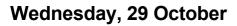
PDA Pyrogens Workshop 2025 Agenda



EDT Daylight Time (UTC -4:00)

Registration Open
P1: Setting the Stage: Risk, Relevance, and the Pyrogens Landscape
Chair: Jay Bolden , Senior Director, Eli Lilly and Company
 Welcome and Opening Remarks from Workshop Chair 14:00 – 14:15 Chair: Jay Bolden , Senior Director, <i>Eli Lilly and Company</i>
The Evolution of Pyrogen Testing and Non-Animal Alternatives 14:15 – 14:40 • Presenter: Thomas Schomogy MS, Senior Principal Scientist, Pfizer
Quality Risk Management: A Practical Approach for Prevention of Pyrogen Contamination 14:40 – 15:05 • Presenter: Patrick Mains, Senior Consultant, ValSource, Inc.
15:05 – 15:30 Q&A
Networking Break in the Exhibit Area
P2: From Framework to Practice: Navigating Pyrogen Testing Strategies
Moderator: Jessica V. Hankins PhD, Director, Bristol Myers Squibb
Overview of Regulatory and Compendial Guidances 16:00 – 16:20 • Presenter: Liliana Gamboa MSc, Head of Microbiological Control, Sanofi
Which Endotoxin Testing Method is Right for You? 16:20 – 16:40 • Presenter: Katie Carroll, Sterility Assurance Manager, Celularity, Inc.
Choosing the Right Test: A Pyrogen Case Study Challenge 16:40 – 17:30 • Presenter: Katie Carroll , Sterility Assurance Manager, Celularity, Inc.

Thursday, 30 October

EDT Daylight Time (UTC -4:00)

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 – 10:30	• 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			
	• 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			
11:00 – 12:30	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			
	• 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			
40.00 45.00	13:30 – 13:50 • Presenter: Dominique Newberry, Senior Scientist, Bristol Myers Squibb			
13:30 – 15:00	Interactive Case Study and Activity			
	• 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			
	Moderator: Jay Bolden , Senior Director, <i>Eli Lilly and Company</i> Update on PDA Technical Report 82			

15:30 – 16:45	15:50 – 16:10	Modernizing Pyrogen Testing: Conservation Without Compromise • Presenter: Phil Duncanson PhD, Senior Director, AstraZeneca
	16:10 – 16:40	Discussion and Reflection: From Workshop to Workplace
	16:40 – 16:45	Closing Remarks from Workshop Chair • Chair: Jay Bolden , Senior Director, Eli Lilly and Company