

STERILIZATION STRATEGIES FOR PHARMACEUTICALS, BIOTECHNOLOGY, MEDICAL DEVICES AND COMBINATION PRODUCTS

Who should attend: Quality Assurance, Quality Control, Microbiologists, Validation, and Process Engineers

DAY 1 – 04 March, 2010

Understanding Gamma Irradiation, and E-Beam Sterilization **Betty Howard, STERIS Isomedix Services**

This presentation will focus on current practices followed for Sterilization using Gamma Irradiation, and E-Beam

- Overview of radiation and how gamma is used
- Gamma materials selection and dosimetry
- Introduction to ethylene oxide sterilization
- Overview of electron beam processing
- E-beam processing, penetration, dose mapping and product compatibility

Validation Gamma and ETO Sterilization Methods **Randy Flaskey, 3M**

This presentation will discuss the general requirements for Sterility Assurance Validation for Gamma and EtO 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
- **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

Participants will benefit from a speaker with more than 30 years of hands on validation of sterile medical devices. The intent of this seminar is an application-based approach to sterility assurance validation.

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DAY 2 – 05 March, 2010

Bioburden Assessment **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.

Current Best Practices for the Design and Validation of Sterilization Processes **John M. Hyde, Chairman, CEO and Founder, Hyde Engineering + Consulting, Inc**

Strategies for implementation of sterilization processes and sterilization validation will be presented for pharmaceutical and biopharmaceutical process systems, support systems and equipment. Specific topics to be discussed include the following:

- Microbiological and physical bases for current practices for sterilization processes and sterilization validation
- Regulatory expectations for validation of sterilization processes
- Review of sterilization related industry and regulatory guidance
- Effective master planning for validation of sterilization processes
- Review of typical sterilization operations for process systems, support systems and equipment
- Auditing strategies for effective management of excursions and deviations including establishment of root causes and proposal of corrective actions for OOS events
- Risk based approaches to sterilization validation and ongoing monitoring of sterilization operation

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ABOUT THE PRESENTERS

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.

John Hyde is President of Hyde Engineering + Consulting, Inc., a firm of 100 engineers and scientists founded in 1993 and specializing in process and control systems engineering, process and equipment validation, and compliance consulting for biopharmaceutical and pharmaceutical process systems. For nearly two years prior to the formation of JM Hyde Consulting, Inc., John was Senior Project Engineer with Synergen, a biopharmaceutical research and manufacturing company located in Boulder, CO. His work at Synergen included design, start-up and validation of key process systems and the overall responsibility for the cleaning validation programs for the firm's large scale and clinical manufacturing facilities. From 1982 to 1992, John was Manager, Process Design with Seiberling Associates, Inc., an engineering firm specializing in the design and start-up of hygienic process systems and the application of CIP technology. He has presented papers at numerous engineering conferences and short courses on topics including biopharmaceutical process systems design, automatic cleaning system design and implementation, and control system design for pharmaceutical processes, and he has published ten articles on these topics. He, as a member of the PDA Subcommittee for Biopharmaceutical Cleaning Validation, contributed two chapters to a book on the subject, and he is completing a book manuscript on CIP technology. John is a regular speaker on conferences presented by the Society of Bioprocessing Professionals (SBP), Pharmaconference, the Institute of Validation Technology (IVT), the International Society of Pharmaceutical Engineers (ISPE), the American Institute of Chemical Engineers (AIChE) and other professional societies. John has also provided CIP systems training to FDA CBER personnel. He holds Bachelors degrees in Food Science and Business Administration, and a Masters degree in Food Engineering, all from the Ohio State University.

Betty Howard (M.S., MBA) is the Gamma Technology Center Manager for STERIS Isomedix Services in Morton Grove, IL. Betty manages technical support and validation activities for gamma sterilization. She has over 20 years experience in Biotechnology research, applications and technical support related to drug discovery, analytic instrumentation, microbiology, biochemistry and sterilization technology with previous positions with Amersham, PerkinElmer, Illinois Department of Public Health.



Practical Series Seminars and Workshops

STERILIZATION STRATEGIES FOR PHARMACEUTICALS, BIOTECHNOLOGY, MEDICAL DEVICES AND COMBINATION PRODUCTS

SCHEDULE AND VENUE

March 04 and 05, 2010

Biltmore Hotel and Suites
2151 Laurelwood Road
Santa Clara, CA 95054

PROGRAM

Day 1 (04 March, 2010): Registration and Breakfast	8.00 AM to 8.30 AM
<i>Understanding Gamma Irradiation, E-Beam Sterilization</i>	8.30 AM to 10.00 AM
<i>Questions and Answers</i>	10.00 AM to 10.15 AM
Break	10.15 AM to 10.30 AM
<i>Understanding Gamma Irradiation, E-Beam Sterilization</i>	10.30 AM to 11.45 AM
<i>Questions and Answers</i>	11.45AM to 12.00 PM
Lunch	12.00 PM to 1.00 PM
<i>Validation Gamma and EtO Sterilization Methods</i>	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
<i>Bioburden Assessment</i>	3.00 PM to 4.15 PM
<i>Questions and Answers</i>	4.15 PM to 4.30 PM
Day 2 (05 March 2010): Registration and Breakfast	8.00 AM to 8.30 AM
<i>Bioburden Assessment</i>	8.30 AM to 9.30 AM
<i>Questions and Answers</i>	9.30 AM to 9.45 AM
Break	9.45 AM to 10.00 AM
<i>Bioburden Assessment</i>	10.00 AM to 11.45 PM
<i>Questions and Answers</i>	11.45AM to 12.00 PM
Lunch	12.00 PM to 1.00 PM
<i>Current Best Practices for the Design and Validation of Sterilization Processes</i>	1.00 PM to 2.45 PM
Break	2.45 PM to 3.00 PM
<i>Current Best Practices for the Design and Validation of Sterilization Processes</i>	3.00 PM to 4.00 PM
<i>Questions and Answers</i>	4.00 PM to 4.15 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: \$950.00 Day 2: \$950.00 Both Days: \$1800.00

Group Discount: 10% discount for each attendee when 4 or more attendees register for any one seminar

Table with 9 columns: Additional Attendees, Choose 1,2, or both days, Day 1, Day 2, Both Days, Last Name, First Name, Title. Contains 4 rows for additional attendees.

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

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Cancellation Policy: Your notice of cancellation must be received in writing via facsimile or email 10 working days prior to the seminar date.

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Email: sales@microrite.com or info@microrite.com.

A 10% cancellation fee is applicable for all credit card payments

Accommodation

Biltmore Hotel and Suites

2151 Laurelwood Road

Santa Clara, CA 95054

408-988-8411

0.96 miles away from Microrite Training Center

Microrite's discounted rates will apply to this hotel.

Standard Garden Room: Rate \$109.00 per night, KING or QQ

Tower Suite: Rate \$129.00 per night, QUEEN w/ sofa Sleeper

Executive Tower Suite: Rate \$ 149.00 per night, QUEEN w/ sofa

Hotel services will include pick-up and drop off, to and from San Jose International Airport and Microrite's Training Center and Shopping within 5 miles of radius from Hotel.

Breakfast and internet access is free of cost at the hotel. Mention "MICRORITE" when reserving room to receive the discounted rate.

Mention "Microrite" to receive the discounted rate

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Business name: _____

CREDIT CARD INFORMATION

Choose one:

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Address of Card Holder

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

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Three digits at the back of card

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Name on Card:

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City and Date of Seminar