TRAINING OFFERINGS

Consulting · Customized Training · Webinars

Pharmaceuticals · Biotechnology · Medical Device · Wastewater · Food

All below training may be delivered as a web based training, on-site and hands on training can be customized per organization requirements.

What is encompassed in these various training methods?

Web based training

This two hour web-based training consisting of 1.5 hr. lecture and 30 minutes of interactive session.

Hands-on training

Hands-on practical training programs on different pharmaceutical topics for all levels of microbiology laboratory analysts; as well as microbiologists with less than three years of experience, this will assist them to sharpen their skills and techniques. This will enhance current job experience, provide a higher confidence level and will also help them in identifying a particular area of interest in order to develop their competence in those areas. Hands on training will cover presentations on basic concepts of microbiology and emphasize on practical aspects of these topics in the laboratory environment. Hands on training focuses on the importance of following good microbiology laboratory practices consistently while working in microbiology laboratory. It also includes training on individual experiments with data evaluation and interpretation of test results.

Onsite Customized training

Onsite customized trainings are customized per organizational requirements, timelines, processes and documentation to better apply training to targeted organizational needs. These trainings are customized from the design phase upwards, and include organization related examples. These trainings are site specific and may include any combination of topics to be discussed prior to training implementation.

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Lab Analyst Training

- Introduction to Pharmaceutical Microbiology
- Microbiology Good Laboratory Practices
- Equipment Related Training
- Cleanroom Gowning Training
- Environmental Monitoring
- Plating and Enumeration
- Water Sampling Technique

Environmental Monitoring

- Airflow Visualization (Smoke) Studies - A Key Component of Contamination Control
- Common Misunderstandings While Setting up and Revising an Environmental Monitoring Program
- Environmental Monitoring Deficiencies
- Environmental Monitoring Program for Medical Devices per Current Guidances
- Fundamentals of an Environmental Monitoring Program
- Investigating and Managing Mold Contamination
- Operational Risks During Environmental Monitoring
- Investigating Environmental Monitoring Excursions
- Understanding and Testing Compressed Gases
- Adequate Documentation of Environmental Monitoring Excursions
- How to Trend Environmental Monitoring Data and Assess Risk to Product

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- Key Elements of Environmental Monitoring Summary Reports
- Current Trends and Guidance for a Risk based EM program
- Non-Sterile and Sterile Manufacturing

Cleanooms

- Auditing Cleanroom Gown Suppliers
- Cleanroom Cleaning Errors-That Lead to Microbial Contamination
- Cleanroom Design and Construction-Cost vs. Compliance
- Cleanroom Standards Update ISO 14644 - Parts 1 & 2
- Non-Viable Particle Monitoring of Cleanrooms - Periodic & Continuous Monitoring
- The Science Behind Gowning

Auditing

- Auditing Contract Microbiology Laboratories
- Auditing Microbiological Aspects of Low Bioburden, Non-Sterile Manufacturing
- Auditing Microbiological Aspects of Manufacturing - Aseptic and Non-Aseptic
- Auditing Microbiology Media Suppliers
- Auditing Strategies for Cleaning Processes and Cleaning Validation
- Auditing Strategies for Sterilization Processes and Sterilization Validation

Water Systems

- Biofilm Basics
- Biofilms - Investigation, Detection and Case Studies
- Nitrogen Dioxide - A Solution for Sterilization and Decontamination

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- Gamma Irradiation
- EtO Sterilization
- E-Beam Sterilization
- Sterilization Validations for Disposable Medical Devices

Cleaning and Disinfection

- Cleaning and Disinfection Deficiencies
- Cleaning Validation - Common Errors
- Common Errors in Disinfectant Qualification Studies
- Disinfectant Efficacy Testing
- Biofilms in Water Systems - Reasons and Solutions
- Early Biofilm Detection Remediation and Control
- Facility Water Management
- Microbial Enumeration Solutions for FDA - Regulated Water Systems
- Pharmaceutical Water System Sampling - The Why's, Where's, and How's of Doing It Right
- Pharmaceutical Water Systems - PAT Approaches to improve water quality and Reduce Testing Costs
- Rouge Formation and Control Strategies in WFI Water
- Water Microbial Test Methods-Harmonization vs. Optimal Quality Control - Your Choice
- Water System Design
- Water System Procurement and Implementation

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- Water System Validations
- Green Initiatives for Water System Design

Compendial Tests

- Antimicrobial Effectiveness Testing - Understanding the Basics
- Challenges in Endotoxin Testing
- Clinical Importance of Objectionable Microorganisms
- In-House Microbial Isolates in Compendial Testing - Regulatory Requirements
- Microbial Contamination Testing and Validation Challenges - Non-Sterile Products and Raw Materials
- Microbial Detection Methods and Their Limitations
- Microbial Limit and Bioburden Tests
- Microbial Testing Requirements for Dietary and Nutritional Supplements - Domestic and International
- Antimicrobial Effectiveness Testing
- Sterility Test Failures and Causes
- USP Sterility Test and Growth Promotion
- Scientifically Sound Microbial Data Deviation Investigations
- Pre-Sterilization Bioburden Failures and Causes
- Investigating Non-Sterile Product Bioburden Failures
- Validation of Rapid and Alternate Sterility Methods for Cell Therapy Products

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Sterilization

- Challenges in Ethylene Oxide Sterilization Validation
- Chemical Sterilization - Alternate Sterilization Methods
- Liquid Chemical Sterilization of Animal Tissue Products
- Disinfectant Qualification-Points to Consider
- What Disinfectants Do You Need - FDA or EPA Registered

Medical Devices

- Cleaning-Sterilization - Disinfection Validation of Reusable Medical Devices
- Common Microbiology Errors in Medical Device Manufacturing
- Microbiology for Medical Device Sterilization
- Regulatory Requirements for the Development of Drug Products & Medical Devices
- Reusable Medical Devices-Device Manufacturer's Responsibilities

Microbial Identification

- Common Errors in Microbial Identification and Implications
- Understanding Mass Spectrophotometry for use in Microbial Identification
- Understanding Microbial Identification with an Emphasis on Phenotypic Methods
- Understanding the Science behind Current and Next Generation Genotypic Microbial Identification
- Rapid Microbiological Techniques - Applications, Strategies, and Regulatory Expectations

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Varied Topics

- Adequate Documentation of Microbial Investigations
- Clinical Site Quality
- Commissioning, Qualification and Validation Requirements and Expectations for FDA Regulated Industries
- Considerations when choosing a LIMS System
- Defining and managing software user requirements
- Filling and Packaging Validation for FDA Regulated Industries
- HVAC in GMP Manufacturing Environments
- New Regulatory Paradigm for Validation
- Process Validation for FDA Regulated Industries
- QMS-Considerations for Startups and Lean Resources
- Risk Based Incoming Quality Assurance (IQA)
- Stability Testing for Commercial Drug Products
- Stability Testing for Pre-Clinical and Early Phase Clinical Drug Products
- Strategies to Accommodate Retrofitting and Remediation Efforts
- Technology Transfer-Critical Points to Consider
- Trial Master File Quality Control: The Light at the end of the Tunnel
- Understanding GxP (GMP, GCP & GLP) for FDA Regulated Industries

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Hands-On Laboratory Training Only

- Disinfectant Qualification
- Bacterial Identification
- Mold Identification
- Antimicrobial Efficacy Study
- Microbial Contamination Testing
- Water Testing Techniques
- Growth Promotion Testing
- Gram Staining
- Culture Dilutions, Plating and Enumeration
- Gowning and Aseptic Techniques
- Sterility Testing
- Qualification of Manufacturing Operators and Laboratory Analysts in Aseptic Techniques
- Working in Containments

Microrite will issue a certificate of attendance for each trainee upon request

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