

PLANNING AND EXECUTING A DISINFECTANT QUALIFICATION STUDY
A Step by Step Workshop

Who should attend: Microbiologists performing, and reviewing Disinfectant Qualification studies, Quality Assurance, Regulatory and Manufacturing personnel.

Participate in the only workshop which will step by step guide you how to choose a compliant disinfectant qualification method that suites your company budget, personnel availability, urgency and time limit

Also learn how to plan study execution schedule and supplies, how to budget costs, and how to execute each step and assess errors that may occur

This workshop will also cover data analysis, establishing expiry dates for diluted and undiluted disinfectants and how to apply the findings to the cleaning procedures

Do not miss this opportunity if planning a disinfectant qualification study or have performed one and wish to verify it

Learn from the case studies presented at this workshop

DAY 1 –November 02, 2009

DISINFECTANT QUALIFICATION WORKSHOP

- Disinfectants commonly used in the industry, their modes of action, efficacy, and toxicity
- Understanding the nature of contaminants in the cleanroom and which disinfectants will be effective against them
- Overview of the many methods and variations used for disinfectant qualifications
 - **Tube dilution method**
 - Using filtration
 - Using neutralizing broth
 - **Representative Hard Surfaces**
 - Using contact plates
 - Using Swab Recovery Method
 - Using Rinse Method
 - Using Neutralizing Broth
 - Using Sonication
- Discussions on the variants of each of the methods and the benefits and shortcomings of each method
- Discussion on the pitfalls expected when choosing each method available
- Disinfectant Qualification Protocol
 - Guidance on drafting a Disinfectant Study Protocol for each of the methods discussed
- Planning the Study-Scheduling and Costs
 - Using planning templates, guidance will be provided for breaking up the study components to manage scheduling, costing and ordering supplies to avoid waste due to expiry of media and buffers
- Managing personnel
 - Planning each section of protocol for execution
 - Planning of daily activities while maximizing testing

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DAY 2 –November 03, 2009

DISINFECTANT QUALIFICATION WORKSHOP

- Method Validation
 - How to validate each method
 - What to look for as acceptance criteria
- Recovery Study
 - Guidance on how to perform swabbing studies to get maximum recovery
 - How to plan a recovery study for various methods of efficacy testing
 - Understand the facts and myths about recoveries
- Efficacy Testing
 - Points to consider when planning an efficacy study
 - How to mitigate inoculum count drop
 - Application of inoculum and disinfectants-what to pay attention to
- Time "0" Verification
 - Understand why this additional step gives more confidence in the data generated from the efficacy study
- Expiry Dating Study for Disinfectants
 - How to review efficacy data to abbreviate expiry study which will generate dependable results for assigning expiry date for pre-diluted disinfectants and concentrated disinfectants that do not have an expiry assigned by the manufacturer
- Reviewing Data
 - How to identify execution errors when reviewing data. Establish and Implement corrective actions
- Log Reduction Calculation
 - Data analysis
 - Common errors
 - Detecting false positive or false negative log values
- Translation of disinfectant qualification results to cleaning procedures to prevent contamination
 - Cleaning procedures-what should be addressed
 - How to monitor efficacy of the cleaning program
- Fogging of Cleanrooms and Biological Safety Cabinets
 - Points to consider when choosing to fog
 - Equipment consideration
 - When and why to fog
- Commonly observed deficiencies in Disinfectant Qualification studies that may lead to contamination or FDA observations

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ABOUT THE PRESENTERS

***Ziva Abraham** has over 25 years of academic, research, clinical and industrial experience in Microbiology, and Quality Assurance. She has trained personnel from various industries in microbiology techniques and methods. Ziva has received her Master's Degree in Microbiology and has conducted research on developing Microbial Insecticides. Ziva has conducted numerous disinfectant qualification studies, and continuously trains companies in establishing protocols and executing such studies. She has established clinical laboratory systems in Israel, and Microrite, Inc. a consulting company based in San Jose, CA that helps Pharmaceutical, Medical Device, and Biotechnology Companies. Microrite conducts hands on training at Microrite Training Center located in Santa Clara, California. Microrite focuses on helping companies with contamination control, microbiological quality control for sterile and non-sterile manufacturing, and Quality Assurance. Ziva has also developed "BACTISPELL" a microbiology spellchecker to spell check genus and species names of microbes and other microbiology related terms. She is a member of PDA, ISPE, AAMI, and PMF and is an active mentor for graduate students at Stanford University working through the American Woman in Science Organization (AWIS). She is involved in Expanding Your Horizons, a program through the Math and Scientific Network to educate young girls about careers in science. Ziva serves on the editorial board of Pharmaceutical Microbiology Forum (PMF) Newsletter.*

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SCHEDULE AND VENUE

November 02 and 03 , 2009

Boston Marriott Newton
2345 Commonwealth Ave.
Newton, MA 02466

PROGRAM

Day 1 (November 02, 2009): Registration and Breakfast	8.00 AM to 8.30 AM
Overview of Disinfectants	8.30 AM to 10.00 AM
Break	10.00 AM to 10.15 AM
Overview of Methods	10.15 AM to 11.45 PM
<i>Questions and Answers</i>	11.45AM to 12.00 PM
Lunch	12.00 PM to 1.00 PM
Planning the Study	1.00 PM to 2.30 PM
<i>Questions and Answers</i>	2.30 PM to 2.45 PM
Break	2.45 PM to 3.00 PM
Organisms and Enumeration	3.00 PM to 4.30 PM
<i>Questions and Answers</i>	4.30 PM to 4.45 PM
Day 2 (November 03, 2009): Breakfast	8.00 AM to 8.30 AM
Method Validation and Recovery Study	8.30 AM to 10.00 AM
Break	10.00 AM to 10.15 AM
Efficacy and Expiry Dating Study including Time "0" Verification	10.15 AM to 11.45 PM
<i>Questions and Answers</i>	11.45AM to 12.00 PM
Lunch	12.00 PM to 1.00 PM
Elements of a Cleaning Program	1.00 PM to 2.30 PM
<i>Questions and Answers</i>	2.30 PM to 2.45 PM
Coffee Break	2.45 PM to 3.00 PM
Fogging	3.00 PM to 3.45 PM
FDA 483 observation	3.45 PM to 4.00 PM
<i>Group Discussion</i>	4.00 PM to 4.45 PM

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REGISTRATION FORM

Personal Information of One Registrant

Last Name: Mr. Ms. Dr. First Name: _____

Title: _____ Organization: _____

Mailing Address: _____

Telephone: (Area _____ Facsimile: (Area Code) _____

Email: _____

Fees: \$1850.00 (US)

Group Discount: 10% discount for each attendee when 4 or more attendees register for any one seminar

Additional Attendees:					
Last Name:		First Name:		Title	
Last Name:		First Name:		Title	
Last Name:		First Name:		Title	
Last Name:		First Name:		Title	

Method of Payment: Check, Credit Card or Purchase Order
Fax : 408-445-1236

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San Jose, CA 95136

Confirmation of registration will be sent via email.

Cancellation Policy: Your notice of cancellation must be received by in writing by letter, facsimile or email 10 working days prior to the Seminar date. Fax: 408-445-1236 Email: sales@microrite.com or zabraham@microrite.com

A 10% cancellation fee is applicable for credit card payments

Accommodation: Seminar attendees requiring hotel accommodation should contact Boston Marriott Newton, 2345 Commonwealth Ave. Newton, MA 02466 at **1-617-969-1000**

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Business name: _____

CREDIT CARD INFORMATION

Credit Card Payment may be made on the Microrite's website-
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Card Number:

Expiration(Month/Year):

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Amount (US Dollars):

Signature:

Name of Attendee(s)

City and Date of Seminar