

<b>Track</b>	<b>Defining and Developing Comparability Strategies for Novel and Complex Biotherapeutics</b>  Forum Co-Chairs: Taro Fujimori, Ultragenyx Pharmaceutical, Jamie Moore, Gilead Sciences, Inc. Swati Verma, CBER, FDA	<b>Innovation in the Formulation and Delivery of Biotherapeutics</b>  Forum Co-Chairs: J.R. Dobbins, <i>Eli Lilly and Company</i> , Douglas Richardson, <i>Merck &amp; Co., Inc.</i> , Maria Cecilia Tami, <i>Genentech, a Member of the Roche Group</i>
<b>08:30 - 08:40</b>	<b>CASSS Welcome</b>  Presented by: Jamie Moore, <i>Gilead Sciences, Inc.</i> , CASSS Board Member	<b>CASSS Welcome</b>  Presented by: Sarah Kennett, <i>Genentech, a Member of the Roche Group</i> , CASSS Board Member
<b>08:40 - 08:50</b>	<b>CMC Strategy Forum January 2023 Introductory Comments</b>  Presented by: Taro Fujimori, <i>Ultragenyx Pharmaceutical</i> CASSS Associate Director	<b>CMC Strategy Forum January 2023 Introductory Comments</b>  Presented by: Douglas Richardson, <i>Merck &amp; Co., Inc.</i> , CASSS Associate Director
<b>08:50 - 10:30</b>	<b>Workshop One: Comparability for Novel Protein-based Modalities</b>  Workshop Co-Chairs: Bharat Dixit, <i>Adiso &amp; ClearB Therapeutics</i> , Jessica Lo Surdo Pinder, <i>Amgen Inc.</i>  <b>08:50 – 09:15</b> <b>Chemically-defined Glycosylation of Monoclonal Antibodies</b> <u>Roger Tam</u> <i>Health Canada</i> , Ottawa, Ontario, Canada  <b>09:15 – 09:40</b> <b>Development of Antibody Drug Conjugate Products from a Cell-Free Synthesis System</b> <u>Judy Hsii</u> <i>Sutro Biopharma, Inc.</i> , South San Francisco, CA, USA  <b>09:40 – 10:05</b> <b>DS Comparability for a Bispecific Antibody Product and Implications for DP</b> <u>Kelsey Dent</u> <i>Genentech, a Member of the Roche Group</i> , South San Francisco, CA, USA  <b>10:05 – 10:30</b> <b>Progressive Risk-based Comparability Strategies for Complex Biologics</b> <u>Doug Watson</u> <i>Merck &amp; Co., Inc.</i> , Rahway, NJ, USA	<b>Workshop One: Innovation in Formulation of Biologics</b>  Workshop Co-Chairs: Jack Kramarczyk, <i>Moderna, Inc.</i> , Aquiles Leyes, <i>Merck &amp; Co.</i> , Maria Cecilia Tami, <i>Genentech, a Member of the Roche Group</i>  <b>08:50 – 09:15</b> <b>Progress on mRNA Delivery of Computationally Designed Nanoparticle Vaccines</b> <u>Lauren Carter</u> <i>University of Washington</i> , Seattle, WA, USA  <b>09:15 – 09:40</b> <b>Technical Challenges and Regulatory Perspectives with Co-Administration and Co-Formulation in mAbs</b> <u>Sreedhara Alavattam</u> <i>Genentech, a Member of the Roche Group</i> , South San Francisco, CA, USA  <b>09:40 – 10:05</b> <b>Co-Formulation Development: Balancing Challenges and Opportunities in Formulation and Process Operation</b> <u>Ashlesha Raut</u> <i>Merck &amp; Co., Inc.</i> , Kenilworth, NJ, USA  <b>10:05 – 10:30</b> <b>Exploring Advanced Drying Techniques for Manufacturing Next Generation Drug Products</b> <u>Francis Kinderman</u> <i>Amgen Inc.</i> , Thousand Oaks, CA, USA
<b>10:30 - 11:00</b>		
<b>11:00 - 12:15</b>	<b>Workshop One - Panel Discussion</b>  Additional Panel Members:  <u>Alpana Naresh</u> <i>Harpoon Therapeutics, Inc.</i> , South San Francisco, CA, USA  <u>Kristen Nickens</u> <i>CDER, FDA</i> , Silver Spring, MD, USA  <u>Murali Pasumarthy</u> <i>Amgen Inc.</i> , Thousand Oaks, CA, USA	<b>Workshop One - Panel Discussion</b>  Additional Panel Members:  <u>Dean Smith</u> <i>Health Canada</i> , Ottawa, Ontario, Canada  <u>Laura Tanenbaum</u> <i>Janssen Research &amp; Development, LLC.</i> , Malvern, PA, USA  <u>Mats Welin</u> <i>Swedish Medical Products Agency</i> , Uppsala, Sweden
<b>12:15 - 14:00</b>		
<b>14:00 - 15:40</b>	<b>Workshop Two: Case Studies from mRNA Vaccines and Microbiome Products</b>  Workshop Co-Chairs: Judy Hsii, <i>SutroBiopharma, Inc.</i> , Nicole Schiavone, <i>Pfizer, Inc.</i>  <b>14:00 – 14:25</b> <b>Development of Microbiome/Live Biotherapeutic Products</b> <u>Bharat Dixit</u> <i>Adiso &amp; ClearB Therapeutics, Concord, MA, USA</i>	<b>Workshop Two: Innovation in Delivery of Biotherapeutics</b>  Workshop Co-Chairs: Jim Searles, <i>Pfizer, Inc.</i> , Andrzej Pitek, <i>GlaxoSmithKline</i> , Young-Ho Song, <i>Eli Lilly and Company</i>  <b>14:00 – 14:25</b> <b>Delivering Oligonucleotides with Exosomes: Development and Optimization of a Platform</b> <u>Andrew Wood</u>

	<p><b>14:25 – 14:50</b>  <b>Quantitative Proteomics and Metaproteomics for Evaluating Microbiota-directed Therapeutics</b>  <u>Xu Zhang</u>  <i>Health Canada, Ottawa, Ontario, Canada</i></p> <p><b>14:50 – 15:15</b>  <b>Building a Complex Manufacturing Network for a Global COVID Vaccine: Quality and Comparability Aspects</b>  <u>Ulrich Blaschke</u>  <i>BioNTech SE, Mainz, Hasia, Germany</i></p> <p><b>15:15 – 15:40</b>  <b>Analytical Comparability Strategies to Enable Rapid Development of SARS-CoV-2 Variant mRNA Vaccines</b>  <u>Tyler Carlage</u>  <i>Moderna, Inc., Norwood, MA, USA</i></p>	<p><i>Codiak Biosciences, Cambridge, MA, USA</i></p> <p><b>14:25 – 14:50</b>  <b>Innovative Technology Platform to Deliver Biologics by Combining Device Technology with Oral Drug Delivery</b>  <u>Karsten Lindhardt</u>  <i>Biograil, Roskilde, Denmark</i></p> <p><b>14:50 – 15:15</b>  <b>Proteolipid Vesicles: A Novel Delivery System for Safe and Effective Delivery of Nucleic Acids</b>  <u>Arun Raturi</u>  <i>Entos Pharmaceuticals, San Diego, CA, USA</i></p> <p><b>15:15 – 15:40</b>  <b>ReCode’s Selective Organ Targeting (SORT), Lipid Nanoparticle (LNP) Platform</b>  <u>Angèle Maki</u>  <i>ReCode Therapeutics, Menlo Park, CA, USA</i></p>
<b>15:40 - 16:25</b>		
<b>16:25 - 17:40</b>	<p><b>Workshop Two - Panel Discussion (Comparability)</b></p> <p>Additional Panel Members:</p> <p><u>Paul Carlson</u>  <i>CBER, FDA, Silver Spring, MD, USA</i></p> <p><u>Thomas Lerch</u>  <i>Pfizer, Inc., Chesterfield, MO, USA</i></p> <p><u>Christopher Paradise</u>  <i>Rion Inc., Rochester, MN, USA</i></p>	<p><b>Workshop Two - Panel Discussion (Innovation)</b></p> <p>Additional Panel Members:</p> <p><u>Advait Badkar</u>  <i>Pfizer, Inc., Andover, MA, USA</i></p> <p><u>Rene Thürmer</u>  <i>BfArM, Federal Institute for Drugs and Medical Devices, Bonn, NRW, Germany</i></p>
<b>17:40 - 17:55</b>	<b>Closing Remarks: Invitation to CMC Strategy Forum July 2023</b>	