Classified Space Cleaning and EM Workshop

Course Description

This one-day interactive training event will provide participants an overview of industry standard cGxP cleaning and environmental monitoring (EM) principles utilized to support the operational readiness of cleanrooms and other classified spaces. Relevant scientific and regulatory requirements and guidelines (such as ISO, EU, and USP) that govern cleaning and EM programs will be reviewed.

This course will also provide examples of how to identify, trace, and troubleshoot potential contamination issues. Utilizing good aseptic technique, developing an efficient cleaning program, and monitoring the space regularly are critical to maintaining classified space status. The day will culminate with a cleanroom activity, allowing participants to apply best practice techniques, and methods in a variety of hands-on activities.

Note: Coffee, water, drinks, snacks, and lunch will be provided for on-site training.

Time	Agenda
9:00 – 9:15 AM	Welcome & Introductions
9:15 – 10:30 AM	Developing a Cleaning Program & Cleaning Best Practices
10:30 – 10:45 AM	Break
10:45 – 12:00 PM	Environmental Monitoring (EM) Overview
12:00 – 1:00 PM	Lunch
1:00 – 3:30 PM	Cleaning & EM Activities (Cleanroom & Classroom)
3:30 – 3:45 PM	Break
3:45 – 4:45 PM	Identifying & Troubleshooting Cleanroom Contamination
4:45 – 5:00 PM	Questions & Wrap-Up

Module	Learning Objectives
Developing a Cleaning Program & Cleaning Best Practices	• Review critical considerations when designing a cleaning program for a facility, room, or equipment • Discuss the importance of having an approved, effective cleaning program combined with an environmental monitoring (EM) program • Describe surfactants, disinfectants, and sporicidal agents and when they should be used • Describe the proper flow of cleaning • Discuss the importance of wiping surfaces with unidirectional strokes or other approved techniques • Review industry standard materials used for cleaning (non-shedding wipes, wall mops, etc.) • Discuss material transfer in relation to cleaning

Aseptic cGMP Workshop

Including Cleanroom Activity

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Module	Learning Objectives
Environmental Monitoring (EM) Overview	• Review room classifications and allowable concentration limits for particulates and microbial contaminants • Define regulatory expectations of an EM program • Discuss the development of a sampling plan (i.e., number of samples required based on room size and room classification) beginning with Environmental Monitoring Performance Qualifications (EMPQ) • Review considerations for selecting media, defining incubation parameters, and performing growth proficiency testing (GPT) • Discuss the importance of a robust data set in an EM program and the expectations for data trending • Review and demonstrate different methods of sampling (particulate readers, air samplers, contact/settle plates), and sampling best practices
Identifying & Troubleshooting Cleanroom Contamination	• Discuss the inevitability of some level of contamination if human operators are present • Review common issues in cleaning and environmental monitoring that may contribute to cleanroom contamination • Discuss operator errors, gowning errors, and training deficiencies • Review critical considerations in current cleanroom procedures that could contribute to contamination • Discuss how to review trend data to identify potential root causes to contamination • Discuss how to develop a meaningful corrective and preventative action (CAPA) when necessary