

# Parenteral Drug Association®

Connecting  
People, Science  
and Regulation®

PDA Good Aseptic Manufacturing Conference 2025

Excellence in Aseptic Manufacturing: Bridging Compliance, Innovation, and Sustainability

Basel, Switzerland

22-23 May 2025

Agenda Preview

## Thursday, 22 May 2025

9:00	Welcome and Introduction	Falk Klar, PDA Europe
	Welcome from the Co-Chairs	Simone Biel, Merck KGaA David Keen, Ecolab
<b>Opening Plenary</b>		
	Title to be announced	GSK
	Title to be announced	Invited Regulatory Speaker
	Advancing Aseptic Fill & Finish: A Collaborative Breakthrough in Next-Generation Production	Pfizer & Novo Nordisk & Syntegon
10:35	<b>Networking Coffee Break, Exhibition</b>	
	How Can We Address Value Chain Emissions?	ten23 health
	Interactive Questionnaire Session	
	<b>Plenary Discussion</b>	

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12:20	Networking Lunch Break, Poster Session, Exhibition			
13:20	<b>LIVE Guided Poster Walk</b> Engage with our Poster Presenters in our Exhibition Hall			
Session 1	Track A Closed Systems		Track B Enablers for Aseptic Manufacturing	
	A Risk-Based Approach for Assuring the Integrity of Closed, Single-Use Systems in Aseptic Processing	MSD	Replace Settle Plates via Continuous Active Air Monitoring	Takeda
	Integrity Assurance of Final Sterile Filtration Process Step With SUS	Merck KGaA	Revision of Technical Report No. 33 Evaluation, Validation and Implementation of Alternative and Rapid Microbiological Methods	Novartis
	Case Study of Aseptic Processing in a Closed System in Clean Room Class C	BioNTech	The Digital Transformation of Sterility Testing: The Case for Alternative Microbiological Methods With Complex Product Formulations	Charles River
	Q&A, Discussion		Q&A, Discussion	
14:55	Networking Coffee Break & Exhibition			
Session 2	Track A First Air		Track B Decontamination	

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	<i>Title to be announced</i>	<i>Invited Speaker</i>	Application and Qualification of an Automated UV Disinfection Robot for Aseptic Cleanrooms	AstraZeneca
	<i>Latest Technologies to Follow First-Air Principles According to Annex 1</i>	<i>Bausch &amp; Ströbel</i>	Case Study: E-Beam Used More Than 15 Years as Transfer Technology for RTU Pre-Filled Syringes at Pfizer Grange Castle Ireland on Multiple Filling Lines	Pfizer & SKAN
	Q&A, Discussion		Q&A, Discussion	
17:45	<b>End of Conference Day 1 &amp; Networking Event</b>			

## Friday, 23 May 2025

Session 3	Track A	Track B		
	<b>Aseptic Process Simulation</b>		<b>Particle Risk Mitigation</b>	
09:00	EU GMP Annex 1, QRM & APS: Practical Approach & Points to Consider	<i>Minipharm</i>	Total Particle Count: Two Options to Be Compliant to EU GMP Annex 1–3-Way Valve Redesign, Counter Resistant to VHP	GSK
	Aseptic Process Simulation: Pragmatic and Innovative Approach	<i>Eli Lilly &amp; Company &amp; Novo Nordisk on behalf of A3P</i>	Achieving Particle Reduction via Supplier Annex 1 Strategies and Innovation in RTU/RTF Packaging	Gerresheimer
	Q&A, Discussion		Q&A, Discussion	

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10:10	Networking Coffee Break, Poster Session & Exhibition					
Session 4	Track A <b>Excellence in Manufacturing Execution</b>		Track B <b>Application for Quality Risk Management</b>			
	Case Study: Syringe and Cartridge Fill-Finish Production	Siegfried Hameln	Title to be announced	Speaker invited		
	Title to be announced	Invited Speaker	Title to be announced	Biogen		
	Q&A, Discussion		Q&A, Discussion			
11:50	Networking Lunch Break, Poster Session & Exhibition					
Closing Plenary						
	Interactive Questionnaire Session					
	Title to be announced		Invited Speaker			
	Regulatory Expectations on Data-Driven Sterile Manufacturing		Invited Regulatory Speaker			
13:45	Plenary Discussion					

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14:30	Networking Coffee Break, Poster Session & Exhibition	
15:00	Passport Raffle	
	Best Poster Presentation	
	Interactive Session	
	Co-Chairs Conference Summary	Simone Biel, Merck KGaA David Keen, Ecolab
	Closing Remarks & Farewell	Falk Klar, PDA Europe
16:30	End of Conference	

*The agenda is subject to change without notice. Speaker invited, pending confirmation.*