

PDA Pyrogens Workshop 2025

Agenda

Wednesday, 29 October

EDT Daylight Time (UTC -4:00)

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| 12:00 – 17:30 | Registration Open |
| 14:00 – 15:30 | P1: Setting the Stage: Risk, Relevance, and the Pyrogens Landscape Chair: Jay Bolden , Senior Director, <i>Eli Lilly and Company</i> |
| | Welcome and Opening Remarks from Workshop Chair 14:00 – 14:15 <ul style="list-style-type: none">• Chair: Jay Bolden , Senior Director, <i>Eli Lilly and Company</i> |
| | The Evolution of Pyrogen Testing and Non-Animal Alternatives 14:15 – 14:40 <ul style="list-style-type: none">• Presenter: Thomas Schomogy MS, Senior Principal Scientist, <i>Pfizer</i> |
| | Quality Risk Management: A Practical Approach for Prevention of Pyrogen Contamination 14:40 – 15:05 <ul style="list-style-type: none">• Presenter: Patrick Mains , Senior Consultant, <i>ValSource, Inc.</i> |
| | 15:05 – 15:30 Q&A |
| 15:30 – 16:00 | Networking Break in the Exhibit Area |
| 16:00 – 17:30 | P2: From Framework to Practice: Navigating Pyrogen Testing Strategies Moderator: Jessica V. Hankins PhD , Director, <i>Bristol Myers Squibb</i> |
| | Overview of Regulatory and Compendial Guidances 16:00 – 16:20 <ul style="list-style-type: none">• Presenter: Liliana Gamboa MSc, Head of Microbiological Control, <i>Sanofi</i> |
| | Which Endotoxin Testing Method is Right for You? 16:20 – 16:40 <ul style="list-style-type: none">• Presenter: Katie Carroll , Sterility Assurance Manager, <i>Celularity, Inc.</i> |
| | Choosing the Right Test: A Pyrogen Case Study Challenge 16:40 – 17:30 <ul style="list-style-type: none">• Presenter: Katie Carroll , Sterility Assurance Manager, <i>Celularity, Inc.</i> |
| 17:30 – 18:30 | Networking Reception in the Exhibit Area |

Thursday, 30 October

EDT Daylight Time (UTC -4:00)

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| 08:00 – 09:00 | Continental Breakfast |
| 08:00 – 16:45 | Registration Open |

P3: Depyrogenation in Practice: Evaluating Endotoxin Reduction Across Sterilization Modalities

Moderator: Liliana Gamboa MSc, Head of Microbiological Control, *Sanofi*

Pre vs Post Sterilization Endotoxin Data and Regulatory Updates

09:00 – 09:20

- **Presenter:** Nick Brydon MS, CISS-EO/RAD/MH, Head of Sterilization, *NextBeam*
- **Presenter:** Peter Rubino , Department Scientist, *Nelson Labs*

Depyrogenation by Sterilization Interactive Case Study

09:20 – 10:00

- **Presenter:** Nick Brydon MS, CISS-EO/RAD/MH, Head of Sterilization, *NextBeam*
- **Presenter:** Peter Rubino , Department Scientist, *Nelson Labs*

10:00 – 10:30

Report Out and Discussion

10:30 – 11:00

Networking Break in the Exhibit Area

P4: Protecting Patients from the Unknown: Real-World Contamination Challenges and Solutions

Moderator: Thomas Schomogy MS, Senior Principal Scientist, *Pfizer*

A Picture is Worth a Thousand Words: Microbial and Endotoxin Contamination in Suspect Samples

11:00 – 11:20

- **Presenter:** Benjamin Claywell , Principal Scientist, *Eli Lilly and Company*

Interactive Case Study and Activity

11:20 – 12:10

- **Presenter:** Benjamin Claywell , Principal Scientist, *Eli Lilly and Company*

12:10 – 12:30

Report Out and Discussion

12:30 – 13:30

Networking Lunch

P5: From Data to Deployment: Confidently Implementing Recombinant Endotoxin Detection

Moderator: Katie Carroll , Sterility Assurance Manager, *Celularity, Inc.*

Advancing Endotoxin Detection: Selection and Validation Strategy for Recombinant Cascade Reagents

13:30 – 13:50

- **Presenter:** Dominique Newberry , Senior Scientist, *Bristol Myers Squibb*

Interactive Case Study and Activity

13:50 – 14:40

- **Presenter:** Jessica V. Hankins PhD, Director, *Bristol Myers Squibb*
- **Presenter:** Dominique Newberry , Senior Scientist, *Bristol Myers Squibb*

14:40 – 15:00

Report Out and Discussion

15:00 – 15:30

Networking Break in the Exhibit Area

P6: Shaping the Future: Evidence to Evolve Expectations and Industry Practices for Pyrogen Testing

Moderator: Jay Bolden , Senior Director, *Eli Lilly and Company*

Update on PDA Technical Report 82

15:30 – 15:50

- **Presenter:** Brian L. Bell PhD, Senior Director Cellular Sciences, *Amgen Inc.*

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| 15:30 – 16:45 | |
| | <div>15:50 – 16:10</div> <div>Modernizing Pyrogen Testing: Conservation Without Compromise<ul style="list-style-type: none">• Presenter: Phil Duncanson PhD, Senior Director, <i>AstraZeneca</i></div> |
| | <div>16:10 – 16:40</div> <div>Discussion and Reflection: From Workshop to Workplace</div> |
| | <div>16:40 – 16:45</div> <div>Closing Remarks from Workshop Chair<ul style="list-style-type: none">• Chair: Jay Bolden , Senior Director, <i>Eli Lilly and Company</i></div> |