

**AUDITING MICROBIOLOGICAL ASPECTS OF MANUFACTURING IN  
PHARMACEUTICALS AND BIOTECHNOLOGY**

**Who should attend:** Quality Assurance, QA Auditors, Quality Control, Operations,  
Regulatory and Manufacturing Personnel

**DAY 1- 28 May 2009**

**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 and data deviations and their traceability for lot release and product reviews
  - Out of trend and out of specification results in microbiology
  - Audit Sterility test failures and investigations
  - EM data trends and trend analysis
  - Microbial Identifications
- Microbiological validation and qualification protocols and reports
- Microbiology Audit Reports- special considerations

**Auditing Pharmaceutical Water Systems-Carolyn Broughton , Genentech, Inc.**

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

**Auditing Microbiology Laboratories—Ziva Abraham, Microrite, Inc.**

Learn the systems to examine when Auditing Microbiology Laboratories. 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

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**DAY 2 - 29 May 2009**

**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  
Hyde Engineering and Consulting**

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  
Hyde Engineering and Consulting**

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

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**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.

**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.

**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**

**May 28, and 29 2009**

**Hilton North Raleigh**

3415 Wake Forest Rd

Raleigh NC 27609

**PROGRAM**

<b>Day 1 (28 May 2009):</b> Registration and Light -Breakfast	8.00 AM to 8.30 AM
<b>GMPS in Microbiology-Ziva Abraham</b>	8.30 AM to 10.00 AM
Break	10.00 AM to 10.15 AM
<b>GMPS in Microbiology - continued</b>	10.15 AM to 11.00 PM
<i>Questions and Answers</i>	11.00AM to 11.15 AM
<b>Auditing Pharmaceutical Water Systems=-Carolyn Broughton</b>	11.15 AM to 12.00 PM
Lunch	12.00 PM to 1.00 PM
<b>Auditing Pharmaceutical Water Systems –continued-C. Broughton</b>	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
<b>Auditing Microbiology Laboratories-Ziva Abraham</b>	3.00 PM to 4.30 PM
<i>Questions and Answers</i>	4.30 PM to 4.45 PM
<b>Day 2 ( 29 May 2009 ):</b> Registration and Light -Breakfast	8.00 AM to 8.30 AM
<b>Auditing Aseptic Operations-Carolyn Broughton</b>	8.30 AM to 10.00 AM
Break	10.00 AM to 10.10 AM
<b>Auditing Strategies for Cleaning Processes and Cleaning Validation-John Hyde</b>	10.15 AM to 12.00 PM
Lunch	12.00 PM to 1.00 PM
<b>Auditing Strategies for Cleaning Processes and Cleaning Validation continued-John Hyde</b>	1.00 PM to 2.00 PM
<i>Questions and Answers</i>	2.00 PM to 2.30 PM
Break	2.30 PM to 2.45 PM
<b>Auditing Strategies for Sterilization Processes and Sterilization of Validation-John Hyde</b>	2.45 PM to 4.15 PM
<i>Questions and Answers</i>	4.15 PM to 4.45 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 \_\_\_\_\_ Facsimile: (Area Code) \_\_\_\_\_

Email: \_\_\_\_\_

**Fees: Day1: \$950.00 Day 2: \$950.00 Both Days: \$1800.00 (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:			
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"/>

**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

**Confirmation of registration will be sent via email.**

**Cancellation Policy:** Your notice of cancellation must be received by in writing by facsimile or email 10 working days prior to the Seminar date. Fax: 408-445-1236 Email: [sales@microrite.com](mailto:sales@microrite.com) or [info@microrite.com](mailto:info@microrite.com)

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

**Accommodation:** Seminar attendees requiring hotel accommodation should contact Hilton North Raleigh, 3415 Wake Forest Rd, Raleigh NC 27609 Tel: 1-919-872-2323.

Hotel Rooms are discounted for this event. Contact June Bazemore at Hilton North Raleigh if help is needed with room reservation.

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Business name:

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**CREDIT CARD INFORMATION**

Choose one:

VISA

Master Card

American Express

Card Holder's Name

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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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Street

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City

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Zip Code

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Country

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Contact Phone Number

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Card Number:

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Expiration(Month/Year):

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Name on Card:

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Amount (US Dollars):

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Signature:

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Name of Attendee(s)

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