

BEST for QC Microbiology Training

Quality Control Microbiology Training for
Bioburden, Endotoxin and Sterility Testing

Who should attend

Quality Control Microbiology and
Quality Assurance Professionals
Sterile Pharmaceutical Compounders

* Basic lab experience is assumed.

2019 Dates and Locations

Boston, MA Area May 7–9, 2019
Carlsbad, CA Area Sep. 10–12, 2019

The life science business
of Merck KGaA, Darmstadt,
Germany operates as
MilliporeSigma in the
U.S. and Canada.

Millipore®

Preparation, Separation,
Filtration & Monitoring Products

Program Material Outline

DAY 1

Bioburden Testing

Dependable Tests Based on Membrane Filtration

Bioburden testing is critical for monitoring water quality and raw materials and for ensuring that manufacturing processes remain in microbiological control. During the first day of the training, you will learn about:

- Advantages and limitations of membrane filtration
- How to choose the right membrane for your application
- The regulations governing bioburden testing
- How to develop a sampling plan for Bioburden testing
- How to qualify and validate a method
- How to set alert and action limits
- How to interpret bioburden test results
- How to troubleshoot membrane filtration issues
- Rapid methods for bioburden testing
- Hands-on session using the EZ-Fit™ Manifold and Milliflex® Plus Pump
- Case studies and troubleshooting guidelines

DAY 2

Endotoxin Testing

BET Methodology and Background

The Bacterial Endotoxin Test (BET) is used for the detection and quantitation of endotoxins from Gram-negative bacteria. Reagents are primarily used to test for endotoxins in injectable pharmaceuticals, biological products, and medical devices. They are also used in renal dialysis centers and a wide range of other applications. During the second day of training, you will learn:

- What are endotoxin and BET reagents
- The regulations governing bacterial endotoxin testing
- The methodology for bacterial endotoxin testing
- How to qualify a chosen BET method
- How to validate samples and how to test them routinely
- How to analyze and interpret data
- How to address sample interference
- Hands-on session – Pyros Kinetix® Flex tube reader and Pyros® EQS software

DAY 3

Sterility Testing

A Complete Solution for Reliable Results

Sterility Testing is considered the most essential QC Microbiological test for releasing sterile final product. This test is heavily regulated and harmonized across most of the globe. During the third day of training, you will learn about:

- The history of sterility testing
- The global harmonized regulations overview
- Environmental monitoring requirements for sterility testing
- Deep dive into USP <71>
- Advantages and limitations of direct inoculation sterility testing
- Advantages and limitations of open funnel sterility testing
- Advantages and limitations of closed system sterility testing
- Overview of sterility testing media and rinse fluids
- Most common sterility questions
- Hands-on session – Steritest™ Symbio
- Case studies and troubleshooting guidelines

BEST Products, BEST Service, BEST Training

For more information, please contact your MilliporeSigma Application Specialist or your Associates of Cape Cod, Inc. Technical Sales Specialist

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BEST Registration Form

Your registration fees cover the cost of classroom and branded conference materials, breakfast, lunch and breaks each day of the training, and dinner on the first evening.

Choose Date and City

- Boston, MA Area May 7–9, 2019
- Carlsbad, CA Area Sep. 10–12, 2019

Contact Information

COMPANY: _____

FIRST NAME: _____

LAST NAME: _____

TITLE: _____

TELEPHONE: _____

EMAIL ADDRESS: _____

DEPARTMENT: _____

ADDRESS 1: _____

ADDRESS 2: _____

CITY OR TOWN: _____

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Visit Bestqctraining.com to register online or complete this form and either fax to **508.540.2019** or email to custservice@acciusa.com to register for the BEST training.

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