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“Myths and facts about disinfection, cleaning, and disinfectant qualification”

An Intensive 1 Day Workshop

**June 15<sup>th</sup>, 2017**

Bridgewater, NJ

**Disinfection and cleaning of controlled environments is a science not an exercise!**

When developing a disinfection and cleaning program, knowledge of the disinfectant activity, importance of supplies, and other factors have to be considered to consistently control contamination. Performing a disinfectant qualification study does not mean that the disinfection program will work. There are many factors to be considered in developing a scientifically sound program. Learn about the myths and facts about disinfection, disinfectant qualification and cleaning to avoid environmental monitoring excursions and product failures due to microbial contamination.

**Which industries does this workshop apply to?**

Pharmaceuticals, Biotechnology, Medical Device, In Vitro Diagnostics, Food, Beverage and Pharmacies

**Who will benefit?**

Cleanroom Supervisors and Operators, Manufacturing, Cleanroom Cleaning Personnel, Microbiologists, Facilities, Quality and Training Personnel



## Overview

### **Understanding Disinfectants-The First Step Towards a Compliant and Effective Cleaning and Disinfection Program**

- Identify disinfectants commonly used in the industry, their modes of action, efficacy, and toxicity
- Understand the nature of contaminants in the cleanroom and which disinfectants will be effective against them
- Learn how label claim testing is performed and why some disinfectants will not meet the label claims

### **Disinfectant Qualification Studies-When, How and How Often**

- 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
    - Other methods
- Discussion on the pitfalls expected when choosing each method available
- Translation of disinfectant qualification results into cleaning procedures

### **Cleaning Procedures-What should be addressed?**

- Why cleaning supplies matter
- Types of supplies for sterile and non-sterile facilities
- Cleaning flows and frequency for sterile and non-sterile facilities
- Interaction between disinfectants
- Residue formation, reasons and consequences
- Frequency of residue removal
- How to monitor efficacy of the cleaning program

### **Fogging of Cleanrooms and Biological Safety Cabinets**

- Points to consider when choosing to fog
- Equipment considerations
- When and why to fog

### **483 Observations related to Disinfection, Disinfectant Qualification and Cleaning**

- FDA's concerns about microbial contamination due to cleaning and disinfection deficiencies

### **Case studies**

- Discussion about various instances where inadequate cleaning and disinfection lead to major contamination events



**VENUE AND CONFERENCE AGENDA**

<b>June 15<sup>th</sup>, 2017</b>	<b>Hilton Garden Inn in Bridgewater NJ 500 Promenade Boulevard Bridgewater New Jersey, 08807 Tel: 732 271 9030</b>
<b>PROGRAM</b>	
<b>Agenda</b>	
Registration and Breakfast	8.00 AM to 8.30 AM
Understanding Disinfectants-The First Step Towards a Compliant and Effective Cleaning and Disinfection Program	8.30 AM to 9.10 AM
Disinfectant Qualification Studies-When, How and How Often	9.10 AM to 10.00 AM
Break	10.00 AM to 10.15 AM
Disinfectant Qualification Studies-When, How and How Often- Cont.	10.15 AM to 11.00 AM
Cleaning Procedures-What should be addressed?	11.00 AM to 12.00 PM
Lunch	12.00 PM to 1.00 PM
Fogging of Cleanrooms and Biological Safety Cabinets	1.00 PM to 2.00 PM
483 Observations related to Disinfection, Disinfectant Qualification and Cleaning	2.00 PM to 3:00 PM
Break	3.00 PM to 3.15 PM
Case studies	3.15 PM to 4.15 PM
Questions and Answers	4.15 PM to 5.00 PM



**REGISTRATION FORM**

<b>Personal Information of One Registrant</b>		
Last Name:      Mr. Ms. Dr.		First Name:
Title:		Organization:
Mailing Address:		
Telephone:		
Email:		
<b>Fee: \$950.00 per attendee</b> (Includes 1 day workshop fee, breakfast, lunch, break, and course material)		
<b>Additional Attendees</b>		
<b>First Name:</b>	<b>Last Name:</b>	<b>Title:</b>
<b>First Name:</b>	<b>Last Name:</b>	<b>Title:</b>
<b>First Name:</b>	<b>Last Name:</b>	<b>Title:</b>
<b>First Name:</b>	<b>Last Name:</b>	<b>Title:</b>
<p><b>Method of Payment: Credit Card and Check payments only. Attendees can register and make payments on Microrite's website-<a href="http://www.microrite.com">www.microrite.com</a> or complete this form and fax to 408-445-1236. Check payments must be cleared before the workshop date. If you have any questions regarding payment methods feel free to contact Microrite at 408-445-0507 or send your enquiry to <a href="mailto:labraham@microrite.com">labraham@microrite.com</a>. Biocom members receive a 10% discount. Please email us to find out more.</b></p>		
<p>Confirmation of registration will be sent via email. For credit card payment on website, a payment receipt will be considered as confirmation of registration. For credit card information faxed to Microrite an email confirmation will be sent with a copy of payment receipt. Please call 408-445-0507 in due time if confirmation is not received after payment.</p>		
<p>Workshop cancellation must be received 10 business days prior to the workshop less a 10% service fee, cancellation requests will be accepted via email only. The organizations primary contact or credit card holder must make all refund requests. Refunds will be credited to the original credit card used to purchase the workshop.</p>		



# microrite, inc.

## Myths and facts about disinfection, cleaning and disinfectant qualification

### Intensive 1 Day Workshop



#### PAYMENT INFORMATION

<b>Choose One (Place X) ►</b>	<input type="checkbox"/> VISA	<input type="checkbox"/> Master Card	<input type="checkbox"/> American Express
<b>Card Holder's Name ►</b>			
<b>Address of Card Holder:</b>	Enter firm address for corporate card or personal address for personal card		
<b>Street:</b>			
<b>City:</b>			
<b>Zip Code:</b>			
<b>Country:</b>			
<b>Contact Ph No &amp; Email:</b>			
<b>Card Number:</b>			
<b>Expiration(Month/Year):</b>			
<b>Name on Card:</b>			
<b>Amount (US Dollars):</b>			
<b>Signature:</b>			
<b>Name of Attendee(s)</b>			
<b>Referred by:</b>	Kindly note the name of the company or person that referred you to this workshop. We would like to thank them.		



#### **About the Presenters**

**Ziva Abraham** is the President and Founder of Microrite, Inc., a California based consulting firm. She has over 25 years of academic, research, clinical and industrial experience in microbiology, and quality assurance. Ziva has received her Master's Degree in microbiology with a focus on Mycology and has worked on developing microbial Insecticides using entomogenous bacteria and fungi for her doctoral research. Her career also includes founding and managing clinical laboratories for Maccabi Medical in Israel. She has trained personnel from various industries in microbiology techniques and methods. She uses her extensive experience to teach why assessing risk of microbial contamination should be in the forefront of any company that has products for human/veterinary use. Her experience in clinical laboratories has provided her with the framework to understand the effects of microbial contamination in products from a patient safety perspective.

#### **Company**

Microrite's goal is to provide practical solutions through consulting and training

#### **Consulting Services**

Microrite is a San Jose, CA based Consulting Company helping Pharmaceuticals, Biotechnology, Medical Devices, In-Vitro Diagnostics and Combination Products in the areas of Quality Assurance, Microbiology, Process Development, Process Validation, Facility, Utility and Equipment Validation. We specialize in Airflow Pattern analysis as part of risk assessment.

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