Best Practices for Environmental Monitoring
Learning and Performance Objectives

**eLearning to be completed prior to Live Training**

**Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling (2 hours CE)**
- Describe why hand hygiene and garbing are important for reducing the risk of contamination to compounded sterile preparations (CSPs)
- Describe gloved fingertip sampling as required by USP Chapter <797> and why it is important
- Correctly perform hand hygiene, garbing and gloved fingertip sampling (GFS)
- Describe considerations for general attire and personal protective equipment (PPE)

**Volumetric Air Sampling (1 hour CE)**
- Define Volumetric Air Sampling as part of an overall Environmental Monitoring Plan including where and when it is performed
- List the steps in Volumetric Air Sampling in the correct sequence
- Describe how to read, interpret and document the results of air sampling
- List the steps to take when results of colony forming unit (CFU) counts are out of limit

**Surface Sampling (1 hour CE)**
- Define Surface Sampling including where and when it is performed
- List the steps to set up and begin Surface Sampling
- Explain the process of obtaining, processing and incubating the surface samples
- Describe how to read, interpret and document the results of surface sampling
- List the steps to take when the counts of colony forming units (CFUs) are beyond established Action Levels

**Live Training Curriculum**

**Day 1**

**The 5 Ws of Environmental Monitoring (1 hour CE)**
- Summarize the importance of having a robust environmental monitoring program.
- Discuss the limitations of environmental monitoring and how those effect program design.
- Identify and source applicable guidance documents.

**Media and Sampling Equipment (0.75 hours CE)**
- Select the appropriate sampling media and equipment based on pharmacy needs.
- Critique media manufacturers to identify those which provide reputable products.
- Evaluate your pharmacy’s need to perform additional growth promotion testing.
- Utilize air samplers and surface sampling devices to perform monitoring.

**Creating a Compliant Environmental Monitoring Program (2 hours CE)**
- Differentiate between required and best practice components of a sampling program.
- Draft the standard operating procedures (SOPs) and forms necessary to document the process.
- Select sampling locations which will provide valuable data.
Best Practices for Environmental Monitoring
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Performing an Environmental Monitoring Session (2 hours CE)
- List and prepare all equipment, materials and documentation needed for the session.
- Execute an environmental monitoring session.
- List the steps to prepare samples for incubation and/or laboratory submission.

Handling Media and Performing Air and Surface Sampling (1.5 hours CE)
- Prepare media, equipment and other components for entry to the controlled environments.
- Perform all elements of surface sampling.
- Perform all elements of viable air sampling.

Day 2

Development of Environmental Sampling Plans (1.5 hours CE)
- Develop a risk-based sampling plan.
- Prioritize sample locations for trending of data.
- Discriminate between one time samples and trended samples.

Sampling Incubation and Analysis (0.75 hours CE)
- List appropriate times and temperatures for sample incubation.
- Evaluate the pharmacy’s ability to incubate and analyze samples inhouse.
- Distinguish between samples which require further evaluation and identification by a laboratory.
- Apply basic microbiology knowledge to begin to critique reports.

Choosing a Laboratory (0.75 hours CE)
- Evaluate laboratories based on their ability to provide the necessary testing.
- Engage confidently in discussion with the laboratory.
- Recognize the essential components of a testing report.

Trending and Remediation (1 hour CE)
- Discuss investigation tools and remediation actions that can be applied to the pharmacy environment.
- Utilize an investigation template and adapt it to the pharmacy’s needs.
- Determine the significance of the types of organisms recovered.
- Evaluate the report results to determine the proper remediation actions.

Reading Media and Review of Laboratory Reports (1.5 hours CE)
- Inspect and read surrogate plate samples correctly.
- Evaluate laboratory reports for missing and incorrect information.
- Interpret laboratory reports of growth for basic morphology and development of remediation plans.

Perform Actual Environmental Sampling (2 hours CE)
- Prepare all equipment, materials and documentation needed for the session.
- Execute an environmental monitoring session.
- Describe the steps to prepare samples for incubation and/or laboratory submission.

Total CE: 4 hours home study and 14.75 hours live = 18.75 hours