



PDA BioManufacturing Conference 2024
 Shaping the Future of Biomanufacturing
 24 – 25 September 2024
 Gothenburg, Sweden
 Agenda

Tuesday, 24 September 2024

9:00	Welcoming		Falk Klar, <i>PDA Europe</i>	
9:10	Welcome from the Co-Chairs			
09:20 – 12:30 Opening Plenary: Addressing Patients Needs			Moderator: Elisabeth Vachette, <i>Sartorius</i>	
	Patient Perspective		Speaker to be Announced	
	<i>Title to be Announced</i>		<i>Paul-Ehrlich-Institut</i>	
	<i>Title to be Announced</i>		<i>Medical Products Agency Sweden</i>	
10:50	Networking Coffee Break, Poster Session & Exhibition			
	Developing Patient Centric Specification for Commercial Biologics: Real World Case Studies		Bristol-Meyers Squibb	
	Plenary Discussion			
12:30	Networking Lunch Break, Poster Walk & Exhibition			
13:15	LIVE Guided Poster Walk Engage with our Poster Presenters in our Exhibition Hall		Moderator:	
13:40 – 15:25 Session 1	Track A: Processes for New Entities in Freeze-Drying	Moderator: Julian Lenger, <i>Bayer</i>	Track B: CMC Strategies for Vaccines Biomanufacturing	Moderator: Cristiana Campa, <i>GSK</i>



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	Developments in in Line and Offline Process Testing for Biologicals	<i>MHRA</i>	Vaccines Interest Group Session - Our 2024 journey!	<i>Merck, Sharp & Dohme</i>
	Building Robustness into the Primary Drying Phase of Lyophilization: A Modelling Framework and Use Cases for Biopharmaceuticals	<i>Coriolis Pharma</i>	#46 Patient-Centric Development for Vaccines	<i>GSK</i>
	Solving the Deep-Frozen Challenge – Lyophilization of an Oncolytic Virus	<i>Boehringer Ingelheim</i>	Applying Prior Knowledge and Patient Centric Based Considerations to Specification Setting	<i>Johnson & Johnson</i>
	Q&A, Discussion		Q&A, Discussion	
15:30	Networking Coffee Break, Poster Session & Exhibition			
16:00 – 17:45 Session 2	Track A: Opportunities for Vaccine Access	Moderator: Mic McGoldrick, <i>MSD</i>	Track B: Innovation in Biomanufacturing	Moderator: Mike De Felippis, <i>Eli Lilly</i>
	<i>Title to be Announced</i>	EFPIA/VE	Cell-Free Manufacturing of Proteins	<i>Invitris GmbH</i>
	Building Health Emergency Preparedness by Harnessing the Potential of Vaccine Platforms	<i>CEPI</i>	Application and Utilization of Heat Inactivation as a Downstream Purification Tool in Biomanufacturing Processes	<i>Eli Lilly</i>
	Regulatory Global Convergence, Harmonization, and Reliance	<i>Merck Sharp & Dohme</i>	Polysorbate Control Strategies in Biopharmaceuticals	<i>Clear Solutions Laboratories</i>



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	Q&A, Discussion		Q&A, Discussion	
17:45	End of Conference Day 1 & Networking Event			
Wednesday, 25 September 2024				
08:00 – 08:45	Interest Group Session: Lyophilization	Anthony Canon, <i>MSD</i>	Interest Group Session: Advanced Manufacturing and Applied Process Digitalization (former Biomanufacturing IG)	Peter Makowenskyj, <i>G-Con</i> & Toni Manzano, <i>Aizon</i>
09:00 – 10:45 Session 3	Track A: Digital Tools Shaping Future Biomanufacturing	Moderator: Adithya Balasubramanian, <i>ten23 health</i>	Track B: Future Techniques in Freeze-Drying	Moderator: Sebastian Groel, <i>Daiichi-Sankyo</i>
	The Key Role of AI in Biomanufacturing and Good Practices to Implement it	Aizon	Sustainable Refrigeration Technologies: Overview and Implementation of Innovative Air-Cooling Technology for Freeze-Drying Processes	<i>HOF Sonderanlagenbau & Roche</i>
	A Regulatory Framework Enabling Digital Innovation in Manufacturing	<i>GSK on behalf of EFPIA</i>	Continuous and Controlled Lyophilization of mRNA-LNPs Based Formulations	<i>RheaVita</i>
	Accelerated Process Development Using End-to-End Digital Twins	<i>Körber Pharma</i>	Understanding Thermal Interactions in Biopharmaceutical Freezing: Implications for Nucleation Temperature Distribution	<i>Politecnico di Torino</i>
	Q&A, Discussion		Q&A, Discussion	
10:45	Networking Coffee Break, Poster Session & Exhibition			



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11:15 – 12:35 Session 4	Track A: Fill & Finish Processing	Moderator: Yves Mayeresse, <i>GSK</i>	Track B: Sustainability	Moderator: Virginie Le Coent, <i>BioMerieux</i>
	Discovering Equivalence in Extractables & Leachables Assessments of Single-Use Systems: An Advanced Mathematical Methodology	<i>Sartorius</i>	Sustainability at the EDQM: A Focus on the Ph. Eur. and the 3Rs	<i>EDQM (remotely)</i>
	VHP Uptake of Manufacturing Tubing Used for Aseptic Fill-Finish Processes of Biopharmaceutical Drug Products	<i>ten23 health</i>	Enhancing Sustainability ESG Scores in BioManufacturing	<i>BioMerieux</i>
	Frame-by-Frame - End-to-End: How Advanced Risk Profiling Accelerated the Development of a Robust Manufacturing Setup for a Brand New Kindeva Fill-Finish Site	<i>Kindeva & Innerspace</i>	Using Sustainable Taxonomy: Recycle, Reuse, Reduce & Re-purpose Water for pharmaceutical Use	<i>Fujifilm</i>
	Q&A, Discussion		Q&A, Discussion	
12:35	Networking Lunch Break, Poster Session & Exhibition			
13:35 – 17:00 Closing Plenary: Innovative Regulatory Strategies for a Globalized World			Moderator: Sabine Hauck, <i>Consultant</i>	



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13:35	Interactive Questionnaire	
	Efficiency in Pharmaceutical Life-Cycle Management: Implementing ICH Q12 and Established Conditions	<i>Sandoz</i>
	Simultaneous Submission to Multiple Health Authorities Using Accumulus Synergy Platform - Using CMC Platform Best Practices for Comparability Assessments and Manufacturing Process Validation as Pilot	<i>CEPI</i>
14:35	Networking Coffee Break, Poster Session & Exhibition	
15:05	Passport Raffle	
	<i>Title to be Announced</i>	<i>U.S. FDA</i>
	<i>Title to be Announced</i>	<i>Regulatory Speaker Invited</i>
16:10	Plenary Discussion	Moderator: Sabine Hauck, <i>Consultant</i>
	Co-Chairs Conference Summary	Sabine Hauck, <i>Consultant</i> Elisabeth Vachette, <i>Sartorius</i>
	Closing Remarks & Farewell	Falk Klar, <i>PDA Europe</i>
16:30	End of Conference	