

**Millipore**<sup>®</sup>

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# BEST<sup>™</sup> QC Microbiology Training

Quality Control Microbiology Training for  
Bioburden, Endotoxin, and Sterility Testing

## Who should attend

- Quality Control Microbiology
- Quality Assurance Professionals
- Sterile Pharmaceutical Compounders

\* Basic lab experience is assumed.

## 2022 Locations and Dates

Boston, MA Area      May 10 - 12, 2022

San Diego, CA Area      Sept. 13 - 15, 2022

## How to Register

For more information or to register, please contact your MilliporeSigma or Associates of Cape Cod Sales Specialist. You may also register online at [bestqctraining.com](https://www.bestqctraining.com)

MilliporeSigma is the U.S. and Canada Life Science business of Merck KGaA, Darmstadt, Germany.



# 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

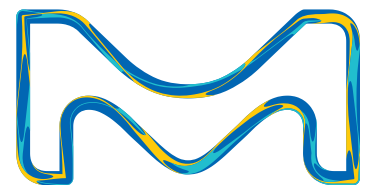
Sterility Testing is considered the most essential QC Microbiological test for releasing sterile final product. This test is heavily regulated and harmonized across most of the globe. During the third day of training, you will learn about:

- 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

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