

Pure Primer: Surface Sampling for USP <797> Compliance

Training Description

Surface Sampling for USP <797> Compliance Live Training is a half-day remote, live training that includes a surface sampling competency utilizing a state-of-the-art surface sampling competency kit. Lectures are combined with a hands-on skill building activity and the training culminates with the competency assessment.

This Pure Primer is designed to provide the necessary training and initial competency for sterile compounding personnel to collect their own viable surface samples. It is appropriate for those who are responsible for the viable surface sampling program and those who would be performing the sampling. These individuals could be pharmacists or pharmacy technicians. Training covers USP General Chapter <797> surface sampling requirements and focuses on industry best practices.

Attendee Benefits

- Copies of the lecture slides
- Pure Microbiology Tools
- Attendance certificate
- Competency results and certificate, if applicable

Facility and Materials Requirements

Pure Microbiology will provide the competency kit and cover the cost of incubation and analysis. The learner must have the ability to join a GoToMeeting presentation and have available:

- At least 10 TSA with lecithin and polysorbate 80 contact plates
- Sterile 70% IPA and wipers
- Sterile gloves
- Cleanroom gown or coverall normally worn during sample collection
- Clean, uncluttered area to perform the competency test
- Shipping container and packing material

The learner is responsible for the cost to ship the competency samples to the contract lab.

Instructor Biography

Abby Roth, CMQ/OE, founder of Pure Microbiology, has been supporting the testing and consulting needs of the pharmaceutical, medical device, and compounding industries since 2004. Her background in pharmaceutical microbiology includes extensive knowledge of environmental monitoring and contamination control. Abby served as a USP Compounding EC member during the 2015-2020 cycle and has been invited to speak for national organizations.

Cost per person

\$895

Learning Objectives

Surface Sampling and Media Overview (USP 797)

- Discuss the general requirements of USP <797> compliant surface sampling.
- List the limitations of a viable sampling program.
- Identify suitable media for the collection of USP <797> surface samples.

The Surface Sampling Program (USP 797)

- List the required and suggested best practice components of a surface sampling program.
- Discuss how to choose valuable sampling locations based on sterile compounding operations and workflow.
- Explain the benefits of sampling under both static and dynamic conditions.

Surface Sampling Technique (USP 797)

- Identify media that is fit for surface sampling.
- Recall the steps for collecting surface samples.
- Describe the proper technique for opening, handling, using, and repackaging media.

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

- Collect surface samples without inadvertently contaminating the sample.

Performing a Surface Sampling Session (USP 797)

- List the necessary materials and documentation that must be gathered to execute a surface sampling session.
- Explain how to choose the best sampling order for your organization.
- Recall the proper preparation of samples for incubation or laboratory submission.

Surface Sample Incubation and Analysis (USP 797)

- List the incubation times and temperatures for surface samples defined by USP <797>.
- Explain when identifications of recovered microorganisms are required.
- Describe what to look for in a contract microbiology lab.

Competency Testing Notes

- Participants are provided with a surface sampling competency kit. This kit assesses the individual's ability to adequately recover viable microorganisms from a surface, as well as their aseptic technique.
- During the competency test, the instructor will review the proper use of the competency kit.
- The learner performs the competency and submits the samples to the lab for analysis.

Agenda

15 min	Welcome
30 min	Surface Sampling and Media Overview (USP 797)
45 min	The Surface Sampling Program (USP 797)
5 min	Break
30 min	Surface Sampling Technique (USP 797)
15 min	Skill Building: Surface Sampling Technique (USP 797)
45 min	Performing a Surface Sample Session (USP 797)
30 min	Surface Sample Incubation and Analysis (USP 797)
5 min	Break
30 min	Competency Testing
5 min	Wrap-up

Total Time 4 hours and 15 minutes