

Alternatives to Compendial Reagents used in the Bacterial Endotoxins Test

USP Virtual Open Forum Final Agenda

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

Day One: Monday, November 15, 2021, 8:00 a.m. – 12:00 p.m.

- 8:00 a.m. USP Welcome and Rules of Engagement**
Facilitator: William J. Pearson, B.Sc., Product Owner | USP
- 8:05 a.m. Opening Remarks**
Speaker: Donald Singer, M.S., Chair, General Chapters, Microbiology Expert Committee | USP
- 8:15 a.m. Setting the Stage: <1085.1> Science and Stakeholders**
Speaker: Karen McCullough, Subcommittee Chair, Endotoxins and Pyrogens | USP
a. Facilitated discussion/Q&A Session
- 8:45 a.m. Pfizer Study Comparing Endotoxin Test Methods on Biopharmaceutical Water Samples**
Speaker: Ned Mozier, Ph.D., Vice President | Pfizer
a. Facilitated discussion/Q&A Session
- 9:30 a.m. Comparability Testing of Recombinant Cascade Reagents as Kinetic Chromogenic Reagents against Traditional LAL Reagents**
Speaker: Veronika Wills, M.Sc., Manager of Technical Services | Associated of Cape Cod
a. Facilitated discussion/Q&A Session
- 10:15 a.m. Endotoxin Testing of About 40 Different Autochthonous and Common Water Contaminating Microorganisms – an LAL and rfc Comparative Study**
Speaker: Christian Faderl, Ph.D., Project Coordinator Endotoxin and Kevin Williams, Senior Scientist | bioMerieux
a. Facilitated discussion/Q&A Session
- 11:00 a.m. Morning Break (15 minutes)**
- 11:15 a.m. The Importance of Data Comparability of LAL and Recombinant Endotoxin Testing Methods with Naturally Contaminated Products**
Speakers: Nicola Reid, Associate Director of Product Management and John Dubczak, Executive Director of Reagent Development & Pilot Plant Operations | Charles River
a. Facilitated discussion/Q&A Session
- 12: 00 p.m. Summary/Closing Remarks**
Speaker: John Duguid, B.Sc., General Chapters, Microbiology Expert Committee Member | USP

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Day Two: Tuesday, November 16, 2021, 8:00 a.m. – 12:00 p.m.

- 8:00 a.m. USP Welcome and Rules of Engagement**
Facilitator: William J. Pearson, B.Sc., Product Owner | USP
- 8:05 a.m. Summary of Day 1 and Objectives for today's session**
Speaker: James Akers, Ph.D., General Chapters, Microbiology Expert Committee Member | USP
- 8:15 a.m. Effect of Formulation on Recovery of Natural Endotoxins**
Speaker: Masakazu Tsuchiya, Ph.D., Senior Research Scientist, and Foster Jordan, Corporate Senior Vice President of Microbial Solutions | Charles River
a. Facilitated discussion/Q&A Session
- 9:00 a.m. Use of an Autochthonous Endotoxin Spike from Upstream Water to Simulate a Process Breach in Four Representative Parenteral Products**
Speaker: Allen Burgenson, Testing Solutions Global SME | Lonza
a. Facilitated discussion/Q&A Session
- 9:45 a.m. Morning Break (15 minutes)**
- 10:00 a.m. FDA Perspective on Recombinant Endotoxins Detection Systems**
Speaker: Reyes Candau-Chacon, Ph.D. | U.S. FDA
a. Facilitated discussion/Q&A Session
- 10:45 a.m. Facilitated Discussion/Q&A**
Facilitator: William J. Pearson, B.Sc., Product Owner | USP
- 11:30 a.m. Final Remarks/Next Steps/Adjourn**
Speaker: Donald Singer, M.S., Chair, General Chapters, Microbiology Expert Committee | USP