those who would be performing the sampling. These individuals could be pharmacists or pharmacy technicians. Training covers USP General Chapter <797> sampling requirements and focuses on industry best practices. The class provide 12.75 hours of ACPE CE hours.

### **Learning Objectives**

#### **Viable Air and Surface Sampling Overview (USP 797)**

- Discuss the general requirements of a USP <797> compliant viable sampling program.
- Explain the value and limitations of a viable sampling program.
- List other industry standards and guidance documents that aid in the development of an effective program.
- Identify suitable media based on sampling needs.

#### **The Sampling Program (USP 797)**

- Discuss the required and suggested best practice components of a viable sampling program.
- List the necessary standard operating procedures (SOPs) and forms used to document the sampling process.
- Identify valuable sampling locations based on sterile compounding operations and workflow, which will assist in making data driven decisions.
- Describe the benefit of implementing different types of viable sampling plans.
- Summarize what trending data is, why it is important to the program, and how different techniques can be implemented.

#### **Skill Building: Choosing Sampling Locations and Creating Forms (USP 797)**

- Choose USP <797> compliant and best practice sample locations.
- Create viable sampling data collection forms that include essential reporting elements.

#### **Sampling Technique (USP 797)**

- Recognize sampling equipment that meets the needs of a sterile compounding pharmacy.
- Recall the steps for collecting viable air and surface samples.
- Describe the proper technique for opening, manipulating, using, and repackaging media.

#### **Skill Building: Viable Air and Surface Sampling Technique (USP 797)**

- Properly load and unload a viable air sampler.
- Collect surface samples without inadvertently contaminating the sample.

### **Performing a Sampling Session (USP 797)**

- Identify the necessary equipment, materials, and documentation that must be gathered to execute a viable sampling session.
- Describe the best sampling order to maintain the integrity of the samples and environment.
- Explain how to prepare samples for incubation or laboratory submission.

### **Incubation and Analysis (USP 797)**

- Explain which incubation times and temperatures are conducive to the growth of cleanroom microorganisms.
- Identify the ideal characteristics of a contract microbiology laboratory and its report.
- Assess a sterile compounding pharmacy's capability to incubate and analyze samples.
- Determine if recovered microorganisms require identification.
- Describe the best method for counting microbial growth recovered on viable samples.

### **Viable Sampling Excursions (USP 797)**

- Evaluate viable sampling results to identify the best way to address microbial excursions.
- Describe the impact the recovery of certain microorganisms could have on a facility.
- List possible corrective and preventive actions relevant to remediating exceeded levels.

### **Skill Building: Sampling Practice Session (USP 797)**

- Perform a viable sampling session, including gathering equipment and materials and collecting air and surface samples.
- Demonstrate the procedure to prepare samples for incubation or lab submission.

**Competency Testing** – Participants perform specific sampling-related skills and are assessed by the instructor. As part of the competency, participants are required to aseptically load and unload a viable air sampler inside a primary engineering control to demonstrate the ability to manipulate a sample without inadvertent contamination. Competency samples are submitted to a third-party microbiology contract testing laboratory for incubation and analysis. Competency is demonstrated if the sample plate does not yield any microbial growth. Results are provided.

### **Facility and Materials Requirements**

The facility must have a conference room or classroom, with a screen to display the lectures. A cleanroom suite, or if appropriate a segregated compounding area, must be available for both the Sampling Practice Session and the Competency Testing. If the learner's location has viable air samplers available, they can be supplied by the learner, otherwise Pure Microbiology will supply air samplers and media.

### **Instructor Biography**

Abby Roth, CMQ/OE, founder of Pure Microbiology, has over 17 years of experience in supporting the testing and consulting needs of the pharmaceutical, medical device, and compounding industries. Her background in pharmaceutical microbiology includes extensive knowledge of environmental monitoring. Abby served as a USP Compounding EC member during the 2015-2020 cycle and has been invited to speak for many national organizations.

## Agenda

### DAY 1

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8:00–8:15 AM	Welcome
8:15–9:15 AM	Viable Air and Surface Sampling Overview (USP 797)
9:15–9:30 AM	Break
9:30 AM–12:00 PM	The Sampling Program (USP 797)
12:00–12:45 PM	Lunch
12:45–1:45 PM	Skill Building: Choosing Sampling Locations and Creating Forms (USP 797)
1:45–2:30 PM	Sampling Technique (USP 797)
2:30–2:45 PM	Break
2:45–4:15 PM	Skill Building: Viable Air and Surface Sampling Technique (USP 797)
4:15–4:30 PM	Wrap-up

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### DAY 2

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8:00–8:15 AM	Welcome and Questions
8:15–9:15 AM	Performing a Sampling Session (USP 797)
9:15 –9:30 AM	Break
9:30 AM–12:00 PM	Incubation and Analysis (USP 797)
12:00–12:45 PM	Lunch
12:45–2:00 PM	Viable Sampling Excursions (USP 797)
2:00–4:15 PM	Skill Building: Sampling Practice Session (USP 797)
4:15–4:30 PM	Wrap-Up

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### DAY 3

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8:00–11:30 AM	Competency Testing
11:30–11:45 AM	Wrap-up

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