2023 PDA BioManufacturing Conference

Agility and Biomanufacturing Excellence to Meet Patients' Needs

12 – 13 September 2023

Seville, Spain

Tuesday, 12 September 2023		**09:00 – 17:50**
9:00	Welcome and Introduction	Falk Klar, *PDA Europe*
9:05	Welcome from the Co - Chairs	Cristiana Campa, *GSK* Elisabeth Vachette, *Sartorius*
Opening Session: Agility and Biomanufacturing Excellence to Meet Patients' Needs		**Moderators:** Cristiana Campa, *GSK* Elisabeth Vachette, *Sartorius*
With the theme of this year: Agility and Biomanufacturing Excellence to meet Patient's Needs the 5th PDA Biomanufacturing Conference provides key trends and latest development in Bioindustry. The first plenary session will provide extensive reflection on regulatory framework for innovations in Chemistry, Manufacturing and Controls (CMC) for biotherapeutics and vaccines, showcasing opportunities and examples of collaboration between Industry and Regulatory Agencies to drive implementation of new technologies and digital strategies in the biopharmaceutical area. Furthermore, perspectives on accelerated CMC development roadmaps will be provided by CEPI, also reflecting on the interdependency between innovation and rapid access to patients.		
09:15	Regulatory Framework for Biomanufacturing Innovations	Mats Welin, *Medical Products Agency Sweden*
09:45	Artificial Intelligence and Digital Twins in Biopharma Manufacturing	Toni Manzano, *Aizon*
10:15	Quality Innovation Group: Regulatory Support for Innovative Manufacturing and Quality Control Approaches	Marcos Timón, *Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)*
10:45	**Coffee Break, Poster Session & Exhibition**	
11:15	The IMI Inno4Vac Project: A Public-Private Partnership Focussing on Innovations to Accelerate Vaccine Development and Manufacture	Wim Van Molle, *Sciensano Belgium*
11:45	Phase Appropriate CMC Deliverables for Vaccine Development	Anna Särnefält, *CEPI*
12:10	Q&A, Panel Discussion	

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13:00	**Lunch Break, Poster Session & Exhibition**			
13:45	**LIVE Guided Poster Walk** Engage with our Poster Presenters in our Exhibition Hall		**Moderator:** Thomas Beutler, *GEA Lyophil*	
Session 1	**Track A Application of AI and ML for Biopharmaceutical Development and Manufacturing**	**Moderator:** Michael De Felippis, *Eli Lilly*	**Track B The Power of Modelling and Microwaves in Lyophilization**	**Moderator:** Julian Lenger, *Bayer*
Artificial Intelligence (AI) and Machine Learning (ML) tools are increasingly being deployed across multiple industries to unlock new value and gain efficiency. The biopharmaceutical industry is recognizing the important role AI/ML can play in improving processes for development and commercialization and accelerating innovative medicines to patients. This session includes three applications of AI/ML including repurposing AI technology implemented at an unrelated industry for a biopharmaceutical manufacturing process, using ML modeling to increase efficiency and probability of technical success for drug candidates in early-phase development, and creating an ML algorithm to optimize excipient selection for biopharmaceutical formulations.			Explore the scientific advancements in lyophilization through the application of modeling techniques and the utilization of microwaves. Gain insights into how modeling enhances the optimization of lyophilization cycles by guiding the selection of process parameters for desired product attributes. Discover the impact of the freezing step on drying efficiency and product quality and learn about the influence of controlled nucleation on primary drying simulation accuracy. Dive into the scientific principles of microwave-assisted freeze-drying (MFD), uncovering its potential to significantly reduce drying times while maintaining product integrity. Join us to delve into the scientific aspects of lyophilization optimization and the utilization of innovative technologies.	
14:15	Model-Driven AI in Operations Management: From Space Exploration to Real World Bio-Manufacturing	Jonas Gibaszek, *Rombio*	Modelling the Lyophilization Process: A Quality by Design Approach to Optimize Cycle Performance and Product Quality	Andrea Arsiccio, *Coriolis Pharma Research GmbH*
14:40	Predicting Holistic Developability Scores for Protein Scaffolds Using Machine Learning	Daniel Pais, *Valgenesis* Karin Felderer, *Pieris*	Effect of the Freezing Step on Primary Drying Experiments and Simulation of Lyophilization Processes	Alex Juckers, *Martin Christ*

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15:05	Machine-Learning Acceleration of Biopharmaceutical Formulation Development Using Excipient Prediction Software (ExPreSo)	Estefania Vidal-Henriquez, *Leukocare*	A Novel Way of Freeze-Drying: Drastic Drying Time Reduction Using Microwave Radiation	Benjamin Ledermann, *GEA Lyophil*
15:30	Q&A, Discussion		Q&A, Discussion	
16:00	**Coffee Break, Poster Session & Exhibition**			
Session 2	**Track A** **Advanced Modeling Strategies for Product and Process Understanding**	**Moderator:** Sabine Hauck, *Leukocare*	**Track B** **Formulation / Fill and Finish**	**Moderator:** Yves Mayeresse, *GSK*
Modelling of processes bears the two-fold advantage of deeper process understanding and gaining speed. Kinetic modelling is a powerful tool to predict process outcome based on real data and process understanding. The speakers in this session will present the success stories of kinetic modelling for manufacturing process on one side, and stability prediction on the other side.			The requirements for drug products evolved over the years to obtain better quality. This evolution can come from new rules or from innovation. The first presentation will discuss how important requirements of the European GMP Annex 1:2022 have changed the qualification of cleanrooms. Continuous environmental monitoring represents one of the most relevant and effective tools to assess in real time the potential risk of contamination in critical environments. With a second presentation we will learn how to design a more resilient vial to physical insults thus minimizing breakage and having better machining capability when compared to existing borosilicate vial. The challenge of implementing these vials and the need to revise USP/EP to broaden the definition of Type I pharmaceutical glass and gaining the approval by US FDA will be explained.	

16:30	Quantifying the Catabolism of CHO Cells to Build Industrially Relevant Kinetic Models	Sergio Rossell, *GSK*	Environmental and Process Monitoring (Viable and Total Particle) According to the EU GMP Annex 1:2022 - New Requirements and Next Challenges	Diego Bompadre, *Rigel Life Sciences*
16:55	A Universal Tool for Stability Predictions of Biotherapeutics, Vaccines and In Vitro Diagnostic Products	Didier Clénet & Warren Roche, *Sanofi*	Regulatory Journey to Approval of a Novel Final Product Container	Navdip Ghai, *Merck Sharp & Dohme*
17:20	Q&A, Discussion		Q&A, Discussion	
17:50	**End of Conference Day 1 & Networking Event**			

Wednesday, 13 September 2023 09:00 – 16:45

Session 3	**Track A** **Sustainability**	**Moderator:** Michael De Felippis, *Eli Lilly*	**Track B** **Enhancements in Supply Capacity**	**Moderator:** Elisabeth Vachette, *Sartorius*
While the pharmaceutical industry is recognized for its unique position on creating value to patients and society based on innovations, expectations have raised in recent years to put focus on sustainability. To achieve the goal of climate neutral operations and supply chain within pharmaceutical industry, it is of crucial importance to implement sustainability targets already from the beginning into the design of pharmaceutical products. In the first presentation industrial case studies are presented on how to meet sustainability targets in context of the existing regulatory frameworks, following the second presentation on how strategies can support sustainability, considering both process design and optimization (mAb example) and techno-economic assessment and modeling (viral vector example) by			Drug availability is one of the key drivers of our industry and serving patients means that drug manufacturing processes must be flexible and resilient enough to cope with numerous constraints including current demand variability. This session will focus on 2 aspects having demonstrated their ability to better serve patients, namely by developing novel processes and increasing flexibility and speed to market via process intensification implementation and via rapid process and regulatory scalability for biologics enabling mass production.	

showing us on how to build these targets from the beginning into the product and process design.				
09:00	Building a Regulatory Framework to Support Innovation to Medicines Supply to Meet, Patient Access, Environmental and Climate Targets	Mónica Perea-Vélez, *GSK*	Intensification of mAbs by Connected Processing: Development to Scale Up to Ensure Robust, Cost Effective, and Fast Manufacturing	Sanket H. Jadhav, *Sartorius*
09:25	Embedding Sustainability in Process Design and Product Distribution	Maria Papathanasiou, *Imperial College London*	Biopharma 4.0 for Biologics Under Pandemic Constraints - Scalable mRNA Machine for Regulatory Approval of 1,000 Clinical to 10 Million Manufacturing Scale Doses	Alina Hengelbrock, *&* Axel Schmidt, *TU Clausthal*
09:50	Q&A, Discussion		Q&A, Discussion	
10:20	**Coffee Break, Poster Session & Exhibition**			
Session 4	**Track A Vaccines**	**Moderator:** Yves Mayeresse, *GSK*	**Track B Advances in Biotherapeutics Developments and Life Cycle**	Sabine Hauck, *Leukocare*
The first presentation will provide general principles on specification setting for different vaccine types, as well as some illustrative examples, showing how to overcome some challenges and providing reflections on future directions as there is no predefined and single set of specifications' quality attributes for vaccines against a given pathogen, since multiple vaccine platforms can be used for the same target. The next presentation will focus on the PDA technical report 89: Strategies for vaccine development and life cycle management.			Developments in biotherapeutic manufacturing will be illustrated for antibodies and cell -based therapies. A case study of a commercial platform mAb process and its global post-approval changes will provide lessons learned with respect to ensuring streamlined lifecycle management. The second talk will discuss allogeneic cell therapies and their potential as "off-the-shelf" products.	

10:50	PDA Technical Report n 89 (Strategies for Vaccine Development and Lifecycle Management	Sabrina Restrepo, *Merck Sharp & Dohme*	Lifecycle Management of a Commercial Platform Monoclonal Antibody Process: The Promise of ICH Q12	Cillian McCabe, *Eli Lilly*
11:15	Specifications for Vaccines	Julia O'Neill, *Direxa Consulting*	What the cell? Next Generation Allogeneic Cell Therapies and Impact on Facility Design	Emily Heffernan, *Arcadis DPS Group*
11:40	Q&A, Discussion		Q&A, Discussion	
12:10	**Lunch Break, Poster Session & Exhibition**			
Closing Session: Health Emergencies Preparedness for the Future			**Moderators:** Cristiana Campa, *GSK* Elisabeth Vachette, *Sartorius*	
The closing plenary session will explore progress of implementation of pandemic- related learnings from Industry and Regulators, including concrete initiatives from vaccines developers and new guidance tools from Health Authorities, especially in case of epidemic or pandemic scenarios. We will benefit from key experts and take the opportunity to network and exchange with EMA and FDA, as well as from Global Health- driven organizations like CEPI to accelerate development and supply of biopharmaceuticals and provide innovative tools for comparability assessment and process validation. Our common goal is to meet patient's needs through agility and biomanufacturing excellence.				
13:10	Interactive Questionnaire			
13:20	Accelerating Access to Vaccines – Next Steps Beyond the Pandemic		Mic McGoldrick, *Merck Sharp & Dohme*	
13:45	Platform Protocol Templates: An Innovative Upcoming Tool for Comparability Assessment and Process Validation		Antonio Guzzi, *CEPI*	
14:15	**Coffee Break, Poster Session & Exhibition**			
14:45	**Passport Raffle**			

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14:50	Expedited Product Development – Learning from Pandemics	Anissa Cheung, *US FDA*
15:20	EMA CMC Toolbox: Facilitating Early Access of Biopharmaceuticals in the EU	Elisa Pedone, *EMA*
15:50	**Closing Panel Discussion** *Join our Discussion with Experts from the Industry and Regulatory:* - Anissa Cheung, *US FDA* - Antonio Guzzi, *CEPI* - Mic McGoldrick, *Merck Sharp & Dohme* - Maria Papathanasiou, *Imperial College London* - Elisa Pedone, *EMA* - Wim Van Molle, *Sciensano Belgium* - Mats Welin, *Medical Products Agency Sweden*	
16:30	**Co-Chairs Conference Summary**	Cristiana Campa, *GSK* Elisabeth Vachette, *Sartorius*
16:40	**Closing Remarks & Farewell**	Falk Klar, *PDA Europe*
16:45	**End of Conference**	

The agenda is subject to change without notice!