

AUDITING MICROBIOLOGICAL ASPECTS OF MANUFACTURING IN PHARMACEUTICALS AND BIOTECHNOLOGY

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

DAY 1

FDA's Perspective on Auditing Microbiological Aspects of Pharmaceutical and Biopharmaceutical Manufacturing-Environmental Monitoring, Bioburden, Sterility Test and Media Fill Failures - Ken Muhvich Ph.D. MicroReliance, LLC.

Learn what the FDA's 2004 Aseptic Processing Guidance requirements are for Environmental Monitoring [EM] Programs

- Pre-filtration bulk solution bioburden Alert, Action and Reject limits
- Learn about FDA requirements for investigations into EM excursions
- Audit Sterility and Media Fill Failures
- How far do you need to go with identification of microorganisms?
- When is microbial characterization enough?
- When is DNA-based identification necessary?
- What are the FDA's expectations for qualification of a microbial identification system?
- How are incubators and refrigerators qualified properly?
- How is EM data trending performed?

Auditing Microbiology Laboratories-Juan Munoz Microbiology and Quality Associates, LLC.

Learn the systems to examine when Auditing Microbiology Labs. This presentation will include:

- QC in the microbiology laboratory
- FDA Guidance on auditing the microbiology laboratory
- Regulatory requirements for microbiological testing
- Validation of test procedures
- Training
- Quality Systems
- Documentation and Data Storage
- OOS and Corrective Actions
- Safety

Auditing Water Systems-Juan Munoz Microbiology and Quality Associates, LLC.

This presentation will outline the aspects of auditing water systems;

- Water system design' what to look for
- What to inspect when reviewing validation documentation of the water systems; IQ/OQ/PQ
- System Monitoring
- QC Microbiology lab
- Equipment validation
- Method qualification
- Water data trend analysis
- Excursion investigations
- CAPA

DAY 1

**Auditing Validation Protocols for An Aseptic Processing Isolator-Dan Mohan Ph.D.
Alza Corporation, Johnson & Johnson**

Understand and learn to how to effectively audit aseptic operations performed using barrier technology isolators. 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)
 - 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) including
 - 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

DAY 2

Auditing Aseptic Operations – Carolyn Broughton Ph.D. Genentech, Inc.

Ensure an effective audit from scheduling to follow-up of observations

Define roles and responsibilities

Address regulatory key elements: procedures, training, records

Apply system-based and risk management approaches focusing on the following areas:

- Quality systems
 - CGMP compliance
 - Discrepancy management and CAPA system
 - Documentation change control
 - Validation protocols and reports
- Production systems
 - Aseptic training and qualification
 - Personnel, equipment and material flow
 - Facility and equipment cleaning and sanitization
 - Equipment identification and calibration
 - Control of microbiological contamination
 - Media fill program
- Laboratory control system
 - Environmental monitoring
 - Media fill results and investigations

**Auditing Strategies for Cleaning Processes and Cleaning Validation - John Hyde
JM Hyde Consulting, Inc.**

This session will address auditing strategies for cleaning processes and cleaning validation for pharmaceutical and biopharmaceutical process systems and equipment. Specific topics to be discussed include the following:

- Chemical and physical bases for current practices of cleaning processes and cleaning validation
- Recent FDA comments and observations with respect to cleaning validation and ongoing monitoring
- Auditing strategies for effective management of OOS events and excursions
- Risk based approaches to cleaning validation and ongoing monitoring of cleaning operations

**Auditing Strategies for Sterilization Processes and Sterilization of Validation - John Hyde
JM Hyde Consulting, Inc.**

Auditing strategies for 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
- Review of typical sterilization operations for process systems, support systems and equipment
- Bases for the establishment of root causes and proposal of corrective actions for OOS events
- Auditing strategies for effective management of excursions and deviations
- Risk based approaches to sterilization validation and ongoing monitoring of sterilization operations

GMPS in Microbiology – Ziva Abraham Microrite, Inc.

This presentation will outline the microbiological aspects of the Quality Systems; learn the systems based approach while auditing microbiological aspects of pharmaceutical and biopharmaceutical manufacturing.

- Audit team for microbiology related audits
- 21 CFR 211 step by step interpretation of the subparts with a focus on microbiology and contamination control perspective
- Microbiological Validation Master Plan – A roadmap to microbiology systems
- Auditing microbiological data deviations and their traceability for lot release and product reviews
 - Out of trend and out of specification results in microbiology
- Microbiology Audit Reports- special considerations

ABOUT THE PRESENTERS

Dr. Carolyn Broughton is currently Senior Manager in Quality Control at Genentech, Inc. Her responsibilities include collaborative and contract projects for both clinical and commercial products. She has more than twenty years experience managing microbiology laboratories in the biotechnology, pharmaceutical and cosmetics industries. She has authored several articles for professional journals and spoken at industry meetings. She received her Ph.D. in Microbiology from North Carolina State University.

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.

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.

ABOUT THE PRESENTERS

Juan Muñoz has a Master's degree in Microbiology and over 20 years of experience in quality assurance, GMP compliance, quality control, microbiological testing of medical devices, biotechnology and pharmaceutical products. He is an expert in clean room design, microbial control, environmental monitoring, sterility testing, general microbiology, microbial limits and other USP/Ph.Eur. microbial tests. Juan has held many positions of high responsibility as manager and associate director of QC of microbiology laboratories at several major biotechnology and pharmaceutical companies across the US. He has been involved in the design, commissioning and validation of several pharmaceutical and biotechnology facilities. He has set-up contamination control at several facilities. Most recently, Mr. Muñoz has managed and executed the qualification testing for a new 100,000 square ft. full service biotechnology facility (cell culture, purification, bulking and filling) and set-up the contamination control program at Abgenix Inc., located in Fremont, California. He has participated in many regulatory inspections by FDA, European, and Canadian regulatory authorities. He is one of the founders of Micro-Virology Testing Laboratories and MQA, Microbiology and Quality Associates, LLC

Dr. Dan Mohan has been an Engineering Fellow with ALZA Corporation, a Johnson & Johnson company, for the last ten years engaged in aseptic process engineering and development for clinical manufacturing of implantable drug delivery devices. 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 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.

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.

SCHEDULE AND VENUE

March 26 and 27, 2007

**Caribe Hilton
Los Rosales Street, San Geronimo Grounds,
San Juan PR 00902**

PROGRAM

Day 1 (26 March, 2007): Registration and Light -Breakfast	8.00 AM to 8.30 AM
FDA's Perspective on Auditing Microbiological Aspects of Pharmaceutical and Biopharmaceutical Manufacturing-Environmental Monitoring, Bioburden, Sterility Test and Media Fill Failures — <i>Ken Muhvich</i>	8.30 AM to 10.00 AM
Break	10.00 AM to 10.15 AM
Auditing Microbiology Laboratories-Juan Munoz	10.15 AM to 11.45 PM
<i>Questions and Answers</i>	11.45AM to 12.00 PM
Lunch	12.00 PM to 1.00 PM
Auditing Water Systems-Juan Munoz	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
Auditing Validation Protocols for An Aseptic Processing Isolator -Dan Mohan	3.00 PM to 4.30 PM
<i>Questions and Answers</i>	4.30 PM to 4.45 PM
Day 2 (27 March 2007): Registration and Light -Breakfast	8.00 AM to 8.30 AM
Auditing Aseptic Operations-Carolyn Broughton	8.30 AM to 10.00 AM
<i>Questions and Answers</i>	10.00 AM to 10.15 AM
Break	10.15 AM to 11.45 PM
Auditing Strategies for Cleaning Processes and Cleaning Validation-John M. Hyde	10.15 AM to 11.45 PM
<i>Questions and Answers</i>	11.45AM to 12.00 PM
Lunch	12.00 PM to 1.00 PM
Auditing Strategies for Sterilization Processes and Sterilization of Validation-John M. Hyde	1.00 PM to 2.30 PM
<i>Questions and Answers</i>	2.30 PM to 2.45 PM
Break	2.45 PM to 3.00 PM
GMPs in Microbiology-Ziva Abraham	3.00 PM to 4.30 PM
<i>Questions and Answers</i>	4.30 PM to 4.45 PM

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: \$895.00 (US) Day 2: \$895.00 (US) Both Days: \$1725.00 (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"/>

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Confirmation of registration will be sent via email.

Cancellation Policy: Your notice of cancellation must be received by in writing by letter, facsimile or email 10 working days prior to the Seminar date. Fax: 408-445-1236 Email: sales@microrite.com or zabraham@microrite.com

A 10% cancellation fee is applicable for credit card payments

Accommodation: Seminar attendees requiring hotel accommodation should contact Caribe Hilton , Los Rosales Street, San Geronimo Grounds, San Juan PR 00902, Tel: 787-721-0303 or 1-800-282-9176.

Mention "**MICA 07**" when booking hotel rooms to receive discounted rates.

Business name:

CREDIT CARD INFORMATION

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

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Zip Code

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Contact Phone Number

Card Number:

Expiration(Month/Year):

Name on Card:

Amount (US Dollars):

Signature:

Name of Attendee(s)
