

USP Modern Methods for Endotoxins and Pyrogens Testing Virtual Workshop

Agenda

All times are in Eastern Daylight Time (EDT) – Washington, DC time zone.

Moderators: William J. Pearson, USP; Lynne Ensor, Microbiology EC Member; David Roesti, Microbiology EC Member

Day One: Tuesday, May 14, 2024, 8:00 a.m. – 1:00 p.m.

1. USP Welcome and Opening Remarks

- Jennifer Devine, Senior Vice President, Documentary Standards & Compendial Policy, USP

2. MAT Session and Panel Discussion

- Seeven Vydelingum, PhD; Sanofi Pasteur; *“MAT Expertise and Experience at Sanofi”*
- Thomas Hartung, MD PhD; Johns Hopkins University; *“All pyrogens MATter”*
- Maria Gajewi; Microcoat Biotechnologie; *“Development and validation of the monocyte activation test as a replacement of the rabbit pyrogen test”*
- Ned Mozier; (formerly Pfizer); *“Applications of the Monocyte Activation Test in Pharmaceutical Quality Investigations”*
- Dr. Ingo Spreitzer, PhD; Paul-Ehrlich-Institut; *“The current status and implementation of MAT”*

3. LER/Standards Session and Panel Discussion

- Christian Faderl, PhD; bioMerieux; *“Endotoxin Demasking using a dedicated sample preparation to reverse the LER effect”*
- Brad Parish; Charles River Laboratories; *“Design of a CSE for complex LER Matrices”*
- Xiaolei Zhuang; US Pharmacopeia; *“Development of USP Endotoxin Reference Standard”*

Day Two: Wednesday, May 15, 2024, 8:00 a.m. – 12:00 p.m.

1. Welcome and Summary of Day 1

- Mark Schweitzer, PhD., Chair, General Chapters, Microbiology Expert Committee I
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2. Recombinant Reagents Session and Panel Discussion

- Timothy Francis; Fujifilm; *"Understanding adoption of rCR as a synthetic alternative to traditional LAL using examples from FUJIFILM Wako's PYROSTAR™ Nec"*
- Allen Burgenson; Lonza; *"Validation of a rFC Method for use in Pharmaceutical Testing"*
- Veronika Wills, M.Sc.; Associates of Cape Cod; *"A Comprehensive Review of rCR Pyrosmart Nextgen® - Studies and Publications"*
- Jordi Iglesias, Charles River Laboratories; *"A Statistical Data Analysis and Validation Approach for Recombinant Cascade Reagent"*
- Joel Gysi; Novartis; *"Comparison of different recombinant assays"*

3. Microbiology EC Updates / Final Remarks / Next Steps / Adjourn

- Mark Schweitzer, PhD., Chair, General Chapters, Microbiology Expert Committee I
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