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Webinar on

GMP Environmental Monitoring For Pharmaceutical Clean Rooms

Learning Objectives

- *GMP Compliance of Clean Room Environment*
- *Regulatory Clean Room Classification and Requirements*
- *Environmental Monitoring Program, Action and Alert Levels*
- *Non-Viable Particulate Monitoring Systems, Microbial Monitoring Systems*
- *Personnel Gowning and Aseptic , Practices in Clean Room*
- *Clean Room Monitoring Practices - Frequency, Locations, and Investigations*
- *Environmental Monitoring Data Trend reports, Product Release*

This webinar explains the various US and international regulatory requirements for the various cleanroom classifications as well as the environmental monitoring of cleanroom environments.

PRESENTED BY:

Roger Cowan is the founder and owner of R Cowan Consulting Services LLC, a consulting company specializing primarily in the area of pharmaceutical contract manufacturing. In his career, Roger has held various manager/director positions in Quality Assurance, QC Laboratory, Technical Services Validation, Manufacturing, and Clinical Supply manufacturing and distribution.

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On-Demand Webinar

Duration : 60 Minutes

Price: $200

Webinar Description

Environmental Monitoring looks at the end results of the Environmental Control program – the microbiological and particulate quality of the clean room.

As the FDA Guideline on Aseptic Processing GMP (2004) states: “In aseptic processing, one of the most important laboratory controls is the environmental monitoring program. This program provides meaningful information on the quality of the aseptic processing environment (e.g., when a given batch is being manufactured) as well as environmental trends of ancillary clean areas. Environmental monitoring should promptly identify potential routes of contamination, allowing for implementation of corrections before product contamination occurs.”

Therefore, ongoing environmental monitoring of a clean room environment is necessary to assure the quality and safety of the pharmaceutical product.

Also, a proper understanding and testing of the clean room environment according to international regulatory standards is important from a compliance perspective.

The presentation details the benefits, the regulatory requirements and the testing requirements for a comprehensive Environmental Monitoring Program.

Description of Action and Alert Levels follows along with a discussion of how these levels are determined for a particular facility. Corrective and Preventative Actions are defined. All current air monitoring systems for the measurement of non-viable particulate are fully reviewed. All current air and surface monitoring systems for the measurement of microbial contaminants in the clean room are discussed in detail. The subject of cleanroom contamination due to personnel is discussed.

This includes both gowning technique and aseptic practices. Ongoing monitoring practices for the clean room environment are discussed with respect to the sampling frequency, sampling locations, and the investigation of action level excursions. This is followed by a discussion of how environmental monitoring data is reviewed for product release.

Finally, a comprehensive look is taken of the current thinking about the generation and review of Environmental Monitoring Data Trend Reports.

Who Should Attend ?

Quality Assurance

Environmental Monitoring

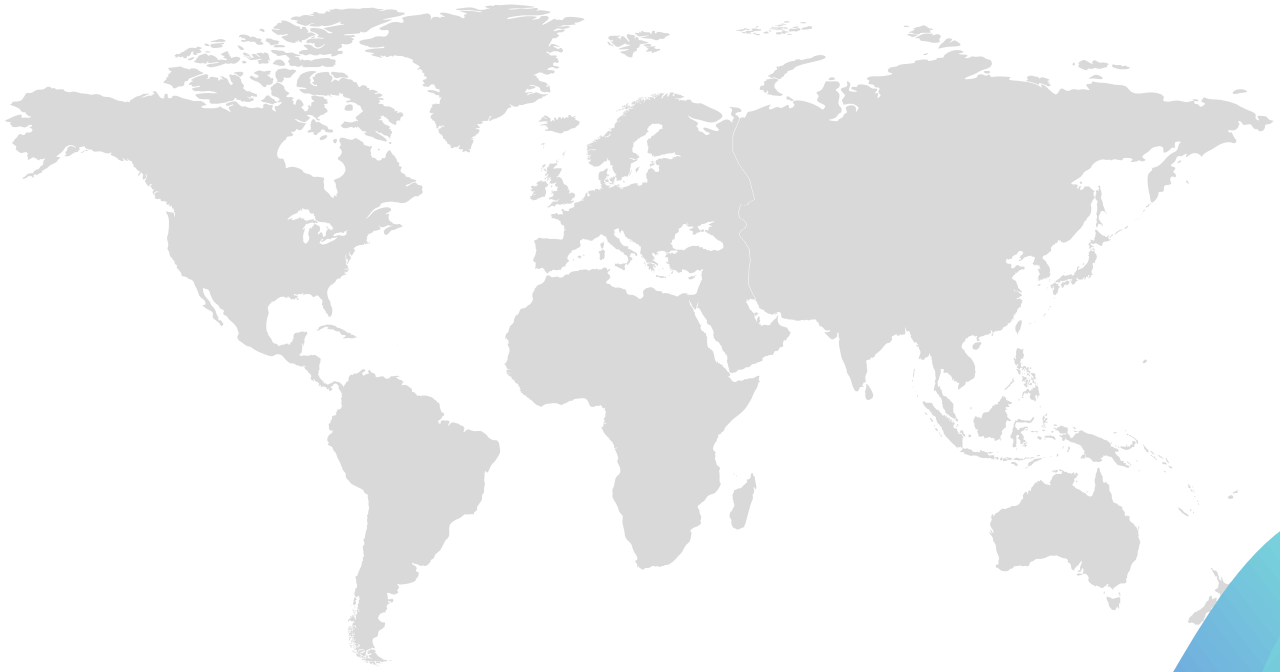
Microbiology

Manufacturing

Validation

Engineering

Maintenance



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