Future of Endotoxins and Pyrogen Testing: Reference Standards and Procedures

June 10-11 • Rockville, MD

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*

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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**
	Session 2 – Alternative Methods: Is an Alternative Source of Factor C Desirable? Moderated by Donald Singer *Member, USP General Chapters- Microbiology Expert Committee*
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*

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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*