

PDA Pyrogens Workshop 2025

Agenda

Wednesday, 29 October

EDT Daylight Time (UTC -4:00)

12:00 – 17:30	Registration Open
	<p>P1: Setting the Stage: Risk, Relevance, and the Pyrogens Landscape Start the Workshop with a grounding in quality risk management principles and a clear look into the complex world of pyrogens. This foundational session will set the stage for deeper discussions ahead by establishing key concepts and context.</p> <p>Chair: Jay Bolden , Senior Director, <i>Eli Lilly and Company</i></p>
14:00 – 15:30	<p>Welcome and Opening Remarks from Workshop Chair</p> <p>14:00 – 14:15</p> <ul style="list-style-type: none">• Chair: Jay Bolden , Senior Director, <i>Eli Lilly and Company</i>
	<p>The Evolution of Pyrogen Testing and Non-Animal Alternatives</p> <p>14:15 – 14:40</p> <ul style="list-style-type: none">• Presenter: Thomas Schomogy MS, Senior Principal Scientist, <i>Pfizer</i>
	<p>Quality Risk Management: A Practical Approach for Prevention of Pyrogen Contamination</p> <p>14:40 – 15:05</p> <ul style="list-style-type: none">• Presenter: Patrick Mains , Senior Consultant, <i>ValSource, Inc.</i>
	<p>15:05 – 15:30 Q&A</p>
15:30 – 16:00	Networking Break in the Exhibit Area
	<p>P2: From Framework to Practice: Navigating Pyrogen Testing Strategies As pyrogen testing methods evolve, selecting the right approach can be complex. This session will review current regulatory and compendial guidance, followed by a focused discussion on method selection. Attendees will then work through a real-world case study and share their testing strategies in a collaborative group discussion.</p> <p>Moderator: Jessica V. Hankins PhD, Director, <i>Bristol Myers Squibb</i></p>
16:00 – 17:30	<p>Overview of Regulatory and Compendial Guidances</p> <p>16:00 – 16:20</p> <ul style="list-style-type: none">• Presenter: Liliana Gamboa MSc, Head of Microbiological Control, <i>Sanofi</i>
	<p>Which Endotoxin Testing Method is Right for You?</p> <p>16:20 – 16:40</p> <ul style="list-style-type: none">• Presenter: Katie Carroll , Sterility Assurance Manager, <i>Celularity, Inc.</i>
	<p>Choosing the Right Test: A Pyrogen Case Study Challenge</p> <p>16:40 – 17:30</p> <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)

08:00 – 09:00		Continental Breakfast
08:00 – 16:45		Registration Open
<p>P3: Depyrogenation in Practice: Evaluating Endotoxin Reduction Across Sterilization Modalities Explore recent studies showing how sterilization processes can inactivate bacterial endotoxins, and what that means for pre- and post-sterilization testing practices. With updates underway to standards like ISO 11737-3 and ANSI/AAMI ST72, now is a critical time for the industry to align on best practices. The session includes an interactive case study to help attendees apply technical insights to real-world decision-making.</p> <p>Moderator: Liliana Gamboa MSc, Head of Microbiological Control, <i>Sanofi</i></p>		
09:00 – 10:30	Pre vs Post Sterilization Endotoxin Data and Regulatory Updates	
	09:00 – 09:20	<ul style="list-style-type: none"> • Presenter: Nick Brydon MS, CISS-EO/RAD/MH, Head of Sterilization, <i>NextBeam</i> • Presenter: Peter Rubino , Department Scientist, <i>Nelson Labs</i>
	09:20 – 10:00	Depyrogenation by Sterilization Interactive Case Study <ul style="list-style-type: none"> • Presenter: Nick Brydon MS, CISS-EO/RAD/MH, Head of Sterilization, <i>NextBeam</i> • Presenter: Peter Rubino , Department Scientist, <i>Nelson Labs</i>
	10:00 – 10:30	Report Out and Discussion
10:30 – 11:00		Networking Break in the Exhibit Area
<p>P4: Protecting Patients from the Unknown: Real-World Contamination Challenges and Solutions Uncover real-world contamination risks revealed by testing variable and uncertain product samples. Attendees will engage in interactive case studies to assess patient safety implications and develop adaptable testing approaches using modern technologies.</p> <p>Moderator: Thomas Schomogy MS, Senior Principal Scientist, <i>Pfizer</i></p>		
11:00 – 12:30	A Picture is Worth a Thousand Words: Microbial and Endotoxin Contamination in Suspect Samples	
	11:00 – 11:20	<ul style="list-style-type: none"> • Presenter: Benjamin Claywell , Principal Scientist, <i>Eli Lilly and Company</i>
	11:20 – 12:10	Interactive Case Study and Activity <ul style="list-style-type: none"> • Presenter: Benjamin Claywell , Principal Scientist, <i>Eli Lilly and Company</i>
	12:10 – 12:30	Report Out and Discussion
12:30 – 13:30		Networking Lunch
<p>P5: From Data to Deployment: Confidently Implementing Recombinant Endotoxin Detection Gain practical insight into transitioning to recombinant endotoxin detection methods, from reagent selection and validation strategy to implementation planning. Attendees will collaborate to identify potential challenges and mitigation approaches, then share key insights and real-world applications through a group report-out.</p> <p>Moderator: Katie Carroll , Sterility Assurance Manager, <i>Celularity, Inc.</i></p>		
13:30 – 15:00	Advancing Endotoxin Detection: Selection and Validation Strategy for Recombinant Cascade Reagents	
	13:30 – 13:50	<ul style="list-style-type: none"> • Presenter: Dominique Newberry , Senior Scientist, <i>Bristol Myers Squibb</i>
	Interactive Case Study and Activity	
	13:50 – 14:40	<ul style="list-style-type: none"> • Presenter: Jessica V. Hankins PhD, Director, <i>Bristol Myers Squibb</i>

- **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

This session will highlight the latest updates to PDA Technical Report 82 and discuss how evolving regulatory expectations are shaping modern testing strategies. Attendees will also explore conservation-focused approaches. The Workshop will conclude with a group discussion to encourage reflection and practical takeaways to bring back to your organization.

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.*

Modernizing Pyrogen Testing: Conservation Without Compromise

15:50 – 16:10

- **Presenter: Phil Duncanson PhD**, Senior Director, *AstraZeneca*

16:10 – 16:40

Discussion and Reflection: From Workshop to Workplace

Closing Remarks from Workshop Chair

16:40 – 16:45

- **Chair: Jay Bolden** , Senior Director, *Eli Lilly and Company*