Alternative Microbiological Methods: 
A Workshop on Current Status and Future Directions of Compendial Standards 
March 16–17, 2015 
USP Headquarters, Rockville, Maryland 

Preliminary Agenda 
(As of February 23, 2015 – Subject to Change) 

Monday, March 16, 2014 (Day 1) 

8:00 a.m. Registration and Coffee 

9:00 a.m. Welcome, Opening Remarks, and Workshop Overview 
James Akers, Ph.D., Chair, USP Microbiology Expert Committee 

9:30 a.m. Plenary Session I: Alternate Methods 
Moderator: TBA 
   a. Current USP Perspectives 
      James Akers, Ph.D., Chair, USP General Chapters–Microbiology Expert Committee 
   b. Current FDA Perspectives 
      Speaker TBA 

10:10 a.m. Discussion / Q&A 

10:30 a.m. Plenary Session II: Status of Current Chapters 
Moderator: Karen McCullough, M.S. 
Member, USP General Chapters–Microbiology Expert Committee 
This session will highlight current status of the chapters on Alternative Microbiological Methods in USP, European, and Japanese Pharmacopoeias. 
   a. New Draft <1223.1>: Alternate Procedures to Antibiotic Microbial Assays 
      Speaker TBA 

10:50 a.m. Break 

11:20 a.m. Plenary Session II: Status of Current Chapters (Continued) 
   b. <1223> Revisions – USP Representative 
      Edward Tidswell, Ph.D. 
      Member, USP General Chapters–Microbiology Expert Committee 
   c. EP 5.1.6. Alternative Methods for Control of Microbiological Quality: 
      Current Status of Revisions 
      Stephen Wicks, Ph.D., European Directorate for the Quality of Medicines (EDQM), 
      France 

12:00 p.m. Discussion / Q&A 

12:45 p.m. Lunch 

1:45 p.m. Plenary Session III: Equivalence Approaches 
This session will include presentations on equivalence approaches to alternative microbiological methods and statistical tools for validation of alternative microbiological methods. 
Moderator: Scott Sutton, Ph.D. 
Member, USP General Chapters–Microbiology Expert Committee 
   a. Equivalence Determination 
      Anthony Cundell, Ph.D. 
      Vice Chair, USP General Chapters–Microbiology Expert Committee 

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b. Statistical Tools for Validation of Alternative Microbiological Methods
   Edwin van den Heuvel, Ph.D., Professor of Medical Statistics, de Eindhoven University of Technology (TU/e) in Eindhoven, Netherlands

3:05 p.m.  Break

3:30 p.m.  Discussion / Q&A

5:00 p.m.  Reception in Corridor of Volunteers

6:00 p.m.  Adjourn for the day

Tuesday, March 17, 2014 (Day 2)

8:00 a.m.  Registration and Coffee

9:00 a.m.  Overview of Days Topics
   Speaker TBA

Plenary Session IV: Modern Microbiological Methods
   Moderator: Donald Singer, M.S.
   Member, USP General Chapters–Microbiology Expert Committee
   Speakers representing the USP General Chapters–Microbiology Expert Committee, Japanese Pharmacopoeia (JP), Industry, and U.S. Food and Drug Administration (FDA) will present on current perspectives on Modern Microbiological Methods (MMM)
   a. Current USP Perspectives on a Compendial MMM Sterility Test
      James Akers, Ph.D., Chair, USP Microbiology Expert Committee
   b. Current FDA perspectives on Sterility Tests FDA/ CBER
      Speaker TBA
   c. Industry Perspective
      David Roesti, Ph.D., Novartis, Switzerland

10:30 a.m.  Break

11:00 a.m.  Plenary Session IV: Modern Microbiological Methods (Continued)
   d. Current JP Perspectives
      Masao Nasu, Ph.D., University of Osaka, Japan
   e. Current Status of Proposed USP Chapter <71.1>
      Anthony Cundell, Ph.D., Vice Chair, USP Microbiology Expert Committee

12:00 p.m.  Lunch

1:00 p.m.  Round Table Discussion / Q&A

2:30 p.m.  Summary of Discussions: What Was Said, What Was Heard, Next Steps
   Moderator: Radhakrishna Tirumalai, Ph.D., USP

3:00 p.m.  Break

3:30 p.m.  Final Remarks / Conclusions
   James Akers, Ph.D., Chair, USP Microbiology Expert Committee

4:00 p.m.  Workshop Adjourns