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Practical Series Seminars and Workshops

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

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

Learn how to use Novatek's process oriented approach to system design that allows for continuous monitoring of the state of your clean facility, and helps in predicting and avoiding product contamination

DAY 1 –June 26, 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 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

5019 New Trier Ave, San Jose, CA 95136
Phone: 408.445.0507 Fax: 408.445.1236 www.microrite.com

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DAY 2 –June 27, 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
- 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
- Learn how to use Environmental Monitoring Data Trends to evaluate cleaning efficacy
- 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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INTENSIVE TRAINING IN ENVIRONMENTAL MONITORING, DISINFECTANT QUALIFICAION AND CLEANROOM CONTAMINATION CONTROL

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 Phamaceutical Microbiology Forum (PMF) Newsletter*

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

June 26 and 27 , 2008

Renaissance Toronto Airport Hotel & Conference Centre
801 Dixon Hotel
Toronto, Ontario M9W-1J5
Canada

PROGRAM

Day 1 (June 26, 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
Questions and Answers	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
Questions and Answers	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
Questions and Answers	4.30 PM to 4.45 PM
Day 2 (June 27 , 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
Questions and Answers	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
Questions and Answers	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
Questions and Answers	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: $900.00 (US) Day 2: $900.00 (US) Both Days: $1750.00 (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:		☐	☐	☐
Last Name:		First Name:		Title:		☐	☐	☐
Last Name:		First Name:		Title:		☐	☐	☐
Last Name:		First Name:		Title:		☐	☐	☐

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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

Renaissance Toronto Airport Hotel & Conference Centre
801 Dixon Hotel
Toronto, Ontario M9W-1J5
Canada
Phone: 1800-630-2594

When booking sleeping rooms for this seminar please identify as being with Microrite's group to receive the discounted rate

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CREDIT CARD INFORMATION

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

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

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