Final Agenda

Monday, June 10, 2019

8:00 – 8:30 a.m.  Registration & Coffee

8:30 – 8:45 a.m.  Welcome  
Jaap Venema, Ph.D.  
Executive Vice President & Chief Science Officer, USP

8:45 – 9:00 a.m.  USP Perspectives  
David Hussong, Ph.D.  
Chair, USP General Chapters- Microbiology Expert Committee

9:00 – 9:15 a.m.  European Pharmacopoeia (Ph. Eur.) Perspectives  
Gwenaël Ciréfice, PharmD  
Scientific Officer, European Pharmacopeia, EDQM

9:15 – 9:30 a.m.  JP Perspectives  
Yukari Nakagawa, Ph.D.  
Director, Department of Reference Standards, Pharmaceutical and Medical Device Regulatory Science Society of Japan (PMRJ)

Session 1 – Endotoxin Standards: Current Test, Reference Standards, Intended Use, Need for New Standards  
Moderated by James Akers, Ph.D.  
Member, USP General Chapters- Microbiology Expert Committee

9:30 – 9:50 a.m.  Current Bacterial Endotoxins Test (BET) and its Intended Use  
Karen Zink McCullough  
Member, USP General Chapters- Microbiology Expert Committee

9:50 – 10:10 a.m.  Current USP Endotoxin RS: Evolution and Intended Use  
Terry Munson  
Technical Vice-President, Parexel Consulting (Retired)

10:10 – 10:30 a.m.  Morning Break

10:30 – 10:50 a.m.  Need for Alternate / Additional Endotoxin Reference Standard  
Edward Tidswell, Ph.D.  
Executive Director, Sterile QA, Merck and Co.  
Member, USP General Chapters- Microbiology Expert Committee
Future of Endotoxins and Pyrogen Testing: Reference Standards and Procedures

June 10-11 • Rockville, MD

10:50 – 11:10 a.m.  Well Characterized Naturally Occurring Endotoxin Standards
John Dubczak
*General Manager, Microbial Solutions, Charles River Laboratories*

11:10 – 12:15 p.m.  Session 1 Roundtable

12:15 – 1:15 p.m.  Lunch

1:15 – 2:30 p.m.  Session 1 Roundtable Continued

2:30 – 2:45 p.m.  Afternoon Break

2:45 – 3:05 p.m.  Recombinant Factor C: Progressive Endotoxin Detection One Year In
Jay Bolden
*Senior Consultant Biologist, Eli Lilly and Co.*

3:05 – 4:00 p.m.  Short Presentations by Individual Suppliers of Kits
Associates of Cape Cod, Inc.
bioMerieux
Lonza

4:00 – 5:15 p.m.  Session 2 Roundtable

5:15 – 5:30 p.m.  Wrap-up, Day 1
Radhakrishna Tirumalai, Ph.D.
*Principal Scientific Liaison, Science-General Chapters, USP*
Tuesday, June 11, 2019

8:00 – 8:30 a.m.  Registration & Coffee

8:30 – 8:45 a.m.  Follow up from Day 1
Radhakrishna Tirumalai, Ph.D.
*Principal Scientific Liaison, Science-General Chapters, USP*

*Session 3 – Pyrogen Tests – Rabbits and MAT - Non Animal Alternatives and Standards*
Moderated by Robert Mello, Ph.D.
*Member, USP General Chapters- Microbiology Expert Committee*

8:45 – 9:05 a.m.
**USP Rabbit Pyrogen Test – History and Current Status**
Marlys Weary
*Owner and Chief Technical Consultant, MERIT Consulting Services*

9:05 – 9:45 a.m.
**Non-Endotoxin Reference Materials for The Monocyte Activation Test (MAT)**
Thomas Hartung, MD, Ph.D.
*Professor, Evidence Based Toxicology, The Johns Hopkins University*

9:45 – 10:15 a.m.
**User Experience with MAT**
Ned Mozier, Ph.D.
*Vice President, PPM, Biotherapeutics Pharmaceutical Sciences, Pfizer*

10:15 – 10:30 a.m.
Morning Break

10:30 – 11:15 a.m.
**Short Presentations by Individual Suppliers of Kits**
CTL-MAT
MilliporeSigma
Sanquin

11:15 – 12:15 p.m.
**Session 3 Roundtable**

12:15 – 12:30 p.m.
**Summary and Conclusions**
Radhakrishna Tirumalai, Ph.D.
*Principal Scientific Liaison, Science-General Chapters, USP*

David Hussong, Ph.D.
*Chair, USP General Chapters- Microbiology Expert Committee*