

April 4 2022

08:30-08:45	Welcome and Introductory Comments Galahad Deperalta, <i>Genentech, a Member of the Roche Group</i>
08:45-09:45	Keynote Session I New Experimental and Computational Methods for Analyzing Antibody Colloidal Interactions Peter Tessier, <i>University of Michigan</i>
09:45-10:30	Networking Break - Visit Posters & Exhibitors
10:35-12:00	Session I: HOS in Development Anne Kim, <i>Pfizer, Inc.</i> , William Matousek, <i>Regeneron Pharmaceuticals Inc.</i> , and Anders Nielsen, <i>Genmab A/S</i> Session Speakers: 10:40 – 11:00 Differences in Human IgG1 and IgG4 S228P Monoclonal Antibodies Viscosity and Self-Interactions: Experimental Assessment and Computational Predictions of Domain Interactions Yao Yu, <i>Merck & Co., Inc.</i> 11:00 – 11:20 Mechanistic Insights into Lipase-Antibody Noncovalent Complexes Achieved Through FPOP, Native MS, and Non-MS Atmospheric Ion Mobility Elizabeth Hecht, <i>Genentech, a Member of the Roche Group</i> 11:20 – 11:40 Leveraging NMR Chemometric Methods for mAb HOS Characterization Victor Beaumont, <i>Pfizer, Inc.</i>
12:00-12:30	Technical Seminar Sponsored by GenNext Technologies
12:30-12:55	Break
13:00-14:25	Session II: Comparability and Similarity Evaluation Ivan Budyak, <i>Eli Lilly and Company</i> , Thomas Cleveland, <i>NIST</i> , and Mats Wikstrom, <i>Amgen Inc.</i> Session Speakers: 13:05 – 13:25 Rapid Qualification of Spectroscopic Methods for Protein HOS Characterization Nicholas Larson, <i>Biogen</i> 13:25 – 13:45 Structural Characterization of Innovator and Biosimilar Monoclonal Antibodies Anna Schwendeman, <i>University of Michigan</i> 13:45 – 14:05 Nano Differential Scanning Fluorimetry for Comparability Studies of Therapeutic Proteins Jie Wen, <i>Amgen Inc.</i>
14:25-14:55	Technical Seminar Sponsored by BioTools, Inc.
14:55-15:25	Break
15:30-17:00	Session III: Biological Consequences of HOS Alexander Bepperling, <i>Sandoz GmbH</i> , George Bou-Assaf, <i>Biogen</i> , and Ivan Budyak, <i>Eli Lilly and Company</i>

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Session Speakers:

15:35 – 15:55

The Role of HDX MS in Revealing the MOA of Low Affinity Compounds Interacting with Parkin
Jing Fang, *Biogen*

15:55 – 16:15

Protein Conformation in Amorphous Solids by Hydrogen-Deuterium Exchange
Elizabeth Topp, *Purdue University*

16:15 – 16:35

Epitope Mapping of PD-L1 Targeted by an Anti-IgG1 Fusion Protein: Solid-State NMR as a New Tool for the Development of Biologics and HOS Evaluation
Marco Fragai, *University of Florence (CERM)*

April 5 2022

08:30-08:35	Welcome and Introduction George Bou-Assaf, <i>Biogen</i>
08:35-09:35	Keynote Session II New Modalities: Using CMC Approaches and New Advances Claire Davies, <i>Sanofi</i>
09:35-10:05	Technical Seminar Sponsored by <i>IonDX</i>
10:15-11:15	Roundtable Discussions 2022 Roundtable Topics - Table 1: Light Scattering and Solution Non-Ideality and Formulation Selection Table 2: Best Practices for Analyzing and Interpreting Routine Biophysical Assays (DLS, CD, DSC) Table 3: Analytical Ultracentrifugation Table 4: Sub-visible Particle Characterization Table 5: Other Modalities in the Protein Area (non mAbs, bi-specific variants, etc.) Table 6: Best Practices in NMR Data Acquisition and Analysis Table 7: Viral Delivery Therapeutics Table 8: COVID Therapeutics
11:15-11:45	Networking Break presented in Remo
11:45-12:30	Break
12:30-13:55	Session IV: HOS Technologies Sergey Arzhantsev, <i>CDER, FDA</i> , Michael Johnston, <i>Health Canada</i> , and William Matousek, <i>Regeneron Pharmaceuticals Inc.</i> Session Speakers: 12:35 – 12:55 Solid-state NMR Investigation of Protein Stability in Biologics Yongchao Su, <i>Merck & Co., Inc.</i> 12:55 – 13:15 Laser-Free Oxidation (Fox™) Hydroxyl Radical Protein Footprinting System for mAb Drug Development Emily Chea, <i>GenNext Technologies</i> 13:15 – 13:35 Single-Molecule Tertiary Structures Reveal RNA Folding Process Using Individual-Particle Cryo-Electron Tomography (IPET) Gary Ren, <i>Lawrence Berkeley National Lab</i>

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13:55-14:25	Break
14:30-15:30	Session V: Next Generation Investigators Alexander Bepperling, Sandoz GmbH, Guodong Chen, <i>Bristol-Myers Squibb Company</i> , and Krishna Mallela, <i>University of Colorado Anschutz Medical Campus</i> Session Speakers: 14:35 – 14:50 Integrative Structural Biology of Higher-Order DNA G-quadruplexes Robert Monsen, <i>University of Louisville</i> 14:50 – 15:05 Receptor Binding Domain Mutations Determine Evolution of SARS-CoV-2 Variant Vaibhav Upadhyay, <i>University of Colorado</i> 15:05 – 15:20 Ion Mobility-Mass Spectrometry and Collision Induced Unfolding of Bispecific Antibody Therapeutics Rosendo Villafuerte-Vega, <i>University of Michigan</i>
15:30-17:00	Session VI: Discovery and Candidate Selection Katherine Bowers, <i>Fujifilm Diosynth Biotechnologies</i> , Galahad Deperalta, <i>Genentech, a Member of the Roche Group</i> , and Krishna Mallela, <i>University of Colorado Anschutz Medical Campus</i> Session Speakers: 15:35 – 15:55 Integrated Approach to Structure-Function Relationship Studies Reveals Antibody Fab–Receptor Interactions Mediate Antibody-Dependent Cellular Cytotoxicity Aaron Weckler, <i>Genentech, a Member of the Roche Group</i> 15:55 – 16:15 Blinded Determination of the Structure of Human NRG1-Ig by HR-HRPF-Informed Computational Modeling, Validated by NMR Joshua Sharp, <i>University of Mississippi</i> 16:15 – 16:35 Combining Refoldability Assessment and Molecular Dynamics Simulations to Select Aggregation-Resistant Antibodies Carolin Berner, <i>VIB-VUB Center for Structural Biology</i>

April 6 2022

08:30-09:55	Session VII: New Modalities Guodong Chen, <i>Bristol-Myers Squibb Company</i> , Michael Johnston, <i>Health Canada</i> , and Krishna Mallela, <i>University of Colorado Anschutz Medical Campus</i> Session Speakers: 08:35 – 08:55 Application of Sedimentation Velocity Analytical Ultracentrifugation in Development of Novel Biologic Modalities Surinder Singh, <i>Bristol-Myers Squibb Company</i> 08:55 – 09:15 Manufacturing Challenges and Rational Formulation Development for AAV Viral Vectors Arvind Srivastava, <i>Avantor</i> 09:15 – 09:35 In-depth Physicochemical Characterization of Antibody-Drug Conjugates Shawn Owen, <i>University of Utah College of Pharmacy</i>
09:55-10:25	Technical Seminar Sponsored by Waters Corporation
10:25-10:55	Break

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11:00- 12:25	<p>Session VIII: Late Breaking George Bou-Assaf, <i>Biogen</i>, Katherine Bowers, <i>Fujifilm Diosynth Biotechnologies</i>, Galahad Deperalta, <i>Genentech</i>, a Member of the Roche Group</p> <p>Session Speakers: 11:05 – 11:25 Considerations for Evaluating the Stability of Insulin Drug Products Anjali Shukla, <i>CDER, FDA</i></p> <p>11:25 – 11:45 Best Practices for Aggregate Quantitation of Antibody Therapeutics by Sedimentation Velocity Analytical Ultracentrifugation Michael Brenowitz, <i>Albert Einstein College of Medicine</i></p>
12:25- 12:35	<p>Closing Remarks George Bou-Assaf, <i>Biogen</i></p>