Aseptic cGMP and EM Workshop

AZZUR TRAINING CENTER
An Azzur Group Company

Course Description

This one-day training event will provide participants with an overview of current industry regulations and industry expectations for working in and monitoring a cleanroom environment. Basic principles surrounding proper aseptic behavior and technique will also be reviewed in class.

Utilizing good aseptic techniques and developing a robust monitoring program are critical to maintaining classified space status. The day will culminate with a discussion of environmental monitoring, including considerations for developing a monitoring program and best practices for sampling, data trending, and tracking the effectiveness of the monitoring program.

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 – 10:45 AM	The Origin and Importance of cGMP
10:45 – 11:00 AM	Break
11:00 – 12:00 PM	Overview of cGDocP and Data Integrity
12:00 – 1:00 PM	Lunch
1:00 – 1:45 PM	Contamination Control
1:45 – 2:45 PM	Aseptic Behavior and Techniques
2:45 – 3:00 PM	Break
3:00 – 4:30 PM	Environmental Monitoring (EM) Overview
4:30 – 5:00 PM	Questions and Wrap-Up

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Module	Learning Objectives
The Origin and Importance of cGMP	• Define GMP and review the historical cases that led to current regulations • Discuss the Code of Federal Regulations (CFR) and consequences of non-compliance • Review cGMP violations and US FDA 483's / Warning Letters pertaining to GMP violations • Discuss Quality Systems and how they align with GMP regulations / requirements
Overview of cGDocP and Data Integrity	• Define GDocP and the importance of compliance • Discuss and distinguish types of documents found in a GMP environment • Identify requirements for record keeping, including entering and correcting data • Review data integrity importance and the data life cycle • Define ALCOA+ principles and application to both paper and electronic records • Discuss significant data integrity issues • Distinguish electronic signature and records as well as the importance of audit trails • Review controls to minimize DI issues
Contamination Control	• Define contamination and distinguish the different types (i.e., viable, non-viable, cross contamination) • Discuss sources of contamination and factors of microbial growth • Review the history of cleanrooms and classifications • Describe the methods to minimize contamination through engineering, procedural, and behavioral controls
Aseptic Behavior and Techniques	• Explain the basic differences between aseptic processing and terminal sterilization • Distinguish between isolation technologies and open vs. closed systems • Discuss the importance of proper health and hygiene practices for personnel who work in cleanrooms • Review key cleanroom behaviors utilized to prevent contamination • Discuss key principles of aseptic technique including critical areas and surfaces, first air rule, aseptic connections, and working with pipettes
Environmental Monitoring (EM) Overview	• 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

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