



2024 PDA Good Aseptic Manufacturing Conference
 Assessing EU GMP Annex 1: 264 Days into the Journey
Stuttgart/Germany
15-16 May 2024
Agenda Preview

Wednesday, 15 May 2024

9:00	Welcome and Introduction	Falk Klar, <i>PDA Europe</i>
	Welcome from the Chairs	Simone Biel, <i>Merck</i> Darren Beckett, <i>Fedegari</i>
Opening Plenary		
	Keynote: Empowering Patients Through Good Aseptic Manufacturing: A Vital Journey Towards Safer Medical Products	<i>World Patients Alliance</i>
	<i>Title to be announced</i>	<i>Speaker to be announced</i>
	<i>Title to be announced</i>	<i>Speaker to be announced</i>
10:45	Coffee Break, Poster Session & Exhibition	
	Annex 1 Implementation: A Case Study of the Sterile Production at F. Hoffmann-La Roche Ltd.	<i>F. Hoffmann-La Roche Ltd</i>
	Interactive Questionnaire Session	
	Q&A, Panel Discussion	
12:40	Lunch Break, Poster Session & Exhibition	
13:30	Guided Poster Walk	



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Session 1	Track A: Impact of EU GMP Annex 1 on Lyophilization	Moderator: Andrea Salmaso, <i>Stevanato Group</i>	Track B: Sustainability in Aseptic Manufacturing	Moderator: Paul Devuyt, <i>GSK Vaccines</i>
	<i>Title to be announced</i>	<i>former AIFA</i>	From sustainability ambitions into action: what about aseptic manufacturing?	<i>Merck</i>
	A better approach to APS for lyophilized products - APS approach for freeze-drying process considering Annex 1 requirements	<i>Merck</i>	Can we have reliable and fast sustainability impact assessments? Merging technology, innovation, and sustainability	<i>ten23 health</i>
	Q&A, Discussion			
15:20	Coffee Break, Poster Session & Exhibition			
Session 2	Track A: Filtration and Closed Systems	Moderator: Peter Makowenskyj, <i>GCon Bio</i>	Track B: Aseptic Set-Up of Filling Machines	Moderator: Klaus Ullherr, <i>Syntegon</i>
	PUPSIT in the revised Annex 1 – Friend or Foe of the Pharmaceutical Entrepreneur?	<i>Roche</i>	Implementing Annex 1 Guidelines: A Comprehensive Approach to Sterility Assurance for Indirect Product Contact Parts	<i>MSD</i>
	Contamination Control Strategies in Processing of Frozen Sterile Bulk Drug Product in Single-use Bag Assembly	<i>BioNTech</i>	Compliance with new Annex 1 on a fill/finish machine: A glance into the future	<i>Vetter Pharma</i>
	Q&A, Discussion			



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17:10	End of Conference Day 1 & Networking Event
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Thursday, 16 May 2024

Session 3	Track A: Environmental Monitoring	Moderator: Hue Kwon, <i>Samsung Bioepis</i>	Track B: Equipment for Aseptic Processes	Moderator: David Keen, <i>Ecolab</i>
	Total Particle Count – tubing Qualification at GSK: lessons learned	<i>GSK Vaccines</i>	Annex 1 and “Good Technology Practice” - Interpretation and engineering for this side of production	<i>Syntegon</i>
	Facility monitoring in the daily practice of a CMO - Annex 1 full-fillment without relying on settle plates	<i>Recipharm</i> & <i>Particle Measuring Systems</i>	Critical factors in the material transfer process	<i>Takeda</i>
	Automated Reading of Agar Plates using AI	<i>AstraZeneca</i>	SELECTION OF MATERIALS FOR AUTOCLAVE STERILISATION PROCESS "When used in aseptic processing, the packaging should be of low particle generation" - Annex 1	<i>AM Instruments</i>

	Q&A, Discussion
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10:30	Coffee Break, Poster Session & Exhibition
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Session 4	Track A: Quality Risk Management	Moderator: Richard Denk, <i>SKAN</i>	Track B: RABS/Isolator	Moderator: Tracy Moore, <i>TM Pharma Group</i>
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	Risk Tool Selection With ICH Q9(R1) In Mind	<i>ValSource</i>	APS for gloveless isolator filling line - experience and lessons learned with the first installation in Germany	<i>PSM</i>
	Embracing the challenge of APS Strategy and Design	<i>Takeda</i>	Leveraging emerging technologies for hydrogen peroxide bio-decontamination: from novel process data to real process impact	<i>SKAN</i>
	Q&A, Discussion			
12:20	Lunch Break, Poster Session & Exhibition			
Closing Plenary:				
	Interactive Questionnaire Session			
	<i>Title to be announced</i>		<i>Speaker to be announced</i>	
	<i>Title to be announced</i>		<i>Speaker to be announced</i>	
14:20	Coffee Break, Poster Session & Exhibition			
14:50	Passport Raffle			
	Introduction of PDA PtC for Sterile Filling		<i>groninger</i>	
	<i>Title to be announced</i>		<i>AbbVie</i>	



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	Panel Discussion	
	Conference Summary from the Chairs	
	Excitement @Syntegon – Insights and preparation for the Syntegon factory tour	<i>Syntegon</i>
	Closing Remarks & Farewell	Falk Klar, <i>PDA Europe</i>
16:35	End of Conference	

The agenda is subject to change without notice