17th Oct 2022

08:30-12:00	**EFPIA Biomanufacturing Working Group Satellite Session** *Burgh Ballroom* Session Chairs: Karoline Bechtold-Peters, *Novartis Pharma AG,* Helen Newton, *MSD,* and Fionnuala O'Driscoll, *Eli Lilly Kinsale Limited* 08:30-08:45 **Welcome & Introduction to the EFPIA Manufacturing and Quality Expert Group (MQEG) - Biomanufacturing Satellite Session** Markus Goese *F. Hoffmann-La Roche Ltd, Basel, BS, Switzerland* Session Speakers - Concept Paper 2022 Updates: 08:45-09:00 **Industry Perspective on Polysorbate Degradation and Control Strategies for Biopharmaceutical Products** Klaus Wüchner *Janssen Pharmaceutical R&D, LLC, Schaffhausen, Switzerland* 09:00-09:15 **Establishing a Platform Master File Approach for Human Medicinal Products in the EU/EEA** Mihai Bilanin *GSK, Wavre, Belgium. EFPIA, Brussels, Belgium. Vaccines Europe, Brussels, Belgium* Session Speakers - Conversion of IV to SubQ Application Scientific Session: 10:15-10:30 **Subcutaneous Administration of Biotherapeutics: An Overview of Current Challenges and Opportunities** Beate Bittner *F. Hoffmann-La Roche, Basel, Switzerland* 10:30-10:45 **Immunogenicity or Not of Biologics in Subcutaneous Space** Sathy Balu-Iyer *SUNY - University at Buffalo, Buffalo, NY, USA* 10:45-11:00 **Modelling of Subcutaneous Injection & Bioavailability to Bridge IV/SubQ** Joel Gresham, Max Dixon *Crux Product Design, Bristol, United Kingdom* 11:00-11:15 **SubQ Bioavailability Considerations** Manuel Sanchez-Felix	09:15-09:45 **Panel Discussion - Questions and Answers** *Burgh Ballroom* 09:45-10:15 **Networking Break** *The Bar / Lobby* 11:30-12:00 **Panel Discussion - Questions and Answers** Burgh Ballroom Additional Panel Members: Katrin Buss, *BfArM-Federal Institute for Drugs and Medical Devices, Germany* Karoline Bechtold-Peters, *Novartis Pharma AG, Switzerland*

	Novartis Pharma AG, Switzerland 11:15-11:30 **CMC Aspects When Switching from IV to SubQ Formulations** Christian Mayer *AGES MEA, Austria*	
12:15-12:30	**Concluding Remarks**	
12:30-13:45	**Networking Lunch** *The Bar / Lobby*	
13:45-14:00	**CASSS Welcome and Introduction / Welcome to the 16th European CMC Strategy Forum** *Burgh Ballroom* Speakers: Kathy Lee, *Genentech, a Member of the Roche Group*, United States and Tara Sanderson, *UCB Pharma Ltd., United Kingdom*	
14:00-15:45	**M4Q and Digital Regulatory Assessment** *Burgh Ballroom* Session Chairs: Richard Keane, *Biogen Idec Limited,* Thomas Stangler, *Novartis Pharma AG,* and Diane Wilkinson, *AstraZeneca* Session Speakers: 14:05-14:30 **EMA Perspectives on ICH M4Q(R2) and Digital Regulatory Assessments** Klara Tiitso *EMA-European Medicines Agency, Netherlands* 14:30-14:55 **FDA Perspective on Opportunities for Modernization of Regulatory Submissions** Ingrid Markovic *CBER, FDA, United States* 14:55-15:20 **M4Q ICH Current Status and Vision from Industry** Sarah Pope Miksinski *AstraZeneca, United States* 15:20-15:45 **The Power of Data Exchange CMC Interoperability and a Cloud-based Ecosystem** Michael Abernathy *Amgen Inc., Thousand Oaks, CA, USA. Accumulus Synergy, Burlingame, CA, USA*	15:45-16:15 **Networking Break** *The Bar / Lobby* 16:15-17:30 **Panel Discussion - Questions and Answers** *Burgh Ballroom* Additional Panel Member: Laurent Lefebvre, *Novartis Pharma AG, Switzerland*
17:30-19:30	**Welcome Back Reception** *Sint Donaas*	

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09:00-10:45	**New Technologies for Analytical Control - Multi-attribute Methodology, HCP-MS, etc.** *Burgh Ballroom* Session Chairs: Mihaela Buda, *EDQM-Council of Europe*, Joan Malmstrøm, *Novo Nordisk A/S*, and Heli Suila, *Finnish Medicines Agency (FIMEA)* Session Speakers: 09:05-09:30 **Regulatory Considerations for the Application of Multi Attribute Method by Mass Spectrometry for Qc Release and Stability Testing of Biopharmaceuticals** Annick Gervais *UCB, Braine l'Alleud, Belgium. [2]EFPIA, Brussels, Belgium.* 09:30-09:55 **A Status Report from the MAM Implementation Phase** Alexander Buettner *Roche, Penzberg, Germany* 09:55-10:20 **A Roadmap to Get Host Cell Protein Analysis by Mass Spectrometry in a GMP Environment** Cyrille Chéry *UCB, Braine-l'Alleud, Belgium* 10:20-10:45 **Novel HCP Analysis and Characterisation Tools Provide Freedom of Operation for Efficient Process Development** Brian Kåre Kristensen, *Novo Nordisk A/S, Måløv, Denmark*	10:45-11:15 **Networking Break** *The Bar / Lobby* 11:15-12:30 **Panel Discussion - Questions and Answers** *Burgh Ballroom* Additional Panel Members: Margareta Ramström, *Swedish Medical Products Agency, Sweden* Martiijn van der Plas, *MEB-Medicines Evaluation Board, Netherlands*
12:30-13:45	**Networking Lunch** *The Bar / Lobby*	
13:45-15:30	**The Acceptance of Modelling Approaches** *Burgh Ballroom* Session Chairs: Michael Abernathy, *Amgen Inc.*, Seán Barry, *HPRA-Health Products Regulatory Authority*, and Lionel Randon, *Ares Trading S.A., An affiliate of Merck Serono S.A.* Session Speakers: 13:50-14:15 **Regulatory Considerations for Modelling as a Tool for Process Understanding and Control** Matthew Popkin *GSK plc., United Kingdom* 14:15-14:40	15:30-16:00 **Networking Break** *The Bar / Lobby* 16:00-17:15 **Panel Discussion - Questions and Answers** *Burgh Ballroom* Additional Panel Members: Michael (Geng) Tian, *CDER, FDA, United States*

	Enhanced Process Characterization Study with Monte-Carlo Simulation - From a Static to a Dynamic Understanding of a Manufacturing Process Hervé Broly *Merck-Serono, Corsier-sur-Vevey, Switzerland* 14:40-15:05 **Using Stability Prior-knowledge from 'Like-molecules' to Determine Shelf-life.** Andrew Lennard *Amgen Ltd, Uxbridge, United Kingdom* 15:05-15:30 **Some Reflections on the Use of Models in Module 3** Nick Lee *HPRA-Health Products Regulatory Authority, Ireland*	Mats Welin, *Swedish Medical Products Agency, Sweden*

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09:00-10:45	**Efficiency Toolbox - Development & Lifecycle Management** *Burgh Ballroom* Session Chairs: Sandra Auguste-Bowler, *Novo Nordisk A/S*, Seán Barry, *HPRA-Health Products Regulatory Authority*, and Teresa Pepper, *BioMarin U.K. Ltd.* Session Speakers: 09:05-09:30 **How to Leverage Pharmaceutical Development and Manufacturing Data for Marketing Authorisations - EMA's Perspective** Veronika Jekerle *European Medicines Agency, Amsterdam, Netherlands* 09:30-09:55 **Setting Acceptance Criteria for Release Specification Based on Limited Batch Data** David Kirke *BioMarin, London, United Kingdom* 09:55-10:20 **Industry Proposal for the Use Of QBD And ICH Q12 Principles To Enable Second Sourcing Of Raw Materials** Kavita Aiyer *Seagen Inc., Bothell, WA, USA* 10:20-10:45 **Efficiency Toolbox - CMC Lessons Learned from COVID** Mark Pellett *AstraZeneca, Cambridge, Cambridgeshire, United Kingdom*	10:45-11:15 **Networking Break** *The Bar / Lobby* 11:15-12:30 **Panel Discussion - Questions and Answers** *Burgh Ballroom* Additional Panel Members: Chana Fuchs, *CDER, FDA, United States* Ilona Reischl, *AGES MEA, Austria*
12:30-13:45	**Networking Lunch** *The Bar / Lobby*	
13:45-15:30	**Innovation for Products and Processes** *Burgh Ballroom* Session Chairs: Katrin Buss, BfArM, *Federal Institute for Drugs and Medical Devices,* Janine Jamieson, *IPQ Publications*, and Tara Sanderson, *UCB Pharma Ltd.* Session Speakers: 13:50-14:15 **Support to Innovation by EMA – Facilitating Translation of Technology into Medicinal Products** Robert Bream *European Medicines Agency, Amsterdam, Netherlands* 14:15-14:40 **Agile Manufacturing - Transfer and Scale-Up of Biologics Aseptic Manufacturing Processes Through Control Site Concept**	15:30-16:00 **Networking Break** *The Bar / Lobby* 16:00-17:15 **Panel Discussion - Questions and Answers** *Burgh Ballroom* Additional Panel Members: Nick Lee, *HPRA-Health Products Regulatory Authority*

	Karoline Bechtold-Peters *Novartis Pharma AG, Basel, Switzerland* 14:40-15:05 **Continuous Manufacturing in Biologics Adoption and Regulatory Engagement** Silvia Nita *Merck Sharp and Dohme, Lucerne, Lu, Switzerland* 15:05-15:30 **Platform Protocol Templates: An Innovative Upcoming Tool for Comparability Assessment and Process Validation** Olga Rovira *CEPI, Oslo, Norway*	Jamie Moore, *CytomX Therapeutics, Inc., United States* Matthew Popkin, *GSK plc., United Kingdom*
17:15-17:30	**Closing Remarks & Invitation to the CMC Strategy Forum Europe 2023** Burgh Ballroom Martijn van der Plas, *MEB-Medicines Evaluations Board, Netherlands*	