WCBP 2020 On Demand Selected Sessions

Tuesday, January 28, 2020

Presentations with red outline have restrictions on recording noted.

TIME	TITLE	SPEAKERS
8:00 - 8:15	CASSS Welcome	Nadine Ritter, *Global Biotech Experts, LLC, Germantown, MD USA*
8:15 – 8:30	9th Annual William Hancock Award – Sponsored by CASSS	Wassim Nashabeh, *Genentech, a Member of the Roche Group, South San Francisco, CA USA*
8:30 - 8:45	WCBP 2020 Introduction	Jamie Moore, *Genentech, a Member of the Roche Group, South San Francisco, CA USA*
8:45 - 10:15	US Food and Drug Administration Panel Discussion	**Moderator**: Joseph Kutza, *AstraZeneca, Gaithersburg, MD USA* **Session Chair**: Jamie Moore, *Genentech, a Member of the Roche Group, South San Francisco, CA USA* **Panel Members**: Marion Gruber, *CBER, FDA* Sau (Larry) Lee, *CDER, FDA* Zhihao (Peter) Qiu, *CDER, FDA* Zenobia Taraporewala, *CBER, FDA* Joel Welch, *CDER, FDA*
10:15 – 10:45 **Break**		
Plenary Session An Antibody, a Vaccine and a Blood Product Walk into a Bar…Challenges and Solutions in the Development of Novel Modalities – Grand Ballroom		
10:45 - 10:50	Introduction	**Session Chairs**: John (JR) Dobbins, *Eli Lilly and Company, Indianapolis, IN USA* and Marjorie Shapiro, *CDER, FDA, Silver Spring, MD USA*
10:50 - 11:15	Robust Bispecific Process Development and Commercial Manufacturing Platform: Overcoming Process Development and Characterization Challenges Leading to Insights for Increasing Understanding and Control of Bispecific Production	Pedro Alfonso, *Janssen Pharmaceutical R&D, LLC, Malvern, PA USA* (AUDIO ONLY RECORDING)
11:15 - 11:40	The Good and the Not-So-Good When It Comes to Accelerated Development and Registration of a Vaccine	Kimberly Duffy and Kimberly Hassis, *Merck & Co., West Point, PA USA*
11:40 - 12:05	Development of rFVIIIFc-VWF-XTEN (BIVV001): Novel FVIII Based Fusion Protein for the Treatment of Hemophilia A	Ekta Seth Chhabra, *Bioverativ, Inc., Waltham, MA USA* (LIVE STREAM ONLY; WILL NOT BE RECORDED)

12:05 - 12:20	Panel discussion	All panelists
12:20 – 14:00 **Break**		
14:00 – 15:35 **Parallel Sessions**		
Parallel Session Analytical Method Modernization for Biologics and Vaccines – Mitigating the Risks Associated with the Introduction of Advanced Technologies – Grand Ballroom		
14:00 – 14:05	Introduction	**Session Chairs:** Nomalie Jaya, *Seattle Genetics, Inc., Bothell, WA USA* and Sonya Kennedy-Gabb, *GlaxoSmithKline, Collegeville, PA USA*
14:05 – 14:30	Multi-attribute Analytical Method Advancing in Viral Release Testing: "All-In-One" Identity, Infectivity and Transgene Expression Quantification for Virus-vectored Vaccines	Marc Fiorucci, *GlaxoSmithKline Vaccines, Rixensart, Belgium*
14:30 - 14:55	From Profile-based Assays to Attribute-focused Analysis: A Case Study of Analytical Method Modernization	Da Ren, *Amgen Inc., Thousand Oaks, CA USA* (LIVE STREAM AUDIO-ONLY; NOT RECORDED)
14:55 - 15:20	A Path Forward: Establishing New NMR Analytical Protocols to Assure the Quality of Biologics	David Keire, *CDER, FDA, St. Louis, MO USA*
15:20 - 15:35	Panel Discussion - Questions and Answers	All panelists
Parallel Session Connecting CQAs to Process Parameters and Materials – District		
14:00 – 14:05	Introduction	**Session Chairs:** Valerie Tsang, *Biogen* and Li Zang, *AbbVie Bioresearch Center, Inc.*
14:05 – 14:30	Leveraging Material Attribute Knowledge as the Foundation for a Predict and Prevent Raw Material Control Strategy	Susan Burke, *Amgen Inc., Thousand Oaks, CA USA*
14:30 – 14:55	Holistic Control Strategy – From Molecular Design to Combination Product	Chandra Webb, *Pfizer, Inc., Andover, MA USA*
14:55 – 15:20	Understanding the Critical Quality Attributes of a mAb and an ADC and Their Relationship to Reduction and Conjugation Parameters	Hillary Schuessler, *GlaxoSmithKline, King of Prussia, PA USA* (THIS PRESENTATION WILL NOT BE STREAMED OR RECORDED.)
15:20 – 15:35	Panel Discussion - Questions and Answers	All panelists
15:35 – 16:00 **Break**		
16:00 – 17:15 **Workshop Session**		

Plen-shop Current Regulatory Trends and Hot Topics Around the Globe: Part One – Grand Ballroom		
16:00 – 17:15	Current Regulatory Trends and Hot Topics Around the Globe: Part One	Elkiane Rama, *ANVISA-Brazilian National Health Surveillance Agency, Brazil;* Anthony Ridgway, *Health Canada, Ottawa, ON Canada*; Patricia Aprea, *ANMAT-National Administration of Medicines, Food and Medical Technology, Argentina*; Steffen Gross, *Paul-Ehrlich-Institut, Germany*
17:15 - 17:30 **Break**		
Plen-shop Perspectives on Q12 Lifecycle Management and Established Conditions / Approved Matters – Grand Ballroom		
17:30 – 18:45	Perspectives on Q12 Lifecycle Management and Established Conditions / Approved Matters	Jennifer Eck, *AstraZeneca, Clarksburg, MD USA;* Minh Luu, *Genentech, a Member of the Roche Group, South San Francisco, CA USA;* Chikako Torigoe, *CBER, FDA, Silver Spring, MD USA;* Qing (Joanna) Zhou, *CDER, FDA, Silver Spring, MD USA*
End of Day One		

Wednesday, January 29, 2020

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TIME	TITLE	SPEAKERS
08:30 – 09:15	Keynote Fireside Chat – Grand Ballroom	**Moderator**: Nadine Ritter, *Global Biotech Experts, LLC, Germantown, MD USA* **Keynote**: Amy P. Abernethy, M.D., Ph.D., *Principal Deputy Commissioner, Food and Drugs, Silver Spring, MD USA*
09:15 – 09:30 **Break**		
09:30 – 11:05 **Parallel Sessions**		
Parallel Session Industry and Regulatory Perspectives on Challenges and Opportunities of Cell & Gene Therapy Product Development– Grand Ballroom		
09:30 – 09:35	Introduction	**Session Chairs**: Ingrid Markovic, *Genentech, a Member of the Roche Group, Washington, DC USA* and Francis Poulin, *Sanofi, Framingham, MA USA*
09:35 – 10:00	ATMPs – New Concepts and the Existing Regulatory Framework	Ilona Reischl, *BASG-Federal Office for Safety in Health Care, Vienna, Austria*
10:00 – 10:25	Specifications for Cell & Gene Therapy Products: Maximizing Patient Access to a Safe & Effective Quality Product	Neil Haig, *Juno Therapeutics, A Bristol-Myers Squibb Company, Seattle, WA USA* (LIVE STREAM ONLY; WILL NOT BE RECORDED)
10:25 – 10:50	Adaptive, Flexible or Novel: Regulatory Frameworks for Advanced Therapies – Case Study: Individualized Neoantigen-specific Therapy (iNeST)	Kathleen Francissen, *Genentech, a Member of the Roche Group, South San Francisco, CA USA* (LIVE STREAM and AUDIO ONLY RECORDING)
10:50 – 11:05	Panel Discussion - Questions and Answers	All speakers
Parallel Session Connecting Critical Quality Product Attributes to Patients' Outcomes – District		
09:30 – 09:35	Introduction	**Session Chairs**: Guoying Jiang, *Genentech, a Member of the Roche Group, South San Francisco CA* and Wayne Kelley, *GlaxoSmithKline, King of Prussia, PA USA*
09:35 – 10:00	Considering Impurity Specifications in the Context of Immunogenicity Risk	Daniela Verthelyi, *CDER, FDA, Silver Spring, MD USA*

10:00 – 10:25	Product Understanding: Connecting the Dots	Claire Davies, *Sanofi, Framingham, MA USA*
10:25 – 10:50	Establishing Patient-centric Specifications by Connecting Product Quality and Clinical Outcomes	Richard Beardsley, *Genentech, a Member of the Roche Group, South San Francisco, CA USA* (LIVE STREAM ONLY; WILL NOT BE RECORDED)
10:50 – 11:05	Panel Discussion - Questions and Answers	All speakers
11:05 – 11:30 **Break**		
Plen-shop Current Regulatory Trends and Hot Topics Around the Globe: Part Two – Grand Ballroom		
11:30 – 12:45	Current Regulatory Trends and Hot Topics Around the Globe: Part Two	Esra'a abedelrahman Alzubi, *JFDA-Jordan Food and Drug Administration, Jordan*; Eric Karikari-Boateng and Patrick Owusu-Danso, *Food and Drugs Authority, Ghana*; Julio Rolón, *National Directorate of Health Surveillance, Ministry of Public Health and Social Welfare, Paraguay*; Susan Zavala Coloma, *DIGEMID-General Directorate of Medicines, Supplies and Drugs, Peru*; Claudia Saidman, *ANMAT-National Administration of Medicines, Food and Medical Technology, Argentina*
12:45 – 14:30 **Break**		
14:30 – 16:05 **Parallel Sessions**		
Parallel Session Putting Prior Knowledge to Immediate Use: Knowledge Management and Digital Tools to Accelerate Development – Grand Ballroom		
14:30 – 14:35	Introduction	**Session Chairs**: Shawn Novick and Stefanie Pluschkell, *Pfizer, Inc., Groton, CT USA*
14:35 – 15:00	Traversing the Pyramid: Data > Information > Knowledge > Wisdom	Richa Sarin, *Biogen, Cambridge, MA USA*
15:00 – 15:25	Been There, Done That: Applying Prior Knowledge in Process and Method Validation	Melody Trexler Schmidt, *Genentech, a Member of the Roche Group, South San Francisco, CA USA* (LIVE STREAM ONLY; WILL NOT BE RECORDED)
15:25 – 15:50	Leveraging Prior Knowledge for Marketing Approval Filings in Accelerated Settings	Athena Nagi, *Merck & Co., Inc., West Point, PA USA*
15:50 – 16:05	Panel Discussion - Questions and Answers	All speakers

Parallel Session Factory of the Future: Considerations for Flexible Adaptive Manufacturing – District Room		
14:30 – 14:35	Introduction	**Session Chairs**: Kevin King, *Pfizer, Inc., Chesterfield, MO USA* and A. Graham Tulloch, *Janssen Pharmaceutical R&D, LLC, Malvern, PA USA*
14:30 – 15:00	On Application of Multi-scale Modelling for Facility Simulation and Process Control Strategy: Moving from Reactive to Proactive Decision Making	Deenesh Kavi Babi, *Novo Nordisk A/S, Kalundborg, Denmark* (LIVE STREAM AUDIO-ONLY; WILL NOT BE RECORDED)
15:00 – 15:25	Future BioProcess in Two Steps – Bioreactor and Integrated Recovery & Purification	Ping Huang, *AbbVie, Inc., Redwood City, CA USA* (LIVE STREAM AUDIO-ONLY RECORDING) Changed as of 1/29/2020.
15:25 – 15:50	Development of an Integrated Manufacturing Process: The iSKID™	Michael Jankowski, *Pfizer, Inc., Chesterfield, MO USA*
15:50 – 16:05	Panel Discussion - Questions and Answers	All Speakers
16:05 – 16:30 **Break**		
16:30 – 17:45 **Workshop Session**		
Plen-shop Strategies for Setting Patient-centric Commercial Specifications for Biotherapeutic Proteins – Grand Ballroom		
16:30 – 17:45	Strategies for Setting Patient-centric Commercial Specifications for Biotherapeutic Proteins	John Dobbins, *Eli Lilly and Company, Indianapolis, IN USA;* Meg Ruesch, *Pfizer, Inc., Andover, MA USA;* John Stults, *Genentech, a Member of the Roche Group, South San Francisco, CA USA;* Mats Welin, *Medical Products Agency (MPA), Uppsala, Sweden* (LIVE STREAM and AUDIO ONLY RECORDING)
End of Day Two		

Thursday, January 30, 2020

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08:45 – 09:00	Acknowledgments – Grand Ballroom	Jamie Moore, *Genentech, a Member of the Roche Group, South San Francisco, CA USA*
Plenary 8 Solutions to Improve Global Access to Healthcare Through Transformative Technologies – Grand Ballroom		
Session Chairs: Nina Cauchon, *Amgen Inc.* and Robert Sitrin, *PATH*		
09:00 – 09:25	Commoditizing Manufacturing of Vaccines and Biopharmaceuticals for Global Health	Christopher Love, *MIT, Cambridge, MA USA* (LIVE STREAM ONLY; WILL NOT BE RECORDED)
09:25 – 09:50	CMC at the Bill & Melinda Gates Medical Research Institute: Cost to Serve Drives Manufacturing and Supply	Jorg Thommes, *Bill & Melinda Gates Medical Research Institute, Cambridge, MA USA* (LIVE STREAM ONLY; WILL NOT BE RECORDED)
09:50 – 10:15	Development of MIMIX Smart Release Patch Vaccines to Improve Compliance and Global Access	Michael Schrader, *Vaxess Technologies, Inc., Cambridge, MA USA*
10:15 – 10:30	Panel Discussion – Questions and Answers	All Speakers
10:30 – 11:00 **Break**		
Plen-shop Implementation of the BioPhorum Technology Roadmap – Grand Ballroom		
11:00 – 12:15	Implementation of the BioPhorum Technology Roadmap	Isabelle LeQueux, *BioPhorum Operations Group, London, United Kingdom*
12:15 – 14:00 **Break**		
Standard Workshop Long-term Care of Products: How to Develop a Sustainable Strategy for Post-approval Changes – Grand Ballroom		
14:00 – 15:15	Long-term Care of Products: How to Develop a Sustainable Strategy for Post-approval Changes	Arulvathani Arudchandran, *CDER, FDA*; Jennifer Bridgewater, *CBER, FDA*; Roman Drews, *Daiichi Sankyo Inc.*; Mic McGoldrick, *Merck & Co., Inc.*
15:15 – 15:45 **Break**		
Plenary 9 Rapid Analytics to Accelerate Process Development and Enable Real-time Release Test – Grand Ballroom		

15:45 – 15:50	Introduction	**Session Chairs**: Ping Hu, *Janssen Pharmaceutical R&D, LLC, Malvern, PA USA* and Anthony Leone, *Bristol-Myers Squibb Company, Pennington, NJ USA*
15:50 – 16:15	Real-time Product Quality Assessment for Large Molecules Using Process Analytical Technologies	Bhumit Patel, *Merck & Co., Inc., Kenilworth, NJ USA* (LIVE STREAM; AUDIO-ONLY RECORDING)
16:15 – 16:40	Rapid, Accurate and Precise Cell-based Potency Assays	Arturo Orjalo, *Genentech, a Member of the Roche Group, South San Francisco, CA USA* (LIVE STREAM; AUDIO-ONLY RECORDING)
16:40 – 17:05	The Use of Label Free Raman Spectroscopy for Monitoring Manufacturing Performance and Product Quality	Jeremy Springall, *AstraZeneca, Gaithersburg, MD USA*
17:05 – 17:20	Panel Discussion - Questions and Answers	All Speakers
17:20 – 17:30	**Closing Remarks & Invitation to WCBP 2021**	Julia Edwards, *Genentech, a Member of the Roche Group, South San Francisco, CA USA*