

ESTABLISHING A COMPLIANT AND EFFECTIVE ENVIRONMENTAL MONITORING PROGRAM FOR FDA REGULATED INDUSTRY

Pharmaceuticals, Biotechnology, Medical Devices and Combination Products

Co-sponsored by Pacific Biolabs
<http://www.pacificbiolabs.com/>

Who should attend: Quality Assurance, Quality Control, Operations, Regulatory and Manufacturing Supervisors

*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*

Learn about the common errors made when establishing EM programs

Know what is required for sterile and non sterile manufacturing facilities

Learn what to look for in Environmental Monitoring Software packages

June 01, 2009

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
- How to avoid common Microbial Identification errors
- Discussion on choice and evaluation of equipment for Environmental Monitoring
- Establishing User Requirements for Electronic Environmental Monitoring Program
- Discussion on evaluation of microbial identification systems
- Guidance on trending EM data using Excel and Novatek System 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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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. 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 prevention, monitoring and control, microbiological quality control for sterile and non-sterile Manufacturing, Quality Assurance, Facility and Equipment Validation, and Process Validation. 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 01, 2009

**Microrite Training Center
 2338 B Walsh Avenue
 Santa Clara, CA**

PROGRAM

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

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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: Day1: \$900.00 (US)

Discounts: 15% discount for each attendee when 2 or more attendees register

15% discount for one attendee registering before 20 May 2009

Discount Code: MAY

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

Checks payable to Microrite, Inc.

**5019, New Trier Avenue
 San Jose, CA 95136**

Confirmation of registration will be sent via email if payment is made by check or PO. 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.

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 info@microrite.com. **A 10% cancellation fee is applicable for credit card payments**

SUGGESTED AIRPORT AND HOTELS

Closest Airport

Norman Y. Mineta San Jose International Airport (SJC)

1732 N 1st St # 600

San Jose, CA 95112

Distance from Microrite Training Center

Estimated Driving Time: 9 minutes Estimated Distance: 4.77 miles

Accommodations-Suggested Area Hotels

Holiday Inn Express 1700 El Camino Real

Santa Clara, CA 95050

877-410-6681

1.35 miles away from Microrite Training Center

Hawthorn Suites-Santa Clara

2455 El Camino Real

Santa Clara, CA 95051

408-241-0514

1.19 miles away from Microrite Training Center

Howard Johnson

2499 El Camino Real

Santa Clara, CA 95051

408-244-9610

1.19 miles away from Microrite Training Center

Embassy Suites

2885 Lakeside Drive

Santa Clara, CA 95054

408-496-6400

1.19 miles away from Microrite Training Center

Biltmore Hotel and Suites

2151 Laurelwood Road

Santa Clara, CA 95054

408-988-8411

0.96 miles away from Microrite Training Center

Business name: _____

CREDIT CARD INFORMATION

Credit Card Payment may be made on the Microrite's website-
<http://www.microrite.com>

Or this form may be faxed to 408-445-1236

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)

City and Date of Seminar