

**INTENSIVE TRAINING IN ENVIRONMENTAL MONITORING, DISINFECTANT
QUALIFICATION AND CLEANROOM CONTAMINATION CONTROL**

Who should attend: Quality Assurance, Quality Control, Operations, Regulatory and Manufacturing Supervisors, Cleanroom Operators and Facilities Personnel?

*Benefit from Microrite.'s expertise in Contamination Control and Environmental Monitoring
Learn from those who routinely establish, execute and evaluate environmental monitoring
programs and assess contamination issues for impact on product*

DAY 1

ENVIRONMENTAL MONITORING-A COMPLEX SYSTEM SIMPLIFIED

Correct use of EM Data will help you maintain control of your facility. This data will provide critical Manufacturing Facility Condition information at a glance.

This seminar will provide the tools to establish compliant and practical environmental monitoring programs and the keys to using the data to control contamination

- Discussion on the various cleanroom classification schemes and Environment Monitoring regulations and guidances
- Guidance on setting up a meaningful Environmental Monitoring plan including number and location of sites
- Microbial Identification, when it is necessary and why
- Discussion on choice and evaluation of equipment for Environmental Monitoring
- How to create a plan to track and trend EM data, and when and why to identify EM isolates
- Discussion on evaluation of microbial identification systems
- Guidance on trending EM data in order to retrieve important information on the condition of the manufacturing facility
- Overview of the key components of EM Summary Reports that will provide rapid review of EM controls and precisely relate this to the manufacturing facility condition
- Environmental Monitoring related investigations, what and where to look for
- How to evaluate automated systems for Environmental Monitoring
- Discussion on FDA 483 observations on environmental monitoring and data trending

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DAY 2

**UNDERSTANDING the QUALIFICATION OF DISINFECTANTS AND KEY ELEMENTS of
CLEANING PROCEDURES**

Contamination Prevention in Manufacturing Facility begins with the choice, qualification, and proper application of disinfectants during cleaning. Cleaning and Disinfecting a Manufacturing Suite is a science, not an exercise. Understanding disinfectant qualification methods and the translation of this qualification to cleaning procedures is the key to avoiding contamination and its pitfalls such as failed media fills or sterility tests. Use your EM trending data to develop effective disinfectant efficacy studies and implement robust cleaning procedures to prevent contamination in your Manufacturing Facility to ensure your product's integrity

This seminar will include:

- Detailed discussion of bacterial and fungal contamination in cleanrooms, their source and quantities
- Disinfectants commonly used, their modes of action, efficacy, and toxicity
- Create your own plan, use your environmental monitoring data to choose the disinfectants and cleaning frequencies
- Discussion on current methods used in the industry to qualify disinfectants
- Tools to develop an effective disinfectant qualification program
- Commonly observed deficiencies in Disinfectant Qualification studies that may lead to observations
- Translation of disinfectant qualification results to cleaning procedures to prevent contamination
- Discussion on FDA 483 observations related disinfectant qualification and cleaning procedures
- Case studies where errors in choice of disinfectants or disinfectant qualification have lead to major contamination issues

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ABOUT THE PRESENTERS

Juan Muñoz has a Master's degree in Microbiology and over 20 years of experience in quality assurance, GMP compliance, quality control, microbiological testing of medical devices, biotechnology and pharmaceutical products. He is an expert in clean room design, microbial control, environmental monitoring, sterility testing, general microbiology, microbial limits and other USP/Ph.Eur. microbial tests. Juan has held many positions of high responsibility as manager and associate director of QC of microbiology laboratories at several major biotechnology and pharmaceutical companies across the US. He has been involved in the design, commissioning and validation of several pharmaceutical and biotechnology facilities. He has set-up contamination control at several facilities. Most recently, Mr. Muñoz has managed and executed the qualification testing for a new 100,000 square ft. full service biotechnology facility (cell culture, purification, bulking and filling) and set-up the contamination control program at Abgenix Inc., located in Fremont, California. He has participated in many regulatory inspections by FDA, European, and Canadian regulatory authorities. He is one of the founders of Micro-Virology Testing Laboratories. He is the founder and President/CEO of Microbiology and Quality Associates, Inc (MQA).

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. 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 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

June 7 and 8, 2007

DOUBLETREE GUEST SUITES BOSTON 400
SOLDIERS FIELD RD., BOSTON, MA 02134

PROGRAM

Day 1 (07 June 2007): Registration and Light -Breakfast	8.00 AM to 8.30 AM
Discussion on ISO, USP and EU limits for Environmental Monitoring	8.30 AM to 10.00 AM
Break	10.00 AM to 10.15 AM
Evaluation of equipment, site selection and schedule	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
Microbial Identification and its importance, discussion on microbial ID systems	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
Managing EM data and important elements of EM Summary Reports, discussion on FDA 483 Observations related to Environmental Monitoring and Data Trending	3.00 PM to 4.30 PM
<i>Questions and Answers</i>	4.30 PM to 4.45 PM
Day 2 (08 June 2007): Registration and Light -Breakfast	8.00 AM to 8.30 AM
Overview of Contamination Sources and Disinfectants	8.30 AM to 10.00 AM
Break	10.00 AM to 10.15 AM
Common methods used in Industry for qualifying Disinfectants	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
Common errors encountered in conducting Disinfectant Qualification studies-case studies	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
Important elements of cleaning procedures, FDA 483 observations related to Disinfectant Qualification and Cleaning Procedures	3.00 PM to 4.30 PM
<i>Questions and Answers</i>	4.30 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 Code) _____ Facsimile: (Area Code) _____

Email: _____

Fees: Day1: \$895.00 (US) Day 2: \$895.00 (US) Both Days: \$1725.00 (US)

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

Additional Attendees:		Choose 1,2, or both days			Day 1	Day 2	Both Days	
Last Name:		First Name:		Title:		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Last Name:		First Name:		Title:		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Last Name:		First Name:		Title:		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Last Name:		First Name:		Title:		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

Checks payable to Microrite, Inc.
5019, New Trier Avenue
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 **Doubletree Guest Suites Boston** 400 Soldiers Field Rd., Boston, MA 02134
Boston Area Tel: 1-617-783-0090.

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Business name:

CREDIT CARD INFORMATION

Choose one:

VISA

Master Card

American Express

Card Holder's Name

Address of Card Holder

**Please note Company Address if it is a Corporate Card and
Personal Address if Personal Card**

Street

City

Zip Code

Country

Contact Phone Number

Card Number:

Expiration(Month/Year):

Name on Card:

Amount (US Dollars):

Signature:

Name of Attendee(s)
