

Current Practices in Qualification and Monitoring of Cleanrooms and Isolators

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

DAY 1 –October 08, 2009

Environmental Monitoring, A Complex System Simplified - Ziva Abraham, Microrite, Inc.

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 a 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
- Using Novatek's software as a training tool learn to evaluate automated systems for Environmental Monitoring
- Discussion on FDA 483 observations on environmental monitoring and data trending

Selection, Implementation, and Use of Equipment and Materials for Environmental Monitoring-Mark Zemler, Diosynth

What you should expect to learn from the presentation:

- Understand what an EM program is meant to do and how the choice and placement of sampling equipment affects the interpretation of your data
- How to get more from your EM program by understanding when and where to collect samples
- Learn how to collect meaningful personnel samples
- Learn the how to select the right viable air sampler
- Understand the rationale for air sampler placement
- Gain insight into how to interpret the results obtained from environmental monitoring
- Learn approaches to upgrading or changing sampling equipment
- Swabs or contact plates- when to use

Current Practices in Qualification and Monitoring of Cleanrooms and Isolators

DAY 2 –October 09, 2009

Specifying, Designing, Installing and Validating a Particle Monitoring System for a Pharmaceutical Facility - Lighthouse Worldwide Solutions

Specifying, Designing, Installing and Validating a Particle Monitoring System for a Pharmaceutical Facility

- Understand the requirements for non-viable particle counting in a regulated environment
- The requirements for continuous particle monitoring
- Specification and soliciting offers.
- Common system design considerations
- Installation Considerations
- Operational Considerations

Qualification Protocols for An Aseptic Processing Isolator - Dr. Dan Mohan

Understand and learn to how to effectively develop aseptic operations performed using Barrier Isolator Technology. This presentation will include:

- **Isolator Decontamination Cycle Development**
 - Chamber Temperature Distribution
 - Vapor Hydrogen Peroxide Concentration
 - Chemical Indicator Testing
 - Biological Indicator Testing
- **Isolator Qualification Protocols:**
 - **Installation Qualification (IQ)**
 - Elements of Equipment / System Verification
 - Document Verification;
 - Equipment / System Instrumentation Verification
 - Utility Verification
 - Major Component Identification / Verification
 - Materials of Construction and Lubrication Verification
 - Ancillary Equipment and Change Parts Verification
 - PM / Cal Procedure Verification; Quality of Installation Verification
 - Ammonia Leak Test Verification
 - Hardware Installation Verification
 - Software / Archive Verification
 - **Operational Qualification (OQ)**
 - Operator Interface Verification
 - Controls / Interlocks / Indicators Verification
 - Lighting Verification
 - Non-Viable Particulate Level Test
 - Pressure Decay Verification
 - Oxygen Control / Humidity Monitoring Test

- Temperature Distribution / VHP Exposure Test; Phase Transition Cycle Verification
- Alarms / Error Message Verification
- Power Failure / Recovery Verification
- Data Storage and Recovery Verification
- Interference Verification

- **Performance Qualification (PQ)**

- VHP Cycle Challenge with BI (Min / Max Loads)
- External Aeration Verification
- Environmental Monitoring (Aerobic / Anaerobic)
- Aseptic Hold Time Study
- D-Value Determination (for BI)
- Container / Closure Integrity Testing

Isolator Monitoring and Glove Testing - Dr. Dan Mohan

- **Isolator Environmental Monitoring Protocol**

- Environmental Monitoring Parameters
- Monitoring Methods and Tools
- Aseptic Transfer Technologies
- Guidelines for Monitoring Frequencies
- USP and EU Action Limits

- **Isolator Glove Integrity**

- Glove Leak Testing Methodologies
- Principle of Operation of Glove Leak Testers
- Developing Leak Rate Acceptance Criteria
- Case Study in an Aseptic Isolator Campaign
- Leak Rate Failure Modes Analysis

Current Practices in Qualification and Monitoring of Cleanrooms and Isolators

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

Dr. Dan Mohan has over 10 years of industrial experience in aseptic process engineering and development for clinical manufacturing of implantable drug delivery devices with Johnson and Johnson Companies. His experience in aseptic manufacturing includes equipment development and integration for commercial manufacturing of combination products. Most recently, he has been responsible for implementing an aseptic manufacturing facility containing multiple barrier isolator systems including several sterilization technologies. Previous to joining Johnson & Johnson, Dr. Mohan has served Becton Dickinson and Company as Director of R&D in the area of product and process development related to medical diagnostics and tissue culture in health care research. He has been instrumental in developing non-destructive product testing technologies including radiographic techniques for quality assurance of implantable medical devices. He holds a PhD in chemical engineering from Stevens Institute of Technology and engineering degrees in Mechanical and Engineering Sciences from the Indian Institute of Science.

Morgan Polen is the vice president of application technology for Lighthouse Worldwide Solutions. He has been working in contamination control and cleanrooms since 1984 and been involved with projects ranging from cleanroom design and construction, environmental monitoring program development, facility monitoring system validation protocol creation, particle counter design, biological sampler design, ultra pure water system design, surface conditioning and cleaning systems, ESD Program creation and auditing, and currently is responsible for developing contamination monitoring programs for customers worldwide.

Mark Zemler holds BS and MS degrees as a Microbiologist and Quality Management professional. Mark has held positions of increasing responsibility in the pharmaceutical, biologics, and biotechnology business with over 30 years experience in allergy, animal health and biotechnology at Hollister-Stier, Bayer Corporation, EMD Pharmaceuticals, and Diosynth Biotechnology. Over these years he has contributed to the quality programs for clean room management, allergenic product manufacturing, validation, animal health, and biopharmaceuticals. During this time, he has been involved in all aspects of the design, construction, validation, quality control, and FDA approval of commercial and clinical manufacturing facilities. Many years were involved with direct responsibility for the development, implementation and oversight of environmental monitoring programs for these companies. Mark has had much experience with the selection, commissioning, qualification and use of environmental monitoring equipment in clean room operations, both for sterile and non-sterile operations. He is responsible for Quality Control and Analytical Development in his current position.

Current Practices in Qualification and Monitoring of Cleanrooms and Isolators

SCHEDULE AND VENUE

October 08, and 09 2009

Hilton North Raleigh

3415 Wake Forest Rd

Raleigh NC 27609

PROGRAM

| | |
|---|----------------------|
| Day 1 (08 October 2009): Registration and Light -Breakfast | 8.00 AM to 8.30 AM |
| Discussion on regulations and guidances | 8.30 AM to 10.00 AM |
| Break | 10.00 AM to 10.15 AM |
| Environmental Monitoring, A complex system Simplified | 10.15 AM to 11.00 PM |
| <i>Questions and Answers</i> | 11.00AM to 11.15 AM |
| Environmental Monitoring, A complex system Simplified | 11.15 AM to 12.00 PM |
| Lunch | 12.00 PM to 1.00 PM |
| Selection, Implementation, and Use of Equipment and Materials for Environmental Monitoring | 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 |
| Trending and Reports-Use of Electronic Systems | 3.00 PM to 4.30 PM |
| <i>Questions and Answers</i> | 4.30 PM to 4.45 PM |
| Day 2 (09 October 2009): Registration and Light - Breakfast | 8.00 AM to 8.30 AM |
| Specifying, Designing, Installing and Validating a Particle Monitoring System for a Pharmaceutical Facility | 8.30 AM to 10.00 AM |
| Break | 10.00 AM to 10.10 AM |
| Qualification Protocols for An Aseptic Processing Isolator | 10.15 AM to 12.00 PM |
| Lunch | 12.00 PM to 1.00 PM |
| Qualification Protocols for An Aseptic Processing Isolator | 1.00 PM to 2.00 PM |
| <i>Questions and Answers</i> | 2.00 PM to 2.30 PM |
| Break | 2.30 PM to 2.45 PM |
| Isolator Monitoring and Glove Testing | 2.45 PM to 4.15 PM |
| <i>Questions and Answers</i> | 4.15 PM to 4.45 PM |

Current Practices in Qualification and Monitoring of Cleanrooms and Isolators

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: \$950.00.(US) Day 2: \$950.00(US) Both Days:\$1800.00 (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 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

Accommodation: Seminar attendees requiring hotel accommodation should contact Hilton North Raleigh, 3415 Wake Forest Rd, Raleigh NC 27609 Tel: 1-919-872-2323.

Hotel Rooms are discounted for this event. Contact June Bazemore at Hilton North Raleigh if help is needed with room reservation.

Current Practices in Qualification and Monitoring of Cleanrooms and Isolators

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:

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 _____