

**CHALLENGES IN IMPLEMENTATION OF COMPENDIAL TEST METHODS
MICROBIAL RISK ASSESSMENT**

The Microbial Limits and other Compendial Tests are Harmonized but there are many questions that remain unanswered
Misinterpretation of these methods is not uncommon!!
Bring your questions and get them ANSWERED by the Experts
Learn how to assess and prevent risk to your product

Who should attend: Quality Assurance Personnel, Microbiology Laboratory Personnel, Microbiology Department Managers and QC Personnel

DAY 1

<61> MICROBIOLOGICAL EXAMINATION OF NONSTERILE PRODUCTS: MICROBIAL ENUMERATION TESTS- Dr. Klaus Haberer
<ul style="list-style-type: none">• Overview of the Method• Method Suitability for product inhibition• The growth promotion organisms and the methodology• Strengths of the Microbial Limits Test• Limitations of the Microbial Limits Test• Revalidation to conform to the new USP <61> and <62> Suitability Test• Gaps that need clarification
<62> MICROBIOLOGICAL EXAMINATION OF NONSTERILE PRODUCTS: TESTS FOR SPECIFIED MICROORGANISMS- Dr. Klaus Haberer
<ul style="list-style-type: none">• Overview of the Method• Discussion on Growth promotion of various media used testing specified microorganisms• Inhibitory properties of media• Specified microorganisms-what to test• Suitability of test method- testing of product for specified microorganisms• Discussion on incubation temperatures and duration• Suitability Test-How to implement• Limitation of test for specified microorganisms
<111> MICROBIOLOGICAL EXAMINATION OF NONSTERILE PRODUCTS: ACCEPTANCE CRITERIA FOR PHARMACEUTICAL PREPARATIONS AND SUBSTANCES FOR PHARMACEUTICAL USE - Dr. Klaus Haberer
<ul style="list-style-type: none">• Acceptance Criteria for Microbiological Quality of Nonsterile Dosage Forms• Selection of specified microorganisms to be tested for your product• Understanding the fine print on identifying objectionable microorganisms in your product
RISK MANAGEMENT OF STERILE AND NON-STERILE PRODUCTS IN REGARDS TO BIOBURDEN - Dr. Klaus Haberer
<ul style="list-style-type: none">• Discussion on ICH Q9 to assess and manage contamination risk to your product• Guidance on how to establish objectionable microorganisms

**CHALLENGES IN IMPLEMENTATION OF COMPENDIAL TEST METHODS
MICROBIAL RISK ASSESSMENT**

DAY 2

<51> ANTIMICROBIAL EFFECTIVENESS TESTING – Dr. Roger Dabbah

- Product Categories- Discussion on the product categories where antimicrobials may be required to keep product contamination free or inhibit contamination after opening
- Test Organisms-Discussion on the specified microorganisms to be used to assess effectiveness of added antimicrobials
- Preparation of Inoculum - Common challenges
- Testing - Overview of the procedures including media, inoculum preparation, procedural details, criteria for the test and common challenges encountered when executing the antimicrobial effectiveness test
- Differences between EP and USP effectiveness criteria
- Q and A- Group discussion on the common issues encountered during executing the test

<1223> VALIDATION OF ALTERNATIVE MICROBIOLOGICAL METHODS - Dr. Roger Dabbah

- Type of microbiological tests
- Qualitative Tests for the Presence or Absence of Microorganisms
- Quantitative Tests for Microorganisms
- Validation of Microbial Recovery
- Validation of Qualitative Tests for Demonstration of Viable Microorganisms in a Sample
- Validation of Quantitative Estimation of Viable Microorganisms in a Sample
- Q and A

<1117> MICROBIOLOGICAL BEST LABORATORY PRACTICES - Dr. Roger Dabbah

- Media Preparation, Storage and Quality Control
- Maintenance of Microbiological Cultures
- Maintenance of Laboratory Equipment
- Laboratory Layout Operations
- Training of personnel
- Documentation
- Maintenance of Laboratory Records
- Interpretation of Assay Results
- Q and A

**CHALLENGES IN IMPLEMENTATION OF COMPENDIAL TEST METHODS
MICROBIAL RISK ASSESSMENT**

ABOUT THE PRESENTERS AND PANEL MEMBERS

Dr. Roger Dabbah is currently the Principal Consultant for Tri-Intersect Solutions that he founded in April 2006. He consults for Science, Technology and Management of Technology in the Pharmaceutical and Biotechnology Industry. Dr Roger Dabbah was Senior Scientific Fellow in the Department of Drug Standard Development, US Pharmacopeia. He was tracking new technologies such as nanotechnology and all the "omics" technologies (genomics, proteomics, metabolomics, bioinformatics, genetic testing, stem cells research) to position USP standards in the future. He was the USP representative to AAMI, ANSI, IEST, PDA, BIO and worked in a number of US-Technical Advisory Groups involved in ISO Technical Committees. He was also the US representative to the WHO Biological Standardization Committee in Geneva.

Dr. Roger Dabbah was previously Director, Complex Actives Division in the Information and Standards Division of USP which he joined in 1986. His responsibilities included management of liaisons with the USP Council of Experts, Industry, Government and Academia in the various areas of biologicals, biotechnology, gene therapy, tissue engineering, microbiology, devices and diagnostics, toxicity testing, biocompatibility, alternatives to animal testing, international harmonization in biotechnology and microbiology, parenterals, radiopharmaceuticals, Pharmaceutical Waters.

Before joining USP Dr. Dabbah had extensive industrial experience in major multinationals in the areas of sterilization, immunology, R & D, information sciences, research and technology management.

Dr. Dabbah earned his PhD degree at the University of Maryland, his MS and BA at the University of Minnesota, and an MBA at the University of Dayton in Ohio. He has also combined his experience and training as an Associate Professor in Technology Management at the University of Maryland, University College Graduate School, and as a Faculty Practitioner at the Johns Hopkins University, Whiting Graduate School of Engineering and at the JHU Continuous Education Graduate School, where he teaches in the Technology Management graduate program and in the Information Systems Program.

Dr. Dabbah is the author of two books on the Pharmaceutical Industry, one on "Total Project Management- Strategies and Tactics for the Healthcare Industries" (Interpharm Press, 1993) and one on "Total R & D Management- Strategies and Tactics for the 21st Century Healthcare Manufacturers" (Interpharm Press, 1999). He has [published widely on a variety of topic and made numerous presentations at national and international scientific meetings

Dr. Dabbah is active in civic activities. He was a Commissioner on the Humanities for Montgomery County and now is a Board member of the Friends of the Humanities Commission. He is also a Director on the Board of the PDA Foundation for Pharmaceutical Sciences and was the Chair of the fund-raising Committee and now is the chair of the Communication Committee. He is also on the editorial board of a number of publication, including Pharmaceutical Technology, Bioprocess International, and others.

**CHALLENGES IN IMPLEMENTATION OF COMPENDIAL TEST METHODS
MICROBIAL RISK ASSESSMENT**

Dr. Klaus Haberer holds a Ph.D. in physiological chemistry from Cologne University. He did postdoctoral studies in microbiology at the University of Ulm where he was appointed Privatdozent and at University of Rochester, NY, USA. He held industrial positions at Hofmann-La Roche-AG in Grenzach, Germany and at Hoechst AG / Hoechst Marion Roussel AG in Frankfurt, Germany where he was Director for global microbiological quality control and quality assurance. He serves as a microbiological Expert nominated from Germany in the European Pharmacopoeia and as Convenor in ISO 198 /WG9 the working group which writes the ISO 13408 series on Aseptic Processing. He was also a member of several PDA working parties. In 1999 Dr. Haberer founded Compliance, Advice and Services in Microbiology, a German Company engaged in Consultancy in microbiological quality assurance questions and in microbiological Laboratory Service.

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

**CHALLENGES IN IMPLEMENTATION OF COMPENDIAL TEST METHODS
 MICROBIAL RISK ASSESSMENT**

SCHEDULE AND VENUE

Monday 22nd and Tuesday 23rd March, 2010

Biltmore Hotel and Suites

2151 Laurelwood Road

Santa Clara, CA 95054

PROGRAM

DAY 1	
REGISTRATION AND LIGHT BREAKFAST	8.00 AM to 8.30 AM
<61> MICROBIOLOGICAL EXAMINATION OF NONSTERILE PRODUCTS: MICROBIAL ENUMERATION TESTS	8.30 AM to 10.30 AM
BREAK	10.30 AM to 10.45 AM
<62> MICROBIOLOGICAL EXAMINATION OF NONSTERILE PRODUCTS: TESTS FOR SPECIFIED MICROORGANISMS	10.45 AM to 12.30 PM
LUNCH	12.30 PM to 1.30 PM
<1111> MICROBIOLOGICAL EXAMINATION OF NONSTERILE PRODUCTS: ACCEPTANCE CRITERIA FOR PHARMACEUTICAL PREPARATIONS AND SUBSTANCES FOR PHARMACEUTICAL USE	1.30 PM to 3.15 PM
BREAK	3.15 PM to 3.30 PM
MICROBIAL RISK MANAGEMENT OF STERILE AND NON-STERILE PRODUCTS	3.30 PM to 4.15 PM
QUESTION AND ANSWER SESSION	4.15 PM to 4.45 PM
DAY 2	
REGISTRATION AND LIGHT BREAKFAST	8.00 AM to 8.30 AM
<51> ANTIMICROBIAL EFFECTIVENESS TESTING	8.30 AM to 10.15 AM
BREAK	10.15 AM to 10.30 AM
<1223> VALIDATION OF ALTERNATIVE MICROBIOLOGICAL METHODS	10.45 AM to 12.30 PM
LUNCH	12.30 PM to 1.30 PM
<1117> MICROBIOLOGICAL BEST LABORATORY PRACTICES	1.30 PM to 3.15 PM
QUESTION AND ANSWER SESSION	3.15 PM to 4.15 PM

**CHALLENGES IN IMPLEMENTATION OF COMPENDIAL TEST METHODS
MICROBIAL RISK ASSESSMENT**

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

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"/>

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 if payment is made by check or PO. For credit card payment on website, a payment receipt will be considered as confirmation of registration. For credit card information faxed to Microrite an email confirmation will be sent with a copy of payment receipt. Please call 408-445-0507 in due time if confirmation is not received after payment.

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 all credit card payments

**CHALLENGES IN IMPLEMENTATION OF COMPENDIAL TEST METHODS
MICROBIAL RISK ASSESSMENT**

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.

**CHALLENGES IN IMPLEMENTATION OF COMPENDIAL TEST METHODS
MICROBIAL RISK ASSESSMENT**

Business name: _____

CREDIT CARD INFORMATION

Choose one: VISA Master Card American Express

Card Holder's Name _____

Card Holder's Email _____

Address of Card Holder

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

Street _____

City _____

Zip Code _____

Country _____

Contact Phone Number _____

Card Number: _____

Expiration(Month/Year): _____

Name on Card: _____

Amount (US Dollars): _____

Signature: _____

Name of Attendee(s) _____

Seminar City and Date _____