

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 Expectation's when Auditing Microbiological Aspects of Pharmaceutical and Biopharmaceutical Manufacturing—Frank Kohn, PhD,SM(NRM),ASCP,CCM- FSK ASSOCIATES, INC.

This session will focus on case studies using a "Quality Audit Tool Kit" for auditing microbiology aspects in manufacturing to meet FDA expectations. This session will discuss the following:

- Preparation for the audit
- Review of microbiological aspects of mfg. and QC
- Review of cGMP requirements
- Discussion of 483 items cited that relate to microbiology
- Components and preparation of the "Quality Audit Tool Kit"
- Basic elements FDA expects in a audit
- Case Study from an audit of a Biotech facility
- Case Study from an audit of a Pharmaceutical facility
- Case Study from an audit of a Vaccine facility
- Advantages of the use of the "Quality Audit Tool Kit" approach to auditing

**Auditing Microbiology Laboratories
Carolyn Broughton, PhD, Genentech, Inc.**

Learn the systems to examine when Auditing Quality Control Microbiology Laboratory

This presentation will include:

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

**Auditing Water Systems
Frank Kohn, PhD, SM (NRM),ASCP,CCM- FSK ASSOCIATES, INC.**

This presentation will outline the aspects of auditing Pharmaceutical Water Systems;

- Water system design-what to audit
- Reviewing validation documentation of the water systems; IQ/OQ/PQ-look for gaps
- Water System Monitoring-points to consider while auditing
- Auditing the role of QC Microbiology Lab. in validation and testing
- Equipment validation – points to remember while auditing
- Auditing elements of method qualification
- Reviewing water data trend analysis
- Water systems related excursions, investigations, corrective and preventive actions and change controls

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DAY 1

**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

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DAY 2

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 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

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ABOUT THE PRESENTERS

Carolyn Broughton, PhD, 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.

Frank Kohn, PhD, SM (NRM), ASCP, CCM is President of FSK ASSOCIATES, INC. He has more than thirty years of industrial experience working in various technical, quality and managerial positions for Schering Plough Corp., Armour Pharmaceutical, Sanofi and Wyeth Vaccines. He holds graduate degrees in environmental microbiology and operations management. Frank is registered as a Specialist Microbiologist by the National Registry of Microbiologist, American Society of Clinical Pathology, and Canadian College of Microbiology. He is Chair for the Vaccine Interest Group for PDA and Section Leader for Biopharm Development Interest Groups. Dr. Kohn has presented more than 150 technical papers, seminars, and lectures and is a frequent speaker and course leader in the US and Europe. FSK ASSOCIATES, INC. is a international consulting company providing services in the area of micro control, environmental monitoring, technology transfer, CGMP, audits, training, and validation.

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

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.

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SCHEDULE AND VENUE

November 1 and 2, 2007

**Embassy Suites Hotel Boston at Logan Airport
207 Porter Street,
Boston, Massachusetts 02128**

PROGRAM

Day 1 (01, November, 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>Frank Kohn</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
Auditing Microbiology Laboratories-Carolyn Broughton	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
Auditing Water Systems-Frank Kohn	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 QC Microbiology Laboratories- Carolyn Broughton	3.00 PM to 4.30 PM
<i>Questions and Answers</i>	4.30 PM to 4.45 PM
Day 2 (02 November 2007): Registration and Light -Breakfast	8.00 AM to 8.30 AM
Auditing Strategies for Cleaning Processes and Cleaning Validation- John M. Hyde	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
Auditing Strategies for Sterilization Processes and Sterilization of Validation-John M. Hyde	10.30 AM to 11.45 PM
<i>Questions and Answers</i>	11.45AM to 12.00 PM
Lunch	12.00 PM to 1.00 PM
GMPs in Microbiology-Ziva Abraham	1.00 PM to 2.45 PM
Break	2.45 PM to 3.00 PM
GMPs in Microbiology-Ziva Abraham	3.00 PM to 4.00 PM
<i>Questions and Answers</i>	4.00 PM to 4.30 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 (US) Day 2: \$900.00 (US) Both Days: \$1750.00 (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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Cancellation Policy: Your notice of cancellation must be received in writing via 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 Embassy Suites Boston- Logan Airport at 617-567-5000. Please mention event code "Microrite" to receive discounted room rates.

Business name: _____

CREDIT CARD INFORMATION

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Card Number:

Expiration(Month/Year):

Name on Card:

Amount (US Dollars):

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Name of Attendee(s)
