

The A to Z's of Microbial Control, Monitoring and Validation of Water System...

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Organizer : METRICSTREAM INC - NewYorkEventsList

Venue :

Location : San Francisco San Francisco, CA United States,
San Francisco, CA , US, ZIP: United States



Description

The A to Z's of Microbial Control, Monitoring and Validation of Water Systems for Pharmaceuticals, Biologics, Medical Devices, Cosmetics, and Personal Care Products

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All facilities manufacturing pharmaceuticals, biologics, medical devices, cosmetics, and personal care products are likely to have high purity water systems. In spite of this purity, microorganisms can flourish within these systems and lead to undesirable contamination of facility processes and their products. Of all the individuals at the facility, it is site's microbiologists who should understand the microorganisms in water systems and how best to monitor and control them. Sadly, this is often not the case due to the lack of familiarity with biofilm and its impact on water system sampling, testing, sanitization, and routine maintenance. This lack of understanding of microbial control often leads to poor system designs, poor system sampling, poor system maintenance and poor sanitization practices, and as a result, ongoing microbial problems with the water.

This course is designed to provide a microbiology-focused education about all aspects of water systems and how biofilm manages to thrive there. Prior microbiological education or training, though a plus, is not a requirement, since this training is for everyone involved with water systems, from the lab to utility room operations. The instructor will provide the necessary background needed to understand this very important subject matter. This understanding is essential for the proper design, validation, operation, monitoring, and maintenance of a high purity water system. Without this understanding, water system control and monitoring consists of a set of rules that often don't work or result in erroneous monitoring data and can cause everything from very costly and unnecessary system downtime to patient injury and product recalls.

Seminar Fee Includes:Lunch
AM-PM Tea/Coffee
Seminar Material
USB with seminar presentation
Hard copy of presentation
Attendance Certificate
\$100 Gift Cert for next seminar

Learning Objectives:

At the completion of the course, attendees will be able to:

- Understand the role of system design, maintenance and sanitization in controlling microbial

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levels in pharmaceutical water systems.

- Successfully troubleshoot problems resulting from poor design/maintenance versus sampling or testing problems.
- Devise water system validation protocols that truly validate microbial control.
- Validate their water microbial test method.
- Develop sound Alert and Action Levels and Water Specifications.
- Defend their test method, in-process control levels and specifications to FDA.

Who Will Benefit:

This 2-day course is particularly relevant to managers, supervisors, and operatives taking on new responsibilities related to water, but also for experienced water personnel to learn the “true” whys behind what they do and perhaps better ways of doing things. Specific positions that will benefit:

- Microbiology Laboratory supervisors and analysts responsible for water sampling and testing
- Quality Assurance personnel responsible for water system deviation management and change control
- Regulatory and Compliance professionals responsible for FDA interactions
- Process and Utility Engineers responsible for water system maintenance, troubleshooting, and excursion mitigation
- Facility Engineers responsible for water system design or renovation
- Validation personnel for water system qualification

Event Categories :