

2005 Nova Seminars
Environmental Monitoring
Technical Seminar & Workshop

March 16th to 18th, 2005



**Take in the latest trends in
Environmental Monitoring and
enjoy a *New York Broadway play!***



**A comprehensive technical
seminar & workshop focusing on
the newest issues and guidelines
on environmental monitoring.**



New York Marriott East Side Hotel
140 East 49th Street,
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NY 10017



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Environmental Monitoring Technical Seminar & Workshop

Dear Seminar Participants,

Nova Seminars is a non-profit organization dedicated to enriching the knowledge of our colleagues in the pharmaceutical, biotech and health care industries.

Nova Seminars' mission is to work relentlessly in bringing you the best speakers to present topics that will increase your knowledge of current industry regulations and trends, as well as provide you with an interactive forum for discussion.

Nova Seminars is proud to have *Novatek International* and *EMD Chemicals Inc.* as sponsors of the Environmental Monitoring Technical Seminar and Workshop, taking place in exciting New York City. The focus this year will be on Environmental Monitoring trends, as well as current FDA guidelines, requirements and expectations. Distinguished speakers will include: *Dr. Frank S. Kohn* (a former director at Wyeth), *Dr. Kenneth Muhvich* (a former FDA review Microbiologist), along with several experts who will be presenting on various industry specific topics. This will provide attendees the opportunity to engage in a comprehensive and hands-on three day conference amongst their peers.

We cordially invite you to this very informative seminar. At our previous two seminars held in California and Montreal, representatives from companies such as Wyeth, Mayne Pharma, Amgen, Bayer, Abbott, Draxis, Novartis, Hoffman LaRoche, Cangene, Cellgene, Genpharm to name a few, found the seminar and workshop to be useful and educational both in regards to the information provided as well as the dialogue created. We have used the excellent feedback received from attendees to expand on the seminar/workshop, as well as the quality of information and discussion topics.

We look forward to seeing you at the seminar in New York City.

Sincerely,

Mike Ghorbanian

Nova Seminars Director



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Wednesday, March 16th, 2005

- 8:00 a.m** **Registration and Continental Breakfast**
Continental breakfast will be provided
- 9:00 a.m** **Introductions**
Brief introductions of seminar speakers and topics
Parsa Famili, Novatek International
- 9:30 a.m** **“Reacting to Environmental Monitoring Excursions”**
Dr. Kenneth H. Muhvich, Micro-Reliance LLC, USA
- 12:00 p.m** **Lunch & Table Top Exhibition**
Lunch will be provided
- 1:00 p.m** **“Strategies for Establishing a Risk Based Approach to Environmental Monitoring”**
Dr. Frank S. Kohn, FSK Associates, USA
- 3:00 p.m** **Coffee Break**
Refreshments will be provided
- 3:30 p.m** **“User Requirements for a Compliant Environmental Monitoring System”**
Susan Cleary, Novatek International



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Thursday, March 17th, 2005

- 8:00 a.m** **Continental Breakfast**
Continental breakfast will be provided
- 9:00 a.m** **“The Qualification and Comparison of Microbial Air Samplers”**
Michael O’Grady, EMD Chemicals Inc, USA
- 10:30 a.m** **“Managing Your Environmental Monitoring Program”**
Dr. Frank S. Kohn, FSK Associates, USA
- 12:00 p.m** **Lunch & Table Top Exhibition**
Lunch will be provided
- 1:00 p.m** **“FDA Requirements for a 21 CFR Part 11 Compliant Environmental Monitoring System”**
Susan Cleary, Novatek International
- 3:00 p.m** **Coffee Break**
Refreshments will be provided
- 3:30 p.m** **“User Group and Workshop” Working on Real Case Studies**
Dr. Frank S. Kohn, FSK Associates, USA
Susan Cleary, Novatek International



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Friday, March 18th, 2005

- 8:00 a.m** **Continental Breakfast**
Continental breakfast will be provided
- 9:00 a.m** **“High Purity Water Systems, Improved Design and PAT Approaches to Improve Water Quality and Reduce Testing Costs”**
Bob Livingston, Arion Water Inc, USA
- 12:00 p.m** **Lunch & Table Top Exhibition**
Lunch will be provided
- 1:00 p.m** **Environmental Monitoring, “A Complex System Simplified”**
Ziva Abraham, Microrite Inc, USA
- 3:00 p.m** **Coffee Break**
Refreshments will be provided
- 3:30 p.m** **“Evaluate and Prevent Risk to Product by Efficiently Tracking and Trending Environmental Monitoring Data”**
Ziva Abraham, Microrite Inc, USA



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Topic Outlines and Speaker Bios:

“Reacting to Environmental Monitoring Excursions”

This topic will define/describe various types of environmental monitoring excursions and how to properly investigate them so that it is possible to elucidate the root cause. Commonly encountered errors in conducting EM investigations for viable counts that exceeded limits are discussed. Several case studies are provided that illustrate what happens when there is a:

- 1) failure to recognize existing sources of microbial contamination
- 2) failure to identify microorganisms that posed a risk to product
- 3) failure to utilize sporicidal disinfectants properly or at all
- 4) failure to recognize the presence of a microaerophilic contaminant in the manufacturing environment
- 5) failure to adhere to existing cleaning SOP's

The talk will describe what to do in terms of cleaning and disinfection in light of EM exceeded limits (failures). Measures of success also will be discussed

Speaker: Kenneth Muhvich, Ph.D.

Dr. Ken Muhvich is the Principal Consultant for Micro-Reliance LLC, which specializes in Microbiology and Regulatory Compliance Consulting. He has more than 35 years experience as a microbiologist. Prior to formation of Micro-Reliance, Ken was Senior Vice President of Regulatory Compliance for The Validation Group, Inc. During his four years at TVG Inc. he provided sterility assurance advice to more than seventy pharmaceutical companies. He has conducted numerous Pre-Approval type audits of sterile manufacturing facilities, including their microbiology laboratories. He is also frequently involved in guiding companies in sterile process design and validation. He is often called upon to investigate batch sterility failures or to review completed sterility failure investigations. From 1992 to 1997 Ken was a Review Microbiologist at the U.S. Food & Drug Administrations Office of Generic Drugs. While at the FDA, he performed more than six hundred sterility assurance reviews. He is a recognized expert in aseptic processing of sterile drug products and is a member of the Parenteral Drug Association's Aseptic Processing Task Force. He holds a Bachelors degree in Health Science from the University of Delaware. He holds a Masters degree in Medical Microbiology from West Virginia University. He supervised the Clinical Microbiology Laboratory at Sinai Hospital in Baltimore, Maryland for a decade. He holds a Doctor of Philosophy degree in Experimental Pathology from the University of Maryland.



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“Strategies for Establishing a Risk Based Approach to Environmental Monitoring”

Successful development of an environmental monitoring program requires a comprehensive scientific risk based approach to meeting governmental regulatory expectations. With the current regulatory focus on environmental monitoring it is important to have a meaningful, manageable and achievable approach that will meet expectations. This session will focus on several practical strategies for conducting a risk-based approach for environmental monitoring. Issues such as product impact, surveillance, data specifications and validation will be reviewed. A comprehensive validation environmental monitoring master plan will be presented.

Speaker: Dr. Frank S. Kohn BS, MS, PhD, SM (NRM)

Dr. Frank S. Kohn is president of FSK Associates, Inc., an international consulting company providing services to the biopharmaceutical, biotechnology and vaccine industry. Frank recently retired from Wyeth Vaccines, where he was Director of Manufacturing in Sanford, NC. Location.

Dr. Kohn has more than thirty years of industry experience in various technical, quality and manufacturing positions. He holds graduate degrees in microbiology and operations management.

FSK Associates Inc has several highly trained scientist and engineers available to provide consulting services in the areas of environmental monitoring, start-up and technology transfer, validation, software solutions, training and technical marketing.

“User requirements for a Compliant Environmental Monitoring System”

This presentation will give guidance in defining user requirement specifications based on the latest guidelines from, ISO 14644-1 and PDA Technical report 13. The presentation will illustrate the comprehensive system features that should be present in any system that manages Environmental Monitoring data and falls under the jurisdiction of FDA, EU and other regulatory bodies. Attendees are encouraged to ask questions and provide feed back based on their experiences.

Speaker: Susan Cleary

Susan Cleary is the Associate Director of Product Development at Novatek International since 2000. Previously she held the position of lead engineer for Finished Products and Environmental Monitoring software programs.



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"The Qualification and Comparison of Microbial Air Samplers"

will cover several practical topics that a user can implement to evaluate and validate viable air samplers. The fundamental operational principles for several of the available air sampling technologies will be discussed. A practical approach for successfully comparing different air sampling technology's will be presented as well as different procedures for performance qualifications. Additional topics include the computer interface of microbial air samplers, collection accuracy, calibration and maintenance. The presentation is based on several years of experience in implementing microbial air sampling programs and will provide valuable tools for any pharmaceutical company to put into practice.

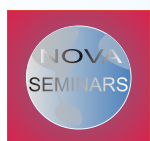
Speaker: Michael O'Grady, EMD Chemicals Inc

Michael O'Grady is the Senior Product Manager for Microbiology and Special Analytics at EMD Chemicals Inc. EMD Chemicals is the US affiliate for Merck KGaA, Darmstadt Germany. His current responsibilities include technical marketing and product management for the Merck dehydrated culture media and the MAS-100 Microbial Air Sampler line for North America. Part of these responsibilities includes the technical support and new product development for microbial air sampling. Mike has helped numerous pharmaceutical companies implement and validate microbial air sampling programs. He has held technical sales and marketing positions in the industrial microbiology market for the past 20 years.

"Twelve Keys to Managing Your Environmental Monitoring Program"

Managing your environmental monitoring program is critical to being able to remain in cGMP compliance. Therefore, this session will focus on twelve key elements that need to be implemented for effective management of your EM program. Employing these keys will help to unlock the information you need to manage to a predetermined outcome. Issues such as alert and action criteria, microbial control, trending and monitoring data will illustrate with real case study information. This talk will provide the management tools to guide you in you EM program.

Speaker: Dr. Frank S. Kohn



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“FDA requirements for a 21 CFR Part 11 Compliant Environmental Monitoring System”

Defining system requirements is a difficult process, especially for something as complex as aseptic environmental monitoring/utilities monitoring software systems. Which features are necessities and which are "bells and whistles"? How are 21 CFR Part 11 regulations met?

In this special session, Susan Cleary will breakdown and interpret the 21 CFR part 11 regulations, focusing on how they are transformed into user requirements for an environmental monitoring solution for your clean facility. Complete solutions with visual examples will provide the attendees insight into a Regulatory Compliant System. Highlights include: trace ability from regulation to user requirements, how to design specification, how to validate test scripts, and how to set up protocols for personnel monitoring.

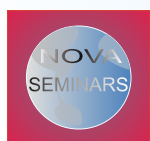
Speaker: Susan Cleary, Novatek International

WORKSHOP & CASE STUDY:

“Environmental Monitoring Real Life Case study”

This workshop will familiarize the participants with analysis of Environmental monitoring data. The workshop consists of compiling real life data, trending the results, evaluating the information, and providing solution(s).

Moderator: Dr. Frank S. Kohn and Susan Cleary



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“High Purity Water Systems, Improved Design and PAT Approaches to Improve Water Quality and Reduce Testing Costs”

Purified Water systems are inordinately important to a facilities validation. We will review pharmaceutical water system designs, common problems and provide highly reliable system designs that provide HP Purified quality water without sanitization or reliance upon expensive vendor servicing contracts. By combining improved water system design with Process Analytical Technologies (PAT) approaches to monitor and document quality, significant savings may be achieved via:

- A) significantly reduced operating cost
- B) on-line monitoring to reduce lab verification testing costs
- C) wider utilization of HP Purified Water for pharmaceutical applications

The presentation will provide engineering reviews of common pharmaceutical water system designs, identify problems associated with common designs, detail effective microbial control strategies for all aspects of water systems from pretreatment through to Point of Use configurations and distribution loop designs. Materials of construction, production and storage issues, sampling concerns and PAT monitoring strategies and data management will be highlighted.

Speaker: Bob Livingston, Arion Water Inc.

Bob Livingston is the President of Arion Water, Inc., a 20-year-old consulting engineering and analytical testing laboratory addressing all aspects of high purity water for pharmaceutical, semiconductor and related industries. Arion Water's high purity water services include system design, analytical testing, operation, application, specifications and validation. Bob has worked for environmental testing laboratories, water system manufacturers and equipment service providers.

Arion Water, Inc. has developed novel approaches and designs for high purity water systems that are widely deployed in the biopharmaceutical, semiconductor and technical manufacturing industries. Bob has spoken on numerous occasions for the ISPE, the ASPE, and teaches the course on Pharmaceutical Water System Design for the PDA. He lectures often for Barnett and IVT on all aspects of High Purity Water production and use



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Environmental Monitoring, “A Complex System Simplified” Understand the definitions related to environmental monitoring and how to use them. Understand US, EU and ISO classification schemes and requirements, and FDA Guidance on Aseptic Manufacturing to qualify the manufacturing facility and develop a practical and compliant Environmental Monitoring program. Evaluate equipment used for environmental monitoring and microbial identification for accurate results and efficient data download and management, to facilitate efficient tracking and trending for evaluating risk to product.

“Evaluate and Prevent Risk to Product by Efficiently Tracking and Trending Environmental Monitoring Data”

Environmental Monitoring trending results are a measure of the condition of the manufacturing facility at one point in time and over a time period. EM data when trended well can depict possible risk to product, deteriorating condition of the manufacturing facility and deficiencies in personnel qualification or training. Using trending results is also a key to evaluating cleaning and gowning procedures. Well-written meaningful EM Summary Reports facilitate the Aseptic Manufacturing Facility condition at a glance.

Speaker: Ziva Abraham

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 towards her Ph.D. degree 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 of microbes and other microbiology related terms.



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Registration Form:

- Full Conference, March 16th to 18th** **\$ 1,470 USD**
- Two Day Package** **\$ 995 USD**

Name:

Title:

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Fax Number:

Signature:

Kindly fax your registration form to: 514-336-6537

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Registration Information

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Hotel Reservation:

New York Marriott East Side

Toll-Free: 1-800-242-8684

Registration includes: Continental breakfasts, refreshments, lunches

For all applications received before February 25th, 2005, Nova Seminars will provide a free Broadway ticket to the "Chicago" show including transportation. Show date Thursday, March 17th. Pick up is from the seminar location.

***** Please note that space is limited. Don't miss the opportunity to hear about the very latest developments in Environmental Monitoring.** Registration without payment will not be processed. Your registration may be transferred to a member of your organization at any time. Request for cancellation should be received by email or fax before February 10, 2005 in order to receive credit for attending another Nova Seminar event. Please note cancellation will not be accepted following this date. All cancellations are subject to \$ 325 USD processing fee. Nova Seminars is not responsible for airfare, hotel, or other costs incurred by registrant. Speakers and Broadway show are subject to change without notice.



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