2021 PDA BioManufacturing Conference

Biomanufacturing in a New Era

ONLINE

14-15 September 2021

Module I: Opening and Joint Plenary

Tuesday, 14 September 2021		**12:00-14:45 CEST**
12:00	Conference Opening	Falk Klar, *PDA Europe*
12:05	LIVE Welcome and Introduction from the Chairs	Cristiana Campa, GSK Vaccines Michael De Felippis, Eli Lilly & Company Raf De Dier, Janssen J&J Anthony Cannon, MSD
Session 1	**Joint Opening Plenary: Advancing Biomanufacturing in a New Era**	**Moderators:** Cristiana Campa, GSK Vaccines Raf De Dier, Janssen J&J
12:10	**Live Session Description** *This session will provide an update on CMC strategies to enable rapid and broad access to biopharmaceuticals, with perspectives provided from both Regulators and Industry. Dialogue in this space started a few years ago to address urgent medical needs with examples in the field of oncology treatments, vaccines to combat the Ebola outbreak and leading to a recently published draft EMA Acceleration Toolbox Guidance, which will be discussed in the session. The COVID-19 Pandemic has further triggered discussion on CMC acceleration enablers, considering development and lifecycle strategies, and EMA's perspective on the topic will be offered. Industry perspectives on innovative CMC strategies and technology innovation will complement the Health Agencies' presentations, with a final panel discussion and live Q&A.*	
12:15	Opening Keynote: Reinventing Pharma through Digital and Analytics – Where are we Today?	Alvaro Carpintero, McKinsey

12:40	EMA's Perspective on the SARS-CoV-2 Pandemic: Regulatory Procedures, Quality Flexibilities, and Future Directions	Ragini Shivji, EMA
13:00	The EMA Acceleration Toolkit	Mats Welin, Swedish Medicines Agency
13:20	Short Break	
13:30	The Annex 1 Revision and the Impact on Biomanufacturing Processes	Yves Mayeresse, GSK Jörg Lümkemann, Roche
13:45	Accelerated End-to-End Process Development for Monoclonal Antibodies	Matthieu Stettler, LONZA
14:00	**Live Q&A, Discussion**	
14:45	**Break & Exhibition**	

Module II: Analytical Technologies & Strategies and Innovations in BioManufacturing

Session 2	**Track A** **Analytical Technologies & Strategies**	**Track B** **Innovations in BioManufacturing**
	Moderators: Mark van Ooij, Janssen J&J Arnaud Paris, BioMeriéux	**Moderators:** Richard Denk, SKAN Glen Bolton, Amgen
15:30	**Live Session Description** *Regulatory thinking is constantly evolving to increase product understanding during process development, and process changes. A relatively new guideline: ICH Q14, provides guidance on improving analytical understanding/ selection of tools and has examples included. The focus of this session is to discuss the impact of ICH14 from different perspectives, ie both regulatory and industry, and different products. In addition; the added value of ICH Q14 to the current*	**Live Session Description** *The Bio Manufacturing Sector of the Pharmaceutical Industry is one of the most innovative global industries. The Track Innovation in Bio Manufacturing will focus on Facility Technology and Manufacturing strategies for the next Generation Bioprocessing which includes further presentations about Digital Twin for Process Development to get medicines faster to the market, considerations for upstream and downstream process intensification, next generation bioprocessing facilities, and Model*

	guidelines in existence will be discussed, and where it influences the design of analytical strategies for a range of different products.	*Based Process Space Identification as another innovative talk. At the end of the track we will have an interactive Q&A session.*
15:35	15:35 – 15:55 Regulatory Perspective on ICHQ14 Martijn van der Plas, Dutch Medicines Evaluation Board	The Digital Twin: Drug Substance and Drug Product Journey Sandrine Dessoy & Antonio Gaetano Cardillo, GSK
15:50	15:55 – 16:10 How can ICHQ14 support development and change management of analytical procedures? Christof Finkler, F-Hoffmann La Roche on behalf of EFPIA	Accelerating Process Development with an Insilico Twin of Process Platform Moritz von Stosch, DataHow
16:05	16:10 – 16:20 Implementing mAb Process Improvements Using an Analytical Comparability Approach Megan Barron, MSD	Model-Based Process Space Identification Steven Sachio, Imperial College London
16:20	**Short Break**	
16:30	Adaptation of the Analytical Control Strategy of a Commercial Vaccine Using the Principles of QbD Jean-Francois Dierick, GSK Vaccines	Requirements, Approaches and Regulatory Considerations for Process Intensification in Upstream and Downstream Processing Ganesh Kumar, Sartorius Stedim Himanshu Gadgil, Enzene Biosciences
16:45	Development of New Ph. Eur. Horizontal Standards as Multi-Product Analytical Procedures for Monoclonal Antibody Analysis Mihaela Buda, EDQM	**Live Q&A, Discussion**

17:05	**Live Q&A, Discussion**	
17:40	**End of Conference Day 1 and IG Meeting**	

Live Interactive Interest Group Meeting

17:45 – 19:15 CEST	**LIVE Vaccines Interest Group Meeting – facilitated via Zoom** *The Vaccines Interest Group (VIG) has been working on the Technical Report "Strategies for Vaccines and Lifecycle Management" which: 1) presents considerations for establishing robust control strategies from process development that support a robust lifecycle management; 2) highlights the benefits of comparability assessments could bring when seeking to accelerate during development or manufacturing different initiatives intended to bring vaccines to patients; and 3) discusses non-regulatory (from a technical, validation and quality aspects) and regulatory considerations, bringing to the reader's consideration the value ICH Q12 could bring to development as well as lifecycle management.* *In addition, next activities for VIG will be presented seeking to engage more members of the vaccines community in Europe to participate.* *Stability modeling is a key enabler of accelerated development, allowing (i) prediction of shelf life based on accelerated stability studies, and (ii) understanding of behavior during shipment or manipulation; nonetheless, stability modelling strategies are not fully exploited for vaccines, likely because of their complexity and diversity, and for the limited availability of dedicated Guidelines or illustrative case studies. In this session, an overview will be initially provided on some recent cross- company discussions related to stability modeling for vaccines; the subsequent panel discussion will allow participants to engage with key experts from Industry and Health Authorities, share learnings and reflect on future directions related to vaccines stability strategies.*	
17:45	Introduction to the Interest Group and Recent Activities	Sabrina Restrepo, MSD Jane Halpern, Consultant
17:55	Updates to the Technical Report	Sabrina Restrepo, MSD Jane Halpern, Consultant
18:10	Q&A for Immediate Questions	
18:20	Summary on the Use of Stability Modeling to Support Accelerated Vaccine Development & Supply	Didier Clénet, Sanofi Cristiana Campa, GSK Vaccines

18:30	Q&A and Final Panel Discussion • Modelling approaches – Choosing an approach for different vaccine platforms • Considerations on Regulatory acceptance • How to choose the right attributes to monitor?	**Moderator:** Cristiana Campa, GSK Vaccines **Panelists:** Mats Welin, Swedish Medicines Agency Didier Clénet, Sanofi Julia O'Neill, Moderna
19:15	End of IG Meeting and Farewell	Sabrina Restrepo, MSD Jane Halpern, Consultant Cristiana Campa, GSK Vaccines

Wednesday, 15 September 2021

9:00 CEST Conference Platform Opens: Enjoy the Exhibition & Poster Session

Morning Session: Scientific Poster Lounge

10:00 – 11:30 CEST	**Live Interactive Poster Lounge** Engage in a live Q&A opportunity with our Poster Presenters in a separate video chat room! • Implementing X-Ray for Single Use Systems Sterilization - *Samuel Dorey, Sartorius Stedim* • 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 Stedim*	**Moderators:** Lucia Ceresa, Charles River Julian Gitter, Bayer
11:30	**Break & Virtual Exhibition**	

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Module III: Control Strategies and Supply Chain and Facilities

Session 3	Track A Control Strategies	Track B Supply Chain and Facilities
	Moderators: Walid El Azab, STERIS Lucia Ceresa, Charles River	**Moderators:** Elisabeth Vachette, Sartorius Stedim Sebastian Teitz, Asahi Kasei
12:00	**Live Session Description** *The development of the control strategy requires an understanding of the process and the process variable that may impact the Critical Quality Attributes derived from the quality target profile product as per ICHQ8. Therefore, the manufacturer tends to identify process variabilities or contamination sources during development and gains process understanding through the product lifecycle to define the controls that would prevent process failure. We will learn from top companies their approach to identifying suitable control strategies for product process development, environmental monitoring, and analytical methods during this session.*	**Live Session Description** *Since the COVID pandemic, having a smooth-running supply chain & getting facilities ready to produce in a timely manner, have been very high concerns. Biomanufacturers deployed a huge amount of effort to bring innovative solutions allowing to deliver vaccines to the patients in an unprecedented timeline. In this session, you will hear testimonials and great solutions to overcome critical raw material shortages, build new facilities, rethink the complete vaccines manufacturing process, and bring more efficiency with advanced PAT tools.*
12:05	Contamination Control Strategy in the Pharmaceutical Industry - Impact on Environmental Monitoring Program Benoît Ramond, Sanofi	Shortages of Critical Raw Materials and Managing Changes and Substitutions Frances Sexton, Eli Lilly & Company
12:20	Defining Limits for Analytical Method Outputs as Part of a Risk-Based Control System Gerald Gellermann, Novartis Pharma	Prefabricated Solutions – De-Risking your Facility Peter Makowenskyj, G-CON Manufacturing
12:35	Detection and Minimization of Risks from Particulate Matter during BioManufacturing using Single-Use Systems Klaus Wormuth, Sartorius Stedim	Evolutive Vaccines Facilities: the Answer to Vaccine Manufacturing New Paradigms Bruno Tricoire, Sanofi

12:50	Quality by Design as Driving Principle to Enable a Rational and Accelerated Product and Process Development Pathway Daniela Stranges, GSK Vaccines	Development of Advanced Process Analytical Technology (PAT) Tools for Live Virus Vaccine Manufacturing Malini Mukherjee and Sijia Yi, MSD
13:05	**Live Q&A, Discussion**	**Live Q&A, Discussion**
13:45	**Break & Virtual Exhibition**	
14:25	**Passport Raffle – don't miss the announcement of the winner of an Apex Action Camera**	

Module IV: Drug Product & Stability Predictions and Tech Transfer – Regulatory and Technical Considerations

Session 4	**Track A** **Drug Product & Stability Predictions**	**Track B** **Tech Transfer – Regulatory and Technical Considerations**
	Moderators Diane Wilkinson, AstraZeneca Susanne Jörg, Consultant	**Moderators** Marta Antunes, MSD Jonny Parsons, Amgen
14:30	**Live Session Description** *There is a critical need for us to continue to explore the application of science risk-based approaches for CMC data generation, through development and lifecycle management, particularly for accelerated programs for unmet medical needs, or pandemic situations. CMC is generally on the critical path in these programs and therefore this session explores several approaches for thinking differently about how we can apply various techniques to model or predict how CMC data will perform, to help prevent delays in getting and sustaining delivery of vital medicines to patients. The areas covered in the session include accelerated predictive stability and stability modelling,*	**Live Session Description** *The registration and maintenance of products worldwide is often cumbersome and unpredictably lengthy, leading to delays in access to patients, especially in emerging countries. Discussion is required to improve the situation, fostering regulatory convergence and streamlining registration procedures through reliance on other experienced regulators or international agencies. Leveraging platform knowledge and share knowledge across industry and health authority is key to accelerate the registration and commercialization of innovative technologies.*

	along with in vivo stability. We will also explore the use of patient centric specifications to help enable and accelerate product supply. We hope you will join several Industry experts in their areas, share latest thinking and for discussion of how we may move forward to apply and gain approval for the use of these approaches.	
14:35	Accelerated Predictive Stability for Biologicals and Vaccines Didier Clénet, Sanofi	Much Needed Convergence of Post Approval Change Guidelines Worldwide Mic McGoldrick, MSD
14:50	Patient Centric Specifications – Enabling and Accelerating Supply Julia O'Neill, Moderna	Leveraging Platform Knowledge to Streamline Commercialization and Enhance Productivity Colette Carmody Culhane and Cillian McCabe, Eli Lilly & Company
15:05	Latest Innovations in Biologic Stability Modelling Using Bayesian Stats and AI Deep Learning Andrew Lennard, Amgen	Improving Process Robustness at Launch and in Early Commercial Supply Through Effective Risk Assessment Erin O'Dea Wilson, GSK
15:20	In-Vivo Stability of Therapeutic Proteins Joachim Schuster and Roman Mathaes, LONZA	The Importance of Knowledge Sharing: Tools and Best Practices Mirko Gabriele, Thermo Fisher Scientific
15:35	**Live Q&A, Discussion**	**Live Q&A, Discussion**
16:10	**Break & Virtual Exhibition**	

Module V: Closing Plenary: Learnings from the Pandemic and Looking Towards the Future

Session 5	**Closing Plenary: Learnings from the Pandemic and Looking Towards the Future**	**Moderators:** Michael De Felippis, Eli Lilly & Company Cristiana Campa, GSK Vaccines
16:40	**Live Session Description**	

	The COVID-19 outbreak has challenged traditional approaches and timelines for development and manufacturing of vaccines and therapeutics, fostering the use of innovative technologies and CMC strategies. In this session, an overview of CMC and regulatory learnings from this pandemic will be described, with speakers from CEPI and cross- industry task forces. A panel discussion involving thought leaders from EMA, CEPI and Industry will provide further perspectives on how to apply the learnings from this experience to speed future biopharmaceutical innovation and to ensure better preparation for other potential public health emergencies.	
16:45	Lessons Learned on the Impact of Manufacturing Platforms on Speed Scale and Access	Ingrid Kroman, CEPI
17:00	Timely Global Access to Vaccines: Some First Learnings from the COVID-19 Pandemic	Thierry Gastineau, Sanofi Pasteur
17:15	Learnings from the PDA COVID Task Force	Jim Polarine, Steris
17:30	**Live Closing Panel Discussion**	Cristiana Campa, GSK Vaccines Michael De Felippis, Eli Lilly & Company Jim Polarine, Steris Diane Wilkinson, AstraZeneca Thierry Gastineau, Sanofi Pasteur Ingrid Kroman, CEPI Ragini Shivji, EMA
18:15	**Live Conference Summaries by the Chairs**	Cristiana Campa, GSK Vaccines Michael De Felippis, Eli Lilly & Company Raf De Dier, Janssen J&J Anthony Cannon, MSD
18:30	**Closing Remarks & Farewell**	Falk Klar, PDA Europe

Agenda is subject to change without notice, all times are noted in CEST