STERILITY ASSURANCE AND BIOBURDEN REDUCTION FOR DRUGS AND MEDICAL DEVICES


Microrite, Inc. brings you this unique course in sterility assurance and bioburden reduction for drugs and medical devices; part of Microrite’s Practical Series Workshops

STERILITY ASSURANCE AND BIOBURDEN REDUCTION FOR DRUGS AND MEDICAL DEVICES

The most comprehensive workshop on conventional and novel sterilization methods, validation strategies, and regulatory aspects taught by speakers who are forward thinking professionals with abundant practical experience. Microrite encourages you to bring your questions to the speakers.

Which industries does this conference apply to?
Industries that will benefit from this training are Medical Devices, Pharmaceuticals, Biotechnology, and Drug/Device Combination Products.

Who will benefit?
Engineering, Manufacturing, Quality Assurance, Microbiology, Validation Personnel.

Who will be teaching?
The speakers include Randy Flaskey, an Advanced Microbiology Specialist in 3M Medical Division’s Quality Assurance Department, with 30 years of experience in sterilization validation. Mike Graybill, a Senior Quality Engineer and Sterility Assurance Microbiologist who chairs 3M’s Global Sterility Assurance Team (GSAT). Mike Valentine, a leading team member for Infection Prevention & Control Chemistries Group at Minntech with twenty five years of experience in providing novel sterilization solutions for medical device, pharmaceutical and research applications. Chris Gustilo, Marketing Director for Infection Prevention Control Chemistries at Minntech Corporation. He has spent the last 9 years working with paracetic acid chemistries for the sterilization of medical devices as well as disinfection of water systems and rooms; and Ziva Abraham, a well known Microbial Contamination Control expert.
Lecture: Common sources of pre-sterilization bioburden by Ziva Abraham (Microrite)

Pre-sterilization bioburden control of devices is crucial in order to gain assurance of sterility during sterilization no matter what method is used. This course will discuss the steps to follow to keep bioburden in room and device.

- Do’s and don’ts in facility/controlled environment design to manage bioburden
- Importance of personnel flows and material flows
- Managing vendors and suppliers and setting incoming specifications
- Scientifically sound cleaning strategies
- Benefits of monitoring room bioburden data
- Q & A

Lecture: Unique Technologies and Applications for Bioburden Reduction by Chris Gustilo (Minntech)

Application of Fogging Technologies
Overview of current area decontamination technologies issues and challenges.

- Cold sterilants and disinfectants-the myths and facts
- PAA versus H2O2
- Manual and automated methods for disinfection using fogging technologies
- Requirements and procedures for room and equipment decontamination using fogging technologies
- Dry fogging principles
- Major contamination related case studies and benefits of fogging
- Q & A

Lecture: Dry Fogging Case Study by Randy Flaskey (3M)

- Spore Coupon Preparation, Use and testing
- Dry Fogging Validation
- Fogging Multiple Rooms - Planning and Setup
- HVAC Shutdown Procedure
- Dry Fogging a Cleanroom Facility
- Safety considerations
- Q & A
Lecture: Latest Trends in Dry Fogging Technology by Chris Gustilo (Minntech)

- Rapid room recovery
- Full automation
- Antimicrobial Coatings
- Gowning Room Case Study
- Q & A

Lecture: Chemical Sterilization – Applicability and Technology by Mike Valentine (Minntech)

Chemical sterilization technology overview:

With device-drug combination products on the rise, it is beneficial to discuss alternate not cumbersome sterilization technologies that can be used for small batches.

- Current methods and trends for chemical sterilization in Medical Device and Pharmaceutical and combination product applications
- Regulatory guidelines and pathway on chemical sterilization
- Packaging considerations and options when opting for chemical sterilization technologies
- Cycle Development and process validation for chemical sterilization using Six Sigma Process Excellence tools
- Q & A
Lecture: Bioburden Assessment by Randy Flaskey (3M)

Bioburden testing of medical devices is an essential part of routine control of manufacturing processes. Bioburden methods must be appropriate for the device to be assessed and must be validated. This seminar will review traditional bioburden and bioburden validation methods. Occasionally, bioburden is underestimated in spite of the validation efforts of the laboratory. This can cause significant problems in certain validation exercises, especially Method 1 gamma validations. A unique approach to bioburden assessment will be reviewed as part of this seminar.

- Traditional bioburden and validation methods
- Bioburden assessment – a unique MPN approach
- This unique approach to bioburden assessment has been invaluable to certain gamma validation studies conducted by the presenter. Participants may find solutions to current bioburden assay problems in this presentation.
- Q & A

Lecture: Gamma Sterility Assurance Method- Overview by Randy Flaskey (3M)

This presentation will discuss the general requirements for Sterility Assurance Validation for Gamma processing of medical devices:

- **Gamma**
  - Overview of ISO 11137 – Sterility Assurance Validation (including any ISO updates)
  - Gamma Dose Setting Validation
  - Gamma Validation reporting
  - Dose auditing
- Q & A

Lecture: How to React to, and Investigate, Dose Audit Failures by Mike Graybill (3M)

This presentation will examine what transpires when a dose audit failure occurs to a medical device following ISO 11137:2006 validation:

- How to interpret lab results and accept/reject them
- How to react in order to continue to produce and sterilize product
- How to investigate root cause
- How to proceed going forward
- Q & A
DAY 2:  4 May, 2012 (Continued)

Lecture:  Managing Dosimetry Systems by Mike Graybill (3M)

Participants will gain from an application-based approach to managing a dosimetry system, whether it be in-house or at a contract irradiator facility, including auditing:

- Calibration & auditing of a dosimetry system and its reporting
- Reporting of the release dose and routine release of product
- Handling non-conformances when they occur
- How to audit a contract irradiator
- Q & A

Lecture:  EtO Sterility Assurance Method-Overview by Randy Flaskey (3M)

This presentation will discuss the general requirements for Sterility Assurance Validation for EtO processing of medical devices:

- EtO
  - Overview of ISO 11135 (including any ISO updates)
  - EtO Validation/Revalidation
  - EtO Validation reporting
- Reviewing Changes to Products or Processes
- The FDA is coming: Preparing for FDA and Notified Body Audits
- Q & A

Lecture:  EtO Residuals: 10993-7:2008 and its challenges by Mike Graybill (3M)

This presentation will discuss the general requirements new to the most recent version of this ISO standard:

- Navigating the challenging standard
- New residual limits
- Introduction to a dually-binding constraint for acute skin irritation, tolerable contact limit (TCL)
- Methods to calculate TCL
- Q & A
## VENUE AND CONFERENCE AGENDA

| 3 and 4 May, 2012 | Crown Plaza Bloomington  
5401 Green Valley Drive  
Bloomington, MN 55437  
Phone: 952-345-1245 |
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### PROGRAM

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<tr>
<th>Day 1 (3 May, 2012): Registration and Breakfast</th>
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<tr>
<td>Common Sources of Pre-Sterilization Bioburden by Ziva Abraham</td>
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<td>Break</td>
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<td>Unique Technologies and Applications for Bioburden Reduction by Chris Gustilo</td>
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<td><strong>Lunch Break</strong></td>
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<td>Dry Fogging Case Study by Randy Flaskey</td>
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<td>Latest Trends in Dry Fogging Technology by Chris Gustilo</td>
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<td>Chemical Sterilization; Applicability and Technology by Mike Valentine</td>
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<td><strong>Day 2 (4 May, 2012): Breakfast and Networking</strong></td>
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<td>Bioburden Assessment by Randy Flaskey</td>
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REGISTRATION FORM

STERILITY ASSURANCE AND BIOBURDEN REDUCTION FOR DRUGS AND MEDICAL DEVICES

May 3rd & 4th, 2012  Crown Plaza-Bloomington, MN

PERSONAL INFORMATION OF ONE REGISTRANT

Last Name: Mr. Ms. Dr. First Name: 

Title: Organization: 

Mailing Address: 

Telephone: 

Email: 

Fee: $1,800.00 per attendee (Includes 2 day seminar fee, breakfast, lunch, break for both days, and course material)

Cutoff date for registration is 19 April, 2012. No door registrations will be permitted. All payments should be received by 19 April, 2012.

ADDITIONAL ATTENDEES

First Name: Last Name: Title: 

First Name: Last Name: Title: 

First Name: Last Name: Title: 

First Name: Last Name: Title: 

Method of Payment: Credit Card and Check payments only. Attendees can register and make payments on Microrite’s website- www.microrite.com or complete this form and fax to 408-445-1236. Check payments must be cleared before the cutoff date. If you have any questions regarding payment methods feel free to contact Microrite at 408-445-0507 or send your enquiry to info@microrite.com.

Confirmation of registration will be sent via email. 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.

ABOUT THE VENUE

Crown Plaza Bloomington

5401 Green Valley Drive - Bloomington, MN 55437

Phone: 952-345-1245, Fax: 952-345-1234

The hotel is conveniently located in close proximity to Minneapolis airport and mall of America. Microrite has negotiated a rate of $99 per night for the sleeping rooms.
### PAYMENT INFORMATION

**STERILITY ASSURANCE AND BIOBURDEN REDUCTION FOR DRUGS AND MEDICAL DEVICES**

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Microrite, Inc. 5019 New Trier Avenue + San Jose, CA 95136 + Ph: 408-445-0507 + Fax: 408-445-1236

www.microrite.com
Our presenters are experts in their field and passionate about teaching. You will wholeheartedly agree to this after attending this workshop.

**Mike Graybill** is a Senior Quality Engineer and Sterility Assurance Microbiologist for 3M Medical Division’s Quality Assurance Department. Mike received his Bachelor’s Degree in Biological Sciences from South Dakota State University (SDSU), and his Masters Degree in Microbiology from SDSU. Mike started his career at 3M working in the Attest Biological Indicator manufacturing facility as a Microbiologist, and more recently has been in charge of medical device gamma and EtO sterility assurance validations and maintenance for the past 6 years. Mike chairs 3M’s Global Sterility Assurance Team (GSAT) and is also the administrator of dosimetry systems used for the release of sterile product from 3M’s two industrial gamma irradiators.

**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. She is the founder of 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 is a well known microbial contamination control expert both nationally and globally.

**Mike Valentine** is the Director of Sales for Minntech – Infection Prevention & Control Chemistries Group. Prior to Minntech, Mike worked for Johnson & Johnson in progressive marketing, sales and business development roles including Worldwide Director for the Scientific & Industrial Business of Advanced Sterilization Products division. Mike brings over twenty five years of experience in providing novel sterilization solutions for medical device, pharmaceutical and research applications. Mike’s expertise includes medical device sterilization and packaging, global medical device regulations, pharmaceutical aseptic and terminal sterilization processes. Mike is well versed in steam, ethylene oxide, hydrogen peroxide gas plasma, chlorine dioxide and other sterilization methods.

**Randy Flaskey** is an Advanced Microbiology Specialist in 3M Medical Division’s Quality Assurance Department. Randy received a Bachelor’s Degree in Microbiology from South Dakota State University and has over 30 years of Quality Assurance experience in 3M medical device and pharmaceutical manufacturing facilities. He has been responsible for the sterility assurance validation program for gamma and EtO sterilized medical devices at the major 3M medical device manufacturing facility and provides 3M global corporate leadership on sterility assurance validation. He is responsible for environmental monitoring programs and microbiological testing of medical devices. He has significant experience in microbiological performance testing of biological indicators and microbiological challenge testing. He has participated in many regulatory inspections by FDA and European Regulatory Authorities regarding sterility assurance validation and related inspections.

**Chris Gustilo** is Marketing Director for Infection Prevention Control Chemistries at Minntech Corporation. Chris has 20 years of experience in the medical device industry and has worked with both startup and medium sized medical device companies bringing new technologies to market. He has spent the last 9 years working with paracetic acid chemistries for the sterilization of medical devices as well as disinfection of water systems and rooms. He holds an MBA from Carlson School of Business and is a member of APIC.