2022 PDA Biomanufacturing Conference

Theme: Biopharmaceutical Solutions to Prepare for Healthcare Challenges

Amsterdam / The Netherlands

20-21 September 2022

Tuesday, 20 September 2022

09:00	Welcome and Introduction	Falk Klar, *PDA Europe*
09:05	Welcome from the Chairs	Cristiana Campa, *GSK* Raf De Dier, *Janssen*
Opening Plenary: **Biopharmaceutical Solutions to Prepare for Healthcare Challenges**		**Moderators:** Cristiana Campa, *GSK* Raf De Dier, *Janssen*
This session will provide an overview of recent developments related to chemistry, manufacturing, and control (CMC) strategies. As an opening topic, CMC acceleration will be covered, offering visibility on concrete options for a rapid response to unmet medical needs, and including learnings from COVID-19 emergency, for future pandemic preparedness. Furthermore, perspectives on current ICH topics will be offered, reflecting the continuous evolutions in the CMC space, with some focused considerations on specifications setting. A final panel discussion, involving Regulators from different areas as well as CEPI, will ensure active dialogue with the attendees.		
09:15	EMA CMC Toolbox on Early Access: Applicability to COVID-19 and Beyond	Dolores Hernan, *EMA*
09:45	CMC Innovations to Achieve CEPI's 100 Days Mission – Lessons Learned from COVID-19 and Plans for the Future	Renske Hesselink, *CEPI*
10:15	Coffee Break, Poster Session & Exhibition	
10:45	Current ICH Topics and Specification Setting Strategies	Mats Welin, *Medicine Products Agency Sweden*
11:15	**Q&A; Discussion**	**Moderators:** Cristiana Campa, *GSK* Raf De Dier, *Janssen*
12:00	Lunch Break, Poster Session & Exhibition	
Session 1	**Track A: Acceleration & Leanings from Pandemics**	**Moderator:** Thierry Gastineau, *Sanofi*
The Covid-19 pandemic has created an unprecedented situation across the world, triggering new ways of working by industry and regulators. This enabled the first vaccines and therapeutics to be developed, authored, sized, and supplied in record times. This session will aim at sharing the lessons learned from this experience and exploring how this could be leveraged for addressing new pandemic situations as well as hopefully be adopted under more routine situations.		
13:00	Strategies for Rapid Development and Commercialization of MAb Therapies for COVID-19	Mónica Perea-Vélez, *GSK*
13:20	How to Accelerate the Supply of Vaccines to all Populations Worldwide - A Regulatory Perspective	Mic McGoldrick, *MSD*
13:40	How has Biomanufacturing Changed from a Supply Chain Integrity Standpoint Because of the Pandemic	James Fries, *Rx-360*
14:00	**Q&A; Discussion**	
Session 1	**Track B: Facilities**	**Moderator:** Yves Mayeresse, *GSK*
In the industry, the way to develop facilities has evolved a lot in the past years. In terms of aseptic processing, this session will focus on reviewing innovative fill and finish technology solutions. This journey will involve		

board thinking through ideation, concept design prototyping, and testing. Concerning multi-modal, flexible, and sustainable solutions the presentation will describe the demand existing for such kind of factory. Then the flexible factory will be explained with a specific focus on single-use equipment and all the associated sustainability and environmental burden. The value of digital will equally be elucidated in this context. Finally, a presentation will teach how to design multi-entities mRNA facilities. The diversity of RNA and product types of the formulation will be reviewed, and the delivery vehicles such as LNP (Lipid Nano Particles) will be discussed and declined in terms of facility requirement for mRNA production and associated inherent flexibility.		
13:00	Aseptic Processing – A Paradigm Shift	Austin Lock, *PM Group*
13:30	Solutions to Multi-Modal, Flexible, and Sustainability Facility Design	Stephen Judd & William Whitford, *DPS Group*
13:45	Designing Flexible and Multi-Entity RNA Production Facilities	Emily Heffernan, *DPS Group*
14:00	**Q&A; Discussion**	
Session 1	**Track C: Lyophilization – Process & Characterization**	**Moderator:** Julian Lenger, *Bayer*
In this session on process and characterization in freeze-drying, the audience will learn about a model-based product temperature and endpoint determination in primary drying, the power of an advanced process analytical technology approach for characterization and control of a lyophilization process as well as the process implications of using nested vials or vials in racks regarding heat transfer and overall process performance.		
13:00	Process Modeling and Process Analytical Technology for Primary Drying Design and Optimization	Alex Juckers, *TU Clausthal*
13:35	The Effect of Nesting and Neighboring Vials in Freeze-Drying	Wolfgang Friess, *LMU Munich*
14:00	**Q&A; Discussion**	
14:30	Poster Session & Exhibition	
Session 2	**Track A: Vaccine Platforms and Control Strategies**	**Moderator:** Sabine Hauk, *Leukocare*
Recent years showed us the need for a fast response to infectious disease outbreaks on a global scale, so we will present approaches that support the fast adaption of vaccines for new pathogens and control of the manufacture. The first talk combines two major topics of interest, the RNA vaccine platform, and the digitalization, of a patient-centric Quality by Digital Design (QbDD) framework for a disease-agnostic RNA platform. You have the chance to discuss our prerequisites for regulatory approval of such digital tools used for process and product quality control. In the next talk, you can learn about a platform for the development of affordable and effective vaccines to combat bacterial diseases. The third talk will present a review of emerging industry and standardization initiatives on vaccine manufacture and will introduce an integrated approach for single-use system integrity.		
14:40	Quality by Digital Design for RNA Vaccine and Therapeutic Production	Zoltán Kis, *The University of Sheffield*
15:00	Platform to Accelerate the Development of Vaccines Against Bacterial Pathogens	Anna Maria Colucci & Francesca Micoli, *GSK*
15:20	How Integrity Testing of Single-Use Systems in Vaccine Manufacturing Can Help to Secure the Fast and Reliable Availability of Vaccines During a Pandemic – and Beyond	Marc Hogreve, *Sartorius*

15:40	**Q&A; Discussion**	
Session 2	**Track B: Sustainability**	**Moderator:** Thierry Gastineau, *Sanofi*
Climate change is a major concern over the planet and the last Intergovernmental Panel on Climate Change (IPCC) 2022 report indicated that "Taking action now can secure our future". The industry has a key role to play in moving towards carbon neutral and zero emissions situations in a timely manner. The pharmaceutical biomanufacturing industry must develop sustainable solutions for manufacturing activities. This session will explore how to address this objective and what are the challenges to overcome.		
14:40	Collaboration, Standardization, and Innovation – Steppingstones to Net Zero in Biopharma	Barry McDermott, *PM Group* Anne Laure Brison, *Sartorius*
15:00	Sustainable Innovative Solutions for a New Agile Manufacturing facility	Estelle Doger & Pierre – Damien Martinet, *Sanofi*
15:20	Designing for Patients and the Planet: Sustainable Solutions for Pharmaceutical Products	Cédric Gysel, *Johnson & Johnson*
15:40	**Q&A; Discussion**	
Session 2	**Track C: Lyophilization Equipment**	**Moderator:** Thomas Beutler, *GEA Lyophil*
In our second lyophilization session today we will hear three presentations about new trends in freeze-drying equipment. First, Thomas de Beer will discuss the latest developments in continuous freeze-drying and to what extent this technology is now GMP compliant. Afterward, Andrea Sardella will talk to us about the state-of-the-art high-accuracy inspection of lyophilized products. Finally, Maik Guttzeit will explore a core issue around the quality of pharmaceutical lyophilization: the shelf temperature distribution. This is the last presentation of the session and will help us to understand the factors surrounding poor temperature distribution.		
14:40	GMP-Ready Continuous and Controlled Freeze-Drying	Thomas De Beer, *Ghent University* Jos Cover, *Rhea Vita*
15:00	Evolution of Vision Technologies for Contaminants Characterization: How to Improve the Detection Rate and Reduce False Reject in Lyophilized Products Inspection	Andrea Sardella, *Stevanato Group*
15:20	Shelf Temperature Mapping- Easy Test or Miracle?	Maik Guttzeit, *Bayer*
15:40	**Q&A; Discussion**	
16:10	Coffee Break, Poster Session & Exhibition	
Session 3	**Track A: Single-Use Systems**	**Moderator:** Elisabeth Vachette, *Sartorius*
Session description: Single-use systems have demonstrated their flexibility and their ability to answer to bioprocessing peak demand even in a pandemic situation. In this session, you will learn about new challenges and success stories when using Single-use systems for early development clinical material as well as for Cell and Gene Therapy, especially on the Extractable & Leachable risk assessment. Supply chain risk is of utmost importance for the global drug supply. In this session, a new supply risk that came out recently for sterilization will be discussed and can be mitigated with an alternative method using X-ray.		
16:40	Single-Use Bioprocess Systems Sterilization by X-Ray: Challenges, Interchangeability, and Flexibility Outcomes	Samuel Dorey, *Sartorius*
17:00	End-to-End Single-Use Manufacturing at Pilot Plant for Early Development Clinical Material	Agnieszka Onder, *Janssen*

17:20	Extractables and Leachable from Single-Use Systems and Their Assessment in Cell and Gene Therapy Applications	Armin Hauk, *Sartorius*
17:40	**Q&A; Discussion**	
Session 3	**Track B: Interest Group Vaccines**	**Moderator:** Michael De Felippis, *Eli Lilly*
Licensed vaccine products are a diverse product class that includes diverse types of molecular entities and in many cases contain multiple antigens in varying combinations. These characteristics require complicated lifecycle management plans to support product changes for multiple licenses in multiple jurisdictions while avoiding risks to product availability. This session will provide an overview of current concepts in vaccine lifecycle management, including a regulatory perspective from the FDA. The application of life cycle management principles as they were applied during the Covid-19 pandemic and the opportunities for more efficient lifecycle management described in ICH Q12 will also be discussed.		
16:40	Welcome from the Session Chairs	Andrew Chang, *Novo Nordisk* Michael De Felippis, *Eli Lilly*
16:45	Overview of PDA Vaccine Technical Report	Jane Halpern, *IAVI*
17:00	Vaccine Lifecycle Management: Regulatory Perspective	Robin Levis, *US FDA*
17:15	Lessons Learned from COVID-19 Pandemic on Vaccine Lifecycle Management	Jennifer Eck, *AstraZeneca*
17:30	Vaccine Case Studies: Identification of Established Conditions (Ecs) and Justification for Reporting Categories When Make Changes to the ECS	Thierry Gastineau, *Sanofi*
17:50	**Q&A & Panel Discussion**	
18:15	End of Conference Day 1 & Networking Event	

Wednesday, 21 September 2022

08:00 – 08:45	**Early Career Professionals - Morning Coffee Chat with the Old Schools** Meet our PDA veterans at the conference foyer and get firsthand information on how you can expand your network, boost your career, and participate in shaping the future of our industry!	Moderator: Cristiana Campa, GSK Julian Lenger, Bayer Dr. Klar, PDA Europe
09:00	Welcome Back from the Chairs & Summary Day 1	Cristiana Campa, *GSK* Raf De Dier, *Janssen*
Session 4	**Track A: Innovations in Formulation & Drug Product Manufacturing**	**Moderator:** Raf De Dier, *Janssen*
In recent years, the biomanufacturing field has witnessed a strong increase in the variety and complexity of compounds that are developed, as well as the processes needed to manufacture them. Related to these challenges, novel approaches and methodologies are required to support formulation development or manufacturing activities and ensure accelerated delivery to patients. In this session, several case studies will be presented that demonstrate how we can embrace and integrate innovations into our research and supply processes to be more efficient, reduce overall time and cost, as well as increase quality for the benefit of the patient.		

09:15	Quickly by Design: How New Methods Reshape the Selection and Formulation Development of Novel Therapeutic Proteins	Hristo Svilenov, *Ghent University*
09:35	Overcoming Challenges in Co-Formulation of Proteins with Contradicting Stability Profiles – EPO plus G-CSF	Dennis Krieg, *A. Menarini Research & Service Business*
09:55	Model Predictive Control for Automated Biologics Drug Product Manufacturing	Renata Pocitarenco & Marius Müller, *Janssen*
10:15	**Q&A; Discussion**	
Session 4	**Track B: ICH Upcoming Topics – Stability & Specifications**	**Moderator:** Cristiana Campa, *GSK*
Setting specifications and the establishment of an appropriate shelf-life is fundamental to supporting a Marketing Authorization Application. For this reason, and to reflect recent developments and challenges associated with these crucial elements, the revision of ICH Guidelines on Stability and Specifications has been prioritized by ICH and will start shortly. This session will reflect some highlights on key industry positions and examples related to these two topics, including, for instance, stability modeling for biologics and innovative approaches for specifications set.		
09:15	Using Stability Prior Knowledge From 'Like-Molecules' to Determine Shelf-Life	Andrew Lennard, *Amgen*
09:35	Accelerated Stability Study: Kinetic or Statistical Models?	Bernard Francq, *GSK*
09:55	Specifications Setting for Biopharmaceuticals in Accelerated Scenarios	Matt Popkin, *GSK*
10:15	**Q&A; Discussion**	
Session 4	**Track C: Quality Control Methods**	**Moderator:** Marta Antunes, *MSD*
Quality Control Methods are intended to demonstrate that manufactured product meets defined criteria of identity, quality, safety, purity, and potency. These should be suitable for their intended purpose and meet standards of accuracy, sensitivity, specificity, and reproducibility. As technology evolves, the quality control methods used in the manufacturing process progress leading to new approaches and methodologies. In this session, two innovative solutions to quality control methods will be presented demonstrating how we can move beyond the traditional approaches.		
09:15	Superior Methods for the Assessment of Particulate Matter Risks when Applying Single-Use Systems: Moving Beyond the Force-Fit of USP	Klaus Wormuth, *Sartorius*
09:45	Spectroscopic Tools to Address Quality Control Challenges in Pharma-Tech Industry	Marta Duchi & Rifat Kamarudheen, *Obviotec*
10:15	**Q&A; Discussion**	
10:45	Coffee Break, Poster Session & Exhibition	
Session 5	**Track A – mAb New Trends**	**Moderator:** Elisabeth Vachette, *Sartorius*
Efficiency gains are recurrent top management demands. In this session, you will learn how to optimize the capture step and how to maximize output with Process Intensification modalities.		
11:15	Strategic Modernization of a Commercial Monoclonal Antibody Process by the Introduction of a Next Generation Protein A Resin	Theresa Ahern, *Eli Lilly*

11:35	Process Intensification and Connected Processing for Robust, Cost-Effective, and Fast Manufacturing of Monoclonal Antibodies	Sanket Jadhav, *Sartorius*
11:55	**Q&A; Discussion**	
Session 5	**Track B: Comparability Strategies & Technical Transfers**	**Moderator:** Marta Antunes, *MSD*
Changes in the manufacturing process of biological products are frequent throughout their lifecycle. A product's Physic-chemical properties and in vitro / in vivo biological activity is required to be well characterized according to state-of-the-art methods demonstrating that there is no difference in the quality of the product before and after the changes that could adversely impact the safety and efficacy of a product. Thus, comparability strategies and technical transfers are of extreme importance, not being limited to strict process validation of the change but also extended to various quality criteria such as in-process controls, thorough analytical and biological characterization of the product, and stability data. In this session, we will learn about two case studies on the comparability and technical transfer of biologics products.		
11:15	Comparability – How Similar is Similar? Lessons Learnt from Experience with Biosimilars	Olga Rovira, *CEPI*
11:35	Using Quality by Design to Accelerate the Biopharmaceutical Product Development Lifecycle: A Case Study	Matthew Henry, *GSK*
11:55	**Q&A; Discussion**	
Session 5	**Track C: Lyophilization Product Considerations**	**Moderator:** Yves Mayeresse, *GSK*
In the first presentation, the freeze-concentration of the product will be analyzed. Indeed, as the water froze in a formulation, this one end-up with a percentage of unfrozen water in which all solute and active ingredients are concentrated. MAb formulation will be presented as a case study to show its influence on stability and to determine the maximum water content remaining during freezing. In a second presentation fogging effect during freeze-drying will be studied and theoretically explained. Fogging is this thin film creeping on the wall of vials a liquid state becoming solid over the lyophilization process and sometimes interfering with visual inspection equipment. A novel analytical method has been applied on the top of classical one to identify the root cause of the phenomenon.		
11:15	Protein Stability in the Freeze Concentrated Solution	Ivonne Stelzl, *Coriolis Pharma*
11:35	Investigation on Solution Creeping in Vials after Filling -A Case Study	Daniel Molnar, *Boehringer Ingelheim*
11:55	**Q&A; Discussion**	
12:25	Lunch Break, Poster Session & Exhibition	
13:10	**LIVE Guided Poster Walk** Engage with our Poster Presenters in our Exhibition Hall	
Closing Plenary	**Digitalization & Innovation**	**Moderator:** Sabine Hauck, *Leukocare*
Digitalization in biomanufacturing offers a better use of process data already available by connecting systems and applying machine learning. Process and product modeling are key tools in a digitalized world that cannot only improve efficiency but can also enhance sustainability. In this session, different concepts of the "Laboratory of the Future" will be discussed and a case study will be presented covering lab automation and a digital notebook. The regulatory perspective on model-based approaches in biomanufacturing will also be		

considered. Through a combination of lecture and interactive discussion, this session will demonstrate how sustainability and Quality Control of vaccines can come together to advance biomanufacturing innovation.		
13:40	Interactive Questionnaire	
13:50	Regulatory Perspective on Model-Based Approaches to Biomanufacturing	Wouter Hoogenboom, *CBG meb Netherlands*
14:15	Transformation to the Laboratory of the Future: Automation Technology, Digitalization, and Artificial Intelligence	Roman Mathaes & Joachim Schuster, *Lonza*
14:40	Coffee Break, Poster Session & Exhibition	
15:10	Sustainability in Quality Control of Vaccines: Applying the 3R's principle and implementing the 4th R.	Wim Van Molle, *Sciensano Belgium*
15:35	**Q&A & Final Panel Discussion**	**Moderators:** Sabine Hauck*, Leukocare* Michael De Felippis*, Eli Lilly*
16:15	**Chairs Conference Summary**	Cristiana Campa, *GSK* Raf De Dier, *Janssen*
16:25	**Closing & Farewell**	Falk Klar, *PDA Europe*
16:30	End of Conference	

The agenda is subject to change without notice, Speakers are invited pending confirmation.