22nd May 2022

13:00-16:00	**Short Course - Characterization of Biopharmaceuticals** Facilitators: Eef Dirksen, *Byondis B.V.*, Marta Germano, *Janssen Vaccines*, and Sigrid Roosendaal, *Quality RA B.V.*

23rd May 2022

09:00-09:15	**Welcome & Introductions** Katarzyna (Kasia) Kozakowska, *AstraZeneca*
09:15-10:10	**Keynote Session I** Cutting-Edge Multi-Level Analytical and Structural Characterization of Antibody-Based Therapeutics Alain Beck, *Pierre Fabre*
10:10-10:40	**Networking Break** **New Member Networking Event**
10:40-12:50	**Session I: MAM Applications in QC** 10:40 - 11:05 Multi-attribute Method Performance Profile for Quality Control of Monoclonal Antibody Therapeutics Eva Vosika, *Roche Diagnostics GmbH* 11:05 - 11:30 Multi-Attribute Monitoring from Development to Marketing Applications Joseph Mulholland, *Janssen* 11:30 - 11:55 Considerations for the Application of Multi-attribute-method by Mass Spectrometry (MAM) for QC Release and Stability Testing of Biopharmaceuticals Thomas Pohl, *European Federation of Pharmaceutical Industries and Associations (EFPIA)* A Perspective on the Contribution of Spectroscopy to Characterising Proteins for Quality Control Alison Rodger, *Macquarie University*
12:50-13:50	**Lunch**
13:50-14:50	**Roundtable Session** 2022 Topics - Table 1: Vaccines Table 2: Stability Table 3: Q2/Q14 Table 4: Analytical Challenges in Development of Novel Modalities Table 5: Why and How to Move New Analytical Technologies from R&D to GMP Table 6: Specs

14:50-15:05	**Transition Time**
15:05-15:35	**Technical Seminar Sponsored by SCIEX**
15:35-17:45	**Session II: Impact of Impurities and Excipients on Critical Quality Attributes** 15:35 - 16:00 A Versatile LC-MS based Workflow with Robust 0.1 ppm Sensitivity for Identifying Residual HCPs in Biotherapeutic Products Feng Yang, *Genentech, a Member of the Roche Group* 16:00 - 16:25 Assessment of Aspartic Acid Isomerisation and Other Peptide Critical Quality Attributes Vivian Lindo, *AstraZeneca* 16:25 - 16:50 Assessing Effects of Leachables and the Quality of Single-Use Systems in Cell Therapy Manufacturing Noemi Dorival-Garcia, *The National Institute for Bioprocessing Research and Training (NIBRT)* 16:50 - 17:15 Mechanisms for the Loss of mRNA Activity in Lipid Nanoparticle Delivery Systems Meredith Packer, *Tome Biosciences*
19:00-21:00	**Conference Event**

24th May 2022

09:00-09:05	**Daily Announcements**
09:05-11:15	**Session III: New Developments in Vaccines** 09:05 - 09:30 Characterization of mRNA Lipid Nanoparticles Vaccines by Taylor Dispersion Analysis and Capillary Electrophoresis Herve Cottet, *Sanofi Pasteur* 09:30 - 09:55 Non-Aqueous Capillary Electrophoresis (CE) for High-Resolution Large RNA Vaccine Analysis Tian Lu, *Merck & Co., Inc.* 09:55 - 10:20 Transmission Electron Microscopy (TEM): Utilising a Powerful Tool in Biosafety as a Novel Approach to Characterise the Product Quality of Biologics, Such as Vector-Based Vaccines and Gene Therapy Products Ashley Layland, *ZUD* Accelerating Global Supply of Vaccines: Lessons Learnt Mark Pellett, AstraZeneca

11:15-12:15	**Poster Session**
12:15-13:15	**Lunch**
13:15-13:45	**Technical Seminar Sponsored by Bruker BioSpin**
13:45-14:15	**Technical Seminar Sponsored by Genovis**
14:15-15:10	**Keynote Session II** The Future is Now: ICH Q14: Analytical Procedure Development and ICH Q2(R2): Analytical Procedure Validation David Keire, *CDER, FDA*
15:10-15:40	**Networking Break**
15:40-17:50	**Session IV: Regulatory Trends** 15:40 - 16:05 Strategies of Overcoming Risk of Changing Analytical Method Gerald Gellermann, *Novartis* 16:05 - 16:30 Development of New Ph. Eur. "Horizontal" Standards as Multi-Product Analytical Procedures for Monoclonal Antibody Analysis Mihaela Buda, *EDQM* The Case for Revision to the ICH Stability Guidelines: An Industry Perspective Andrew Lennard, *Amgen Inc.* Regulatory Experience from the Rolling Review Process and the Conditional Marketing Authorization Process for COVID-19 Vaccines Elisa Pedone, *European Medicines Agency*
17:50-18:50	**Exhibitor Reception**

25th May 2022

09:00-09:05	**Daily Announcements**
09:05-10:00	**Keynote Session III** Advances in Bioprocessing and Analytics to Accelerate Vaccine Production António Roldão, *iBET*

10:00-10:25	**Networking Break**
10:25-11:15	**Emerging Professionals Showcase** Chemical Mobilization-Based Capillary Isoelectric Focusing Mass Spectrometry Using the nanoCEasy Interface for Pharmaceutical Proteins Analysis Elaheh Naghdi, *Aalen University* Online Native CEX-IM(CIU)-MS to Monitor the Conformational Landscape of Therapeutic Monoclonal Antibody Proteoforms Guusje van Schaick, *Leiden University Medical Center* Site-specific Glycosylation Analysis of the SARS-CoV-2 Spike Yasunori Watanabe, *AstraZeneca* Capillary and Microchip Electrophoresis for Amino Acid Monitoring during Biopharmaceutical Cultivation Leila Josefsson, *Kantisto BV*
11:15-12:15	**Polysorbate Workshop** Co-lead: Carl Jone, *Narwhal Sciences* and Harold Taylor, *Merz Pharmaceuticals GmbH* Current State and Common Practices for Handling and Control of Polysorbates for Biopharmaceutical Products Klaus Wuchner, *Cilag AG*
12:15-13:15	**Lunch**
13:15-15:25	**Session V: Novel Technologies & Improvements in Analytical Technologies** 13:00 - 13:25 Functional Characterization of Antibody Proteoforms using Affinity CE-MS Christoph Gstöttner, *Leiden University Medical Center* 13:25 - 13:50 Enabling PAT in Insect Cell Bioprocesses: A Monitoring Toolbox for rAAV Production Inês Isidro, *iBET* 13:50 - 14:15 Genome Analysis for Recombinant Adeno Associated Viruses by Capillary Electrophoresis Andrei Hutanu, *F. Hoffmann - La Roche Ltd* 14:15 - 14:40 The Fine Art of Destruction for In-Depth Mass Spectrometry-Based Glycoproteomics: Advances in Measurement and Data Analysis — Exploiting the Diagnostic Potential of Fragment Ions Erdmann Rapp, *Max Planck Institute*
15:20-15:30	**Closing Remarks** Birgit Schmauser, *BfArM, Federal Institute for Drugs and Medical Devices*