Webinar on

Risk Based Environmental Monitoring

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Learning Objectives

- *Current regulatory requirements for environmental monitoring*
- *How to select sample locations based on risk*
- How to perform a risk assessment to support your EM Program
- Differences in room classifications and impact to your EM Program
- Monitoring methods, equipment, and media types
- Data collection, microbial identifications, and data trending options



This Webinar will discuss how to establish a riskbased Environmental **Monitoring Program** and how to perform a reassessment of your current Environmental **Monitoring Program**

PRESENTED BY:

Danielle DeLucy, MS, is the owner of ASA Training and Consulting, LLC which provides Pharmaceutical and Biologics based companies with training and quality systems assistance in order to meet Regulatory compliance. Prior to this role, Danielle has been in the industry for 15 years serving in numerous Quality Management *Roles, such as the Director of Product Quality, the oversight of* Sterility Assurance practices and provided QA oversight of numerous filling and packaging operations.



On-Demand Webinar

Duration : 60 Minutes

Price: \$200

Webinar Description

Environmental Monitoring (EM) programs for pharmaceutical manufacturing are evolving to a risk-based approach. The use of sampling data for the identification and mitigation of risk becomes a critical element in this process. No longer is it enough to utilize data for reactive excursion reporting.

This presentation will discuss how to establish a risk-based Environmental Monitoring Program. During this session, we will discuss how to set up a new Environmental Monitoring Program based on risk as well as how to perform a reassessment of your current Environmental Monitoring Program to re-establish sampling locations and frequencies based on results of your risk assessments coupled with the knowledge gained from your current EM Program historical data.



Who Should Attend ?

Environmental Monitoring Samplers/Managers

Quality Assurance/Quality Control professionals

Sterility Assurance professionals



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