

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

Co-sponsored by Pacific Biolabs

<http://www.pacificbiolabs.com/>

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*

*Participate in the only course available that ties your Environmental Monitoring Data and Trends to your
Disinfectant Choice and Cleanroom Cleaning Procedures*

*Using Novatek's process oriented approach to system design learn how to continuously monitoring the
state of your clean facility, predicting and avoiding product contamination*

DAY 1 –September 15, 2008

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
- Establishing User Requirements for Electronic Environmental Monitoring Program
- Using Novatek's EM Software Module as training tool learn how to create a plan to track and trend EM data
- When and why to identify EM isolates
- 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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DAY 2 –September 16, 2008

**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 training 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
- Discussion why pH is underappreciated as a critical factor for bleach effectiveness
 - Focus on how the sporicidal efficacy of bleach is markedly enhanced when pH is 6.5 – 7.0 vs. 10
- 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-What is expected from regulatory agencies and who should qualify disinfectants
- Tools to develop an effective disinfectant qualification program
- Commonly observed deficiencies in Disinfectant Qualification studies that may lead to contamination or FDA observations
- Translation of disinfectant qualification results to cleaning procedures to prevent contamination
- 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. 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

Anne Frazer received her doctorate from Tulane University in medical microbiology and immunology and did postdoctoral work at the Oak Ridge National Laboratory. She has held research and teaching appointments at the University of Alabama in Birmingham Medical School, New York University Medical Center, and Rutgers University, working in the areas of microbial physiology, genetics, and ecology. She began focusing on pharmaceutical microbiology in 2000 while a member the QC department at Berlex Biosciences in Richmond, CA. In 2004-2005, her group performed a disinfectant qualification study of five agents, including sodium hypochlorite. She has discussed the design and outcome of this study at several internal corporate meetings and in a poster presented at PDA's First Annual Global Conference on Pharmaceutical Microbiology (2006). Since 2007 she has been a Senior Scientist in QC Validation at Bayer HealthCare in Berkeley, CA.

Marina Angelozzi is currently Senior Manager of Technical Sales at Novatek International. She has been with company since 2002 and has actively participated in many events related to the topic of Environmental Monitoring. Between 2004 and 2006 she acted as moderator for the bi-annual NovaSeminar EM conferences, she presents regularly online on EM related webinars and she will return to the PDA-TRI for the 3rd time to be part of their recurring workshop on environmental monitoring database management and trending. Over the course of her career at Novatek she has been involved in support, training, system set up, and internal audits all related to their Environmental Monitoring Program software.

Ms. Angelozzi holds a degree in Network Administration and previously was Operations Supervisor at Bell Nexxia, a major telecommunication help desk. In her role there she was part of the project team that was instrumental in the desk receiving their COPC (Customer Operations Performance Center) certification.

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SCHEDULE AND VENUE

September 15 and 16 , 2008

**CROWNE PLAZA FOSTER CITY
1221 CHESS DRIVE
FOSTER CITY, CA 94404**

PROGRAM

Day 1 (September 15, 2008): 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 (September 16, 2008): 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

Business name: _____

CREDIT CARD INFORMATION

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

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

Choose one:

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Master Card

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

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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**