

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

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

DAY 1 - 29 May, 2008

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
 - Gamma Dose Setting Validation
 - Gamma Validation reporting
 - Dose auditing
- **EtO**
 - Overview of ISO 11135
 - 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.

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.

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DAY 2 - 30 May, 2008

Rapid Technologies for Sterilization Verification Craig Wallace, 3M

Use of rapid readout biological indicators for monitoring industrial steam and ethylene oxide sterilization process:

- Description of the technology
- Performance information
- Regulatory status

Dry Heat Sterilization - Dan Mohan

- Basic Principles of Dry Heat Sterilization / Depyrogeneration
- Endotoxin Assay (LAL) Development
- Pyroburden Reduction Requirements
- Load Configuration for Effective Depyrogeneration
- Dry Heat Oven Design Considerations
- Validation of Dry Heat Sterilization Process

Chemical Sterilization Claire Fritz –Steris Corporation

Introduction to Vapor Phase Hydrogen Peroxide Technology including chemistry and microbiology

- Cycle Descriptions for both Surface and Vacuum Applications
- How is it Generated?
- New and Existing Applications
- Design Requirements for a Room Application

Current Best Practices for the Design and Validation of Sterilization Processes, John M. Hyde, Chairman, CEO and Founder, JM Hyde 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
- 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.

Dan Mohan holds a Ph.D in Chemical Engineering from Stevens Institute of Technology, NJ. He has served as an Engineering Fellow with Johnson & Johnson Companies in California during the last ten years. Prior to joining J&J, Dan held the position of Director of Product Development with Becton Dickinson & Company in New Jersey. His expertise is in the area of medical device development, aseptic process development, barrier isolator systems, scale-up, equipment engineering and validation. He has successfully implemented pilot plant facilities capable of manufacturing drug/device combination products for clinical trials and commercial production. Dan's contributions to the industry include diagnostic & tissue culture product development, aseptic process engineering and viscous suspension formulation development. Currently, Dan is an independent consultant to the Pharma / Biotech industry.

John Hyde is President of JM Hyde Consulting, Inc., a firm of 85 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.

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ABOUT THE PRESENTERS

Ms. Claire Fritz, B.S., is a VHP Process Engineer for STERIS Corporation and has been responsible for supporting the Western U.S. and Western Canadian customers in vapor phase hydrogen peroxide decontamination/sterilization applications for over 10 years. Previously, she held a scientist position in R & D at American Sterilizer Company (AMSCO) where she assisted with cycle development and technical support of hydrogen peroxide sterilizers for both the pharmaceutical/ medical device and health care industries. Shortly after AMSCO was acquired by STERIS Corporation in 1996, she transferred to the marketing division to promote VHP technology and its applications.

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.

Craig Wallace is a Senior Technical Specialist in 3M Medical Sterilization Specialties. He holds Bachelor of Science degrees in Microbiology and Biochemistry from the University of Minnesota. Craig has held a number of positions in 3M Healthcare over the last 25 years, including roles in R&D management in both medical device and pharmaceutical laboratories. He has worked in the area of sterilization for the last 15 years, and is currently a member of the American Society for Microbiology (ASM), the Parenteral Drug Association (PDA), and the Association for the Advancement of Medical Instrumentation (AAMI), At AAMI, he is an active member of working groups focused on biological indicators and industrial ethylene oxide sterilization.



Practical Series Seminars and Workshops

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

SCHEDULE AND VENUE

May 29 and 30, 2008

1221 CHESS DRIVE
FOSTER CITY, CA 94404

PROGRAM

Day 1 (29 May, 2008): Registration and Light -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 and EtO 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 (30 May 2008): Registration and Light -Breakfast	8.00 AM to 8.30 AM
<i>Rapid Technologies for Sterilization Verification</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>Dry Heat Sterilization</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: \$900.00 Day 2: \$900.00 Both Days: \$1750.00

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

Table with 5 columns: Last Name, First Name, Title, Day 1, Day 2, Both Days. Includes header row and four data rows for additional attendees.

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