

## IMPLEMENTATION OF HARMONIZED COMPENDIAL TESTS

**WHAT IS DIFFERENT?  
 WHAT IS THE SAME?  
 WHAT YOU NEED TO DO TO BE COMPLIANT?**

**GET YOUR QUESTIONS ANSWERED AT THIS TWO DAY CONFERENCE**

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

**DAY 1  
 (18 October 2007, Crowne Plaza, Foster City, California)**

<b>Introduction</b>
<ul style="list-style-type: none"> <li>■ Introduction by Ziva Abraham and brief overview of current challenges in implementing harmonized compendial testing discussed for the day-user perspective</li> </ul>
<b>The Harmonization Process</b>
<ul style="list-style-type: none"> <li>■ Background on the Harmonization Process: Where do we come from, role of compendial tests, The Harmonization Process</li> <li>■ The Pharmacopoeia Perspective.....Dr. Roger Dabbah</li> <li>■ The Experts Perspective.....Dr. Haberer Klaus</li> </ul>
<b>Microbiological Examination of Non-Sterile Products          Microbial Enumeration Tests-USP &lt;61&gt;, EP, 26.12</b>
<ul style="list-style-type: none"> <li>■ The EP Perspective .....Dr. Haberer Klaus</li> <li>■ The USP Perspective .....Dr. Roger Dabbah</li> </ul>
<b>Microbiological Examination of Non-Sterile Products          Tests for Specific Microorganisms-USP &lt;62&gt;, EP, 26.13</b>
<ul style="list-style-type: none"> <li>■ The EP Perspective.....Dr.Haberer Klaus</li> <li>■ The USP Perspective.....Dr. Roger Dabbah</li> </ul>
<b>Microbiological Examination of Non-Sterile Products          Acceptance Criteria for Pharmaceutical Preparations and Substances- USP &lt;1111&gt;, EP, 5.1.4</b>
<ul style="list-style-type: none"> <li>■ The EP Perspective..... Dr.Haberer Klaus</li> <li>■ The USP Perspective .....Dr. Roger Dabbah</li> </ul>
<b>Panel Discussion on Differences between USP and EP Harmonized Texts</b>
<ul style="list-style-type: none"> <li>■ Dr. Roger Dabbah, Dr. Haberer Klaus, Ann Warford, and Ziva Abraham</li> </ul>
<b>Questions and Answers</b>
<ul style="list-style-type: none"> <li>■ Group discussion- Attendee questions will be discussed and answered</li> </ul>

## IMPLEMENTATION OF HARMONIZED COMPENDIAL TESTS

### DAY 2

(19 October 2007, Crowne Plaza, Foster City, California)

<b>Introduction</b>
<ul style="list-style-type: none"> <li>■ Introduction by Ziva Abraham and brief overview of current challenges in implementing harmonized compendial testing discussed for the day-user perspective</li> </ul>
<b>Validation of Alternate Microbiological Methods, USP &lt;1223&gt;, Alternate Methods for Control of Microbiological Quality, EP, 5.1.6</b>
<ul style="list-style-type: none"> <li>■ The EP Perspective by DR. Haberer Klaus</li> <li>■ The USP Perspective by Dr. Roger Dabbah</li> </ul>
<b>Panel Discussion on Harmonized Sterility Tests</b>
<b>USP &lt;71&gt; , EP 2.6.1</b>
<ul style="list-style-type: none"> <li>■ Implementation.....Dr. Roger Dabbah, DR. Haberer Klaus, Ann Warford and Ziva Abraham</li> </ul>
<b>Differences between and USP and EP texts for Sterility Test</b>
<ul style="list-style-type: none"> <li>■ Comments by attendees on issues related to the implementation of the Harmonized Sterility Tests Chapters- Open Forum</li> </ul>
<b>Pharmaceutical Waters- Microbial Considerations for Future Harmonization</b>
<b>USP &lt; 1231&gt;, EP Water Monographs</b>
<ul style="list-style-type: none"> <li>■ The EP Perspective.....Dr.Haberer Klaus</li> <li>■ The USP Perspective.....Dr. Roger Dabbah</li> </ul>
<b>Questions and Answers</b>
Group discussion- Attendee questions will be discussed and answered
<b>Adjournment</b>

## IMPLEMENTATION OF HARMONIZED COMPENDIAL TESTS

### 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 21<sup>st</sup> 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.

## IMPLEMENTATION OF HARMONIZED COMPENDIAL TESTS

**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 responsible for microbiological quality control and quality assurance.

He serves as a microbiological Expert 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.

**Ann L. Warford, DPH, ABMM** initially a board-certified infectious disease laboratory director in microbiology/virology from 1980-1999 at Stanford University Medical Center and Kaiser Medical, transitioned into pharmaceutical-biotechnology medical devices via positions at Cepheid, Johnson and Johnson and finally, pharmaceutical microbiology at Bayer HealthCare in 2001. All of her publications have concentrated on the enhanced detection of infectious agents with new methodologies since 1980. During the period from 2003 to present, she has lead validations and implementation for Bactec 9240 Sterility testing, ScanRDI Laser microbial detection method, LaCalhene Sterility Isolators, modified viral detection, Vitek-2 Compact and MIDI- GC ID Systems and Mycoplasma PCR method (in collaboration with Barbara Potts, Genentech). Ann is currently QU Product Line Manager & Senior Microbiology SME at Bayer HealthCare in Berkeley California.

**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.

## IMPLEMENTATION OF HARMONIZED COMPENDIAL TESTS

### SCHEDULE AND VENUE

**October 18 and 19, 2007**

**Crowne Plaza Hotel  
 SAN FRANCISCO-PENINSULA-ARPT**

**1221 CHESS DRIVE  
 FOSTER CITY, CA 94404 UNITED  
 STATES  
 Hotel Front Desk: 1-650-570-5700  
 Hotel Fax: 1-650-570-0540**

**Book Online or Call  
 1 800 972 3124**

### PROGRAM

<b>Day 1 (18 October, 2007 ):</b> Registration and Continental Breakfast	8.00 AM to 8.30 AM
USP <61>, EP 26.12	8.30 AM to 10.00 AM
Break	10.00 AM to 10.30 AM
USP <62>, EP 26.13	10.30 AM to 12.00 PM
Lunch	12.00 PM to 1.00 PM
USP <1111>, EP 5.1.4	1.00 PM to 3.00 PM
Break	3.00 PM to 3.30 PM
Panel-Differences in EP and USP	3.30 PM to 4.15 PM
<i>Q &amp; A Session</i>	4.15 PM to 4.45 PM
<i>Reception</i>	
<b>Day 2 (19 October 2007 ):</b> Registration and Continental Breakfast	8.00 AM to 8.30 AM
USP <1223>, EP 5.1.6	8.30 AM to 10.00 AM
Break	10.00 AM to 10.30 AM
Sterility Tests- Panel Discussion	10.30 AM to 12.00 PM
Lunch	12.00 PM to 1.00 PM
USP <1231>, EP Water Monographs	1.00 PM to 3.00 PM
Break	3.00 PM to 3.30 PM
Q & A	3.30 PM to 4.30PM

**IMPLEMENTATION OF HARMONIZED COMPENDIAL TESTS**

**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

**Group Discount:** 10% discount for each attendee when 4 or more attendees register for both days

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"/>
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 letter, facsimile or email 10 working days prior to the Seminar date. Fax: 408-445-1236 Email: [sales@microrite.com](mailto:sales@microrite.com) or [zabraham@microrite.com](mailto:zabraham@microrite.com)

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

**Accommodation:** Seminar attendees requiring hotel accommodation should contact Crowne Plaza Hotel Front Desk: 1 800 972 3124 or 1-650-570-5700. Mention Microrite's Event code "MC1" to enjoy the reduced room block rates for this event.

**From 280: Northbound:**

Bear right onto the CA-92 ramp to Half Moon Bay/San Mateo/Hayward  
Take the CA-92 E ramp to San Mateo/Hayward  
Take the exit to Foster City Boulevard  
Bear right onto the ramp to Shell Blvd  
Bear right at Metro Center Blvd  
Turn right at Vintage Park Drive  
Turn right at Chess Drive

**Southbound:**

Bear right onto the I-380 ramp to S F Intl Airport (US-101)  
Merge into I-380 E  
Take the US-101 S ramp to S F Intl Airport/San Jose  
Bear right onto the CA-92 ramp to Hayward/Half Moon Bay/Fashion Island Blvd  
Take the CA-92 E ramp to Hayward/Fashion Island Boulevard  
Take the CA-92 E ramp to Hayward  
Take the exit to Foster City Blvd  
Bear right onto the ramp to Shell Blvd  
Bear right at Metro Center Blvd  
Turn right at Vintage Park Drive  
Turn right at Chess Drive

**From 101: Northbound:**

Take the CA-92 ramp to Hayward/San Mateo Bridge/Half Moon Bay  
Take the CA-92 ramp to Hayward/San Mateo Bridge  
Merge into CA-92 E  
Take the exit to Foster City Blvd  
Bear right onto the ramp to Shell Blvd  
Bear right at Metro Center Blvd  
Turn right at Vintage Park Drive  
Turn right at Chess Drive

**Southbound:**

Bear right onto the CA-92 ramp to Hayward/Half Moon Bay/Fashion Island Blvd  
Take the CA-92 E ramp to Hayward/Fashion Island Blvd  
Take the CA-92 E ramp to Hayward  
Take the exit to Foster City Blvd  
Bear right onto the ramp to Shell Blvd  
Bear right at Metro Center Blvd  
Turn right at Vintage Park Drive  
Turn right at Chess Drive

**From Santa Cruz, CA-17 NORTH**

Take the CA-85 ramp to Mountain View/Gilroy  
Take the CA-85 N ramp to Mountain View  
Bear right at US-101 N  
Take the CA-92 ramp to Hayward/San Mateo Bridge/Half Moon Bay  
Take the CA-92 ramp to Hayward/San Mateo Bridge  
Merge into CA-92 E  
Take the exit to Foster City Blvd  
Bear right onto the ramp to Shell Blvd  
Bear right at Metro Center Blvd  
Turn right at Vintage Park Drive  
Turn right at Chess Drive

**IMPLEMENTATION OF HARMONIZED COMPENDIAL TESTS**

**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

**Street**

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**City**

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**Zip Code**

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**Country**

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**Contact Phone Number**

---

**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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